MATHANGI GOPALAKRISHNAN, M. PHARM, PH.D.

Phone: 301-233-9805
mgopalakrishnan@rx.umaryland.edu
Pharmacy Hall-N517, 20, N.Pine St
Baltimore, Maryland-21201

EDUCATION

2007-2013	Ph.D. Statistics University of Maryland, Baltimore County Baltimore, MD, USA
2005-2007	M.S Statistics University of Maryland, Baltimore County Baltimore, MD, USA
1993-1998	M.Pharmacy Birla Institute of Technology & Science, Pilani Rajasthan, India
1993-1998	B.Pharmacy [Honors] Birla Institute of Technology & Science, Pilani Rajasthan, India

EMPLOYMENT

2022- present	Graduate Program Director – MS in Pharmacometrics University of Maryland, Baltimore (UMB)
2019-present	Assistant Professor (Tenure-track) Center for Translational Medicine (CTM) Department of Pharmacy Practice & Science (PPS) University of Maryland, Baltimore (UMB)
2013-2019	Research Assistant Professor Center for Translational Medicine (CTM) Department of Pharmacy Practice & Science (PPS) University of Maryland, Baltimore (UMB)
2018-2020	Contractor-Research Fellow Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA)
2015-2017	ORISE Fellow Center for Drug Evaluation and Research (CDER)

Food and Drug Administration (FDA)

2012-2013 Clinical Research Assistant
Center for Translational Medicine (CTM)
PPS, UMB

HONORS AND AWARDS

2021 University of Maryland Institute for Clinical and Translational Research (ICTR) Accelerated Translational Incubator Pilot (ATIP) Award
Title: *Transfusion Risk Assessment using Vital Sign Dynamics based Machine Learning Algorithms*

2018 AACP Teacher of the year
American Association of Colleges of Pharmacy (AACP)

2018 University of Maryland Center for Addiction Research, Education and Service (CARES) Pilot Award
Title: *Translational research for optimizing pharmacotherapeutic care in infants with neonatal abstinence syndrome*

2017 Quality Abstract Award
International Society of Pharmacometrics (ISoP)
Presentation title: *Shortening the duration of acute schizophrenia registration trials is a possibility*

2012 Oral presentation Competition Winner at Probability and Statistics Day Conference, University of Maryland Baltimore County, Baltimore, MD
Presentation title: *Validation of Surrogate Endpoints by Bayesian Equivalence testing*

2011 Poster presentation Competition Winner at Contemporary Statistical Methods in Biostatistics, University of Maryland Baltimore County, Baltimore, MD
Presentation title: *Non-iterative Bayesian Sampling for analyzing Zero-Inflated Count Data*

2008 Poster presentation Competition Winner at Probability and Statistics Day Conference, University of Maryland Baltimore County, Baltimore, MD
Presentation title: *Bayesian Approach to Clinical Trials: Are We There Yet?*

2004 Poster podium presenter at American Association of Pharmaceutical Scientists (AAPS)

Presentation title: *A Pharmacokinetic-Pharmacodynamic model for insulin to guide in optimal drug delivery*

SKILLS & EXPERTISE

Statistics

- Highly proficient in frequentist and Bayesian statistics
- Experience in pre-clinical and clinical trial design and analysis for varied endpoints in multiple drug development projects pertaining to
    - Medical Countermeasure (MCM) development
    - 505b (2) application pathway
    - Generic drugs (ANDA)
- Experience in application of Bayesian methods for design of pediatric trials and optimizing clinical therapeutics
- Proficient in advanced quantitative analysis methodologies (Item response theory, Machine learning)
- Highly proficient in the use of statistical software – R, SAS
- Course manager for graduate level applied statistics courses

Pharmacometrics

- Advanced knowledge of pharmacokinetics (PK), pharmacodynamics (PD)
- Highly experienced in utilizing advanced quantitative methods (PK/PD modeling and simulation) for go-no/go decisions in drug development and optimizing clinical therapeutics
    - Design of first in human (FIH), SAD, MAD, bioavailability studies
    - Translational research – dose selection and scaling from animals to humans
    - Precision therapeutics
- Experience in Model-Informed Drug Development (MIDD)
- Authored documents submitted to the FDA to support labeling and approval of new products
- Proficiency in Pumas, Phoenix NLME and NONMEM
- Training future clinical pharmacologists and pharmacometricians

GRANTS AND CONTRACTS

Current grants

Source: NIH, 1R21HD105648
Title: Intergenerational Transmission of Low-calorie Sweeteners via the Breast Milk
Time period: 01/01/2022 – 07/31/2023
Amount: $21,305
Role: Co-I and Sub-recipient PI

Source: NIH-NIAID, U01
Title: DON in Pediatric Cerebral Malaria: A Phase I/II Dose-Escalation Safety Study
Time period: 09/01/2021 – 06/30/2026
Amount: $907,316
Role: Co-I

Source: George Washington University/Bill & Melinda Gates Foundation
Title: Optimizing Maternal Nutrition: Adaptive trials and molecular methods to improve maternal and newborn health (MM4MN)
Time period: 11/15/2020 – 04/15/2022
Amount: $21,935
Role: Co-I and Sub-recipient PI

Source: UMB-University of Maryland College Park- MPowering the State (MPower) Pilot Award
Title: Developing an Artificial Intelligence Tool to Improve Caregiver Engagement for Rural Child Behavioral Health Services
Time period: 08/15/2020 – 08/14/20221
Amount: $90,522
Role: Co-I

Source: NIH-NIAID, U19AI150574
Title: Intercollaborative Radiation Countermeasure (INTERACT) Consortium for Advanced Development of Medical Countermeasures to Mitigate/Treat Acute and Delayed Radiation Syndromes
Time period: 06/16/2020 – 05/31/2025
Amount: $9,594,032
Role: Co-I

Source: NIH
Title: Comparing Direct and Indirect Methods for Cascade Screening in Familial Hypercholesterolemia (FH) and Long QT Syndrome (LQTS)
Time period: 04/01/2022 – 03/31/2027
Amount: $36,964
Role: Co-I

Pending grants

Source: DoD-DARPA
Title: CONCERT: Consortium for Optimized Integration of Bio-artificial Blood Components for Adaptive Resuscitation and Therapy
Time period: 07/01/2022 – 19/03/2027
Amount: $90,800,450
Role: Co-I

Source: MPRINT -P30
Title: A Prospective, Real-world, Clinical Pharmacokinetic Study to Assess InfantExposure to Delta-9-Tetrahydrocannabinol Through Placental and Breast Milk Transfer
Time period: 10/01/2022–09/30/2023
Amount: $ 150,000
Role: PI

Completed grants

Source: UMB-Institute of Clinical and Translational Research (ICTR)-Accelerated Translational Incubator Pilot (ATIP) Award
Title: Transfusion risk assessment using vital sign dynamics based machine learning algorithms
Time period: 05/01/2021 – 04/31/2022
Amount: $40,000
Role: PI

Source: DoD – W911QY-15-C-0134
Title: Evaluation of 17-alpha-Ethynylestradiol_3-sulfate in severe Hemorrhage and Poly-Trauma
Time period: 07/01/2020 – 06/30/2021
Amount:
Role: Co-I

Source: BARDA HHSO10033004T
Title: Evaluation of Coagulation Pathway-Targeting Drugs in the minipig model of Acute Radiation Syndrome (ARS)
Time period: 04/01/2018 – 03/31/2021
Amount: $3,299,555
Role: Co-I

Source: HHS-NIH-NIAID-BAA2017
Title: A NHP efficacy study of BIO300 for the mitigation of DEARE-induced pneumonitis and pulmonary fibrosis
Time period: 04/01/2018 – 03/31/2021
Amount: $3,973,653
Role: Co-I

Source: NIH - 16-0075.B2C2D2.0053
Title: A Population Pharmacokinetics Study to Evaluate the Dose needed to Achieve Vancomycin AUC/MIC >400 in Critically Ill Pediatric Patients
Time period: 11/01/2016 – 08/01/2021
Amount:
Role: Co-I

Source: UMB - Institute of Clinical and Translational Research (ICTR)- Voucher Award
Title: Evaluation of Switchback Rates as an Indicator for Generic Ineffectiveness in Patients taking Antidepressants
Time period: 01/10/2019 – 01/09/2020
Amount: $4500
Role: PI

Source: UMB Center for Addiction Research, Education and Service (CARES) Pilot Award
Title: Translational research for optimizing pharmacotherapeutic care in infants with neonatal abstinence syndrome
Time period: 04/10/2018–04/09/2019
Amount: $75,000
Role: PI

Source: BARDA ID/IQ HHS0100201
Title: Evaluation of coagulation pathway-targeting drugs in the rabbit model of acute radiation syndrome for potential new indications as ARS Medical Countermeasures
Time period: 09/20/2017-09/19/2019
Amount: $2,977,246
Role: Co-I

Source: BAA NIAID-DAIT-NOIHAIAI2015042
Title: Development of TP508 as a mitigator of the hematopoietic subsyndrome of the acute radiation syndrome
Time period: 09/1/2016- 01/31/2019
Amount: $2,810,930
Role: Co-I

Source: FDA - 1U01FD005192-01
Title: Pharmacometric modeling and simulation for generic drug substitutability evaluation and post marketing risk assessment
Time period: 09/10/2014 – 08/31/2017
Amount: $605,783
Role: Co-I

Source: FDA-1U01FD005188-01
Title: Population pharmacokinetic and pharmacodynamic, dose-toxicity modeling and simulation for narrow therapeutic index (NTI) drugs
Time period: 09/10/2014 – 08/31/2017
Amount: $605,783
Role: Co-I

Current Contracts

Source: Partner Therapeutics, Inc

Title: A Meta-analysis of Leukine trials
Time period: 11/25/2020-11/24/2022
Amount: $350,000
Role: PI

Source: West Therapeutic Development, LLC
Title: The use of MIDD strategy to demonstrate efficacy of Ketamine Nasal Spray for acute pain indication
Time period: 09/04/2020-09/04/2022
Amount: $110,000
Role: PI

Completed Contracts

Source: G1Therapeutics
Title: Pharmacometric modeling of G1T48
Time period: 03/01/2020 – 11/30/2021
Amount: $110,000
Role: PI

Source: Dr. Reddy's Laboratories
Title: Application of MIDD-II for DFN-15 for acute pain indications
Time period: 08/01/2020 – 11/30/2020
Amount: $155,000
Role: PI

Source: Dr. Reddy's Laboratories
Title: Application of MIDD-II for DFN-15 for acute pain indications
Time period: 05/01/2020 – 7/31/2020
Amount: $195,000
Role: PI

Source: HHSF22301013T FDA Contract
Title: Identifying patterns in placebo responders to inform future clinical trial design in schizophrenia
Time period: 09/10/2018- 01/31/2020
Amount: $46,080
Role: PI

Source: Dr. Reddy's Laboratories
Title: Exposure-response analysis for DFN-15
Time period: 11/15/2018 – 07/01/2020
Amount: $74,756
Role: PI

SCHOLARLY ACTIVITY

Publications

*# Corresponding author; *Graduate student (Advisee) work*

1. *#Kalaria SN, Armahizer M, McCarthy P, Badjatia N, Gobburu JV, **Gopalakrishnan M**. Development and Use of an Ex-Vivo In-Vivo Correlation to Predict Antiepileptic Drug Clearance in Patients Undergoing Continuous Renal Replacement Therapy. *Pharm Res*. 2022;39(5):827-836.
2. *#Salem AM, Jackson IL, Gibbs A, et al. Interspecies Comparison and Radiation Effect on Pharmacokinetics of BIO 300, a Nanosuspension of Genistein, after Different Routes of Administration in Mice and Non-Human Primates. *Radiat Res*. Published online February 4, 2022.
3. *#Salem AM, Niu T, Li C, Moffett BS, Ivaturi V, **Gopalakrishnan M**. Reassessing the Pediatric Dosing Recommendations for Unfractionated Heparin Using Real-World Data: A Pharmacokinetic-Pharmacodynamic Modeling Approach. *J Clin Pharmacol*. Published online November 23, 2021.
4. Hertz DL, Ramsey LB, **Gopalakrishnan M**, Leeder JS, Van Driest SL. Analysis Approaches to Identify Pharmacogenetic Associations With Pharmacodynamics. *Clin Pharmacol Ther*. 2021;110(3):589-594.
5. *Kalaria, Shamir N., Omayma A. Kishk, **Mathangi Gopalakrishnan**, and Dayanand N. Bagdure. "Evaluation of an Ex-Vivo Neonatal Extracorporeal Membrane Oxygenation Circuit on Antiepileptic Drug Sequestration." *Perfusion*, June 30, 2021, 2676591211028183.
6. Hertz, Daniel L., Laura B. Ramsey, **Mathangi Gopalakrishnan**, J. Steven Leeder, and Sara L. Van Driest. "Analysis Approaches to Identify Pharmacogenetic Associations with Pharmacodynamics." *Clinical Pharmacology and Therapeutics*, May 27, 2021.
7. *#Kalaria, Shamir N., Michael Armahizer, Paul McCarthy, Neeraj Badjatia, Jogarao V. Gobburu, and **Mathangi Gopalakrishnan**. "A Prospective, Real-World, Clinical Pharmacokinetic Study to Inform Lacosamide Dosing in Critically Ill Patients Undergoing Continuous Venovenous Haemofiltration (PADRE-02)." *British Journal of Clinical Pharmacology*, April 14, 2021.
8. *#Kalaria S, Spence O, Hong K, dosReis S, Gopalakrishnan M. Evaluation of Switch-to-Brand Rates as a Potential Signal for Therapeutic Equivalency of Generic Antidepressants: A Real-World Retrospective Cohort Study. *Clin Pharmacol Ther*. 2021;110(2):443-451.
9. Jones AK, Ngaimisi E, **Gopalakrishnan M**, Young MA, Laffont CM. Population Pharmacokinetics of a Monthly Buprenorphine Depot Injection for the Treatment of Opioid Use Disorder: A Combined Analysis of Phase II and Phase III Trials. *Clin Pharmacokinet*. 2021;60(4):527-540.
10. *#Wijekoon N, Aduroja O, Biggs JM, El-Metwally D, **Gopalakrishnan M**. Model-Based Approach to Improve Clinical Outcomes in Neonates With Opioid Withdrawal Syndrome Using Real-World Data. *Clin Pharmacol Ther*. 2021;109(1):243-252.
11. * Kalaria S, Williford S, Guo D, et al. Optimizing ceftaroline dosing in critically ill patients undergoing continuous renal replacement therapy. *Pharmacotherapy*. 2021;41(2):205-211.

12. #Blackman, Alison L., Praneeth Jarugula, David P. Nicolau, Sai Ho Chui, Manjari Joshi, Emily L. Heil, and **Mathangi Gopalakrishnan**. "Evaluation of Linezolid Pharmacokinetics in Critically Ill Obese Patients with Severe Skin and Soft Tissue Infections." *Antimicrobial Agents and Chemotherapy* 65, no. 2 (January 20, 2021).
13. Huang, Ruihao, Qi Liu, Ge Feng, Yaning Wang, Chao Liu, **Mathangi Gopalakrishnan**, Xiangyu Liu, Yutao Gong, and Hao Zhu. "A Novel Approach for Personalized Response Model: Deep Learning with Individual Dropout Feature Ranking." *Journal of Pharmacokinetics and Pharmacodynamics*, October 26, 2020.
14. **Gopalakrishnan M**, Farchione T, Mathis M, et al. Shortened Positive and Negative Symptom Scale as an Alternate Clinical Endpoint for Acute Schizophrenia Trials: Analysis from the US Food & Drug Administration. *PRCP*. Published online November 6, 2020:n/a-n/a.
15. *#Kalaria SN, Armahizer M, McCarthy P, Badjatia N, Gobburu JV, **Gopalakrishnan M**. A Practice-Based, Clinical Pharmacokinetic Study to Inform Levetiracetam Dosing in Critically Ill Patients Undergoing Continuous Venovenous Hemofiltration (PADRE-01). *Clin Transl Sci*. 2020;13(5):950-959.
16. Younis IR, **Gopalakrishnan M**, Mathis M, et al. Association of End Point Definition and Randomized Clinical Trial Duration in Clinical Trials of Schizophrenia Medications. *JAMA Psychiatry*. 2020;77(10):1064-1071.
17. **Gopalakrishnan, Mathangi**, Hao Zhu, Tiffany R. Farchione, Mitchell Mathis, Mehul Mehta, Ramana Uppoor, and Islam Younis. "The Trend of Increasing Placebo Response and Decreasing Treatment Effect in Schizophrenia Trials Continues: An Update From the US Food and Drug Administration." *The Journal of Clinical Psychiatry* 81, no. 2 (March 3, 2020).
18. Zhao, X., J. Shen, V. Ivaturi, **M. Gopalakrishnan**, Y. Feng, B. J. Schmidt, P. Statkevich, et al. "Model-Based Evaluation of the Efficacy and Safety of Nivolumab Once Every 4 Weeks across Multiple Tumor Types." Annals of Oncology: Official Journal of the European Society for Medical Oncology 31, no. 2 (February 2020): 302–9.
19. *Masich, Anne M., Shamir N. Kalaria, Jeffrey P. Gonzales, Emily L. Heil, Asha L. Tata, Kimberly C. Claeys, Devang Patel, and **Mathangi Gopalakrishnan**. "Vancomycin Pharmacokinetics in Obese Patients with Sepsis or Septic Shock." Pharmacotherapy, January 19, 2020.
20. *Kalaria, Shamir N., Tiffany R. Farchione, Mitchell V. Mathis, **Mathangi Gopalakrishnan**, Islam Younis, Ramana Uppoor, Mehul Mehta, Yaning Wang, and Hao Zhu. "Assessment of Similarity in Antipsychotic Exposure-Response Relationships in Clinical Trials Between Adults and Adolescents With Acute Exacerbation of Schizophrenia." Journal of Clinical Pharmacology, January 28, 2020.
21. * Kalaria SN, **Gopalakrishnan M**, Heil EL. A Population Pharmacokinetics and Pharmacodynamic Approach To Optimize Tazobactam Activity in Critically Ill Patients. *Antimicrob Agents Chemother*. 2020;64(3): e02093-19.
22. Jackson, Isabel L., Ganga Gurung, Yannick Poirier, **Mathangi Gopalakrishnan**, Eric P. Cohen, Terez Shea-Donohue, Diana Newman, and Zeljko Vujaskovic. "A New Zealand White Rabbit Model of Thrombocytopenia and Coagulopathy Following Total Body Irradiation Across the Dose Range to Induce the Hematopoietic-Subsyndrome of Acute Radiation Syndrome." *International Journal of Radiation Biology*, September 17, 2019, 1–36.

23. Parikh, Abhinav, **Mathangi Gopalakrishnan**, Ahad Azeem, Anastasia Booth, and Dina El-Metwally. "Racial Association and Pharmacotherapy in Neonatal Opioid Withdrawal Syndrome." *Journal of Perinatology: Official Journal of the California Perinatal Association*, August 6, 2019.
24. #*Kalaria, Shamir N., Susan L. McElroy, Jogarao Gobburu, and **Mathangi Gopalakrishnan**. "An Innovative Disease-Drug-Trial Framework to Guide Binge Eating Disorder Drug Development: A Case Study for Topiramate." *Clinical and Translational Science*, August 6, 2019.
25. *Kalaria, Shamir N., Hao Zhu, Tiffany R. Farchione, Mitchell V. Mathis, **Mathangi Gopalakrishnan**, Ramana Uppoor, Mehul Mehta, and Islam Younis. "A Quantitative Justification of Similarity in Placebo Response Between Adults and Adolescents With Acute Exacerbation of Schizophrenia in Clinical Trials." *Clinical Pharmacology and Therapeutics*, May 9, 2019.
26. Jackson, Isabel L., Allison Gibbs, Yannick Poirier, Lynne Wathen, John Eley, Emily Draeger, **Gopalakrishnan Mathangi** et al, , 'Hematological Effects of Non-Homogenous Ionizing Radiation Exposure in a Non-Human Primate Model', *Radiation Research*, 2019
27. #Singh, Renu, Shailly Mehrotra, **Mathangi Gopalakrishnan**, Ivana Gojo, Judith E. Karp, Jacqueline M. Greer, Alice Chen, et al. 2019. "Population Pharmacokinetics and Exposure-Response Assessment of Veliparib Co-Administered with Temozolomide in Patients with Myeloid Leukemias." *Cancer Chemotherapy and Pharmacology* 83 (2): 319–28.
28. #*Kalaria, Shamir N., Elyes Dahmane, Michael Armahizer, Paul McCarthy, and **Mathangi Gopalakrishnan**. 2018. "Development and Validation of a HPLC-UV Assay for Quantification of Levetiracetam Concentrations in Critically Ill Patients Undergoing Continuous Renal Replacement Therapy." *Biomedical Chromatography: BMC* 32 (8): e4257.
29. #Bhatia A, Tawade S, Mastim M, Kitabi EN, **Gopalakrishnan M**, Shah M, et al. Comparative evaluation of pharmacokinetics and pharmacodynamics of insulin glargine (Glaritus®) and Lantus®in healthy subjects: a double-blind, randomized clamp study. ***Acta Diabetol***. 2018 Feb 16;
30. Franquiz MJ, Kalaria SN, Armahizer MJ, **Gopalakrishnan M**, McCarthy PJ, Badjatia N. Lacosamide Pharmacokinetics in a Critically Ill Patient Receiving Continuous Venovenous Hemofiltration. *Pharmacotherapy*. 2017 Nov 21;
31. #Mehrotra S, **Gopalakrishnan M**, Gobburu J, Ji J, Greer JM, Piekarz R, et al. Exposure-Response of Veliparib to Inform Phase II Trial Design in Refractory or Relapsed Patients with Hematological Malignancies. *Clin Cancer Res*. 2017 Nov 1;23(21):6421–9.
32. Pal A, Shenoy S, Gautam A, Munjal S, Niu J, **Gopalakrishnan M**, et al. Pharmacokinetics of DFN-15, a Novel Oral Solution of Celecoxib, Versus Celecoxib 400-mg Capsules: A Randomized Crossover Study in Fasting Healthy Volunteers. *Clin Drug Investig*. 2017 Oct;37(10):937–46.
33. #*Desrochers J, Wojciechowski J, Klein-Schwartz W, Gobburu JVS, **Gopalakrishnan M**. Bayesian Forecasting Tool to Predict the Need for Antidote in Acute Acetaminophen Overdose. *Pharmacotherapy*. 2017 Aug;37(8):916–26.
34. Gamalo-Siebers, Margaret, Jasmina Savic, Cynthia Basu, Xin Zhao, **Mathangi Gopalakrishnan**, Aijun Gao, Guochen Song, et al. "Statistical Modeling for Bayesian

Extrapolation of Adult Clinical Trial Information in Pediatric Drug Evaluation." *Pharmaceutical Statistics*, April 27, 2017. doi:10.1002/pst.1807.

35. #*Niu, Jing, Christie Scheuerell, Shailly Mehrotra, Sharon Karan, Shannon Puhalla, Brian F. Kiesel, Jiuping Ji, et al. "Parent-Metabolite Pharmacokinetic Modeling and Pharmacodynamics of Veliparib (ABT-888), a PARP Inhibitor, in Patients with BRCA 1/2-Mutated Cancer or PARP-Sensitive Tumor Types." *Journal of Clinical Pharmacology*, April 7, 2017. doi:10.1002/jcph.892.
36. #*Mehrotra, Shailly, **Mathangi Gopalakrishnan**, Jogarao Gobburu, Jacqueline M. Greer, Richard Piekarz, Judith E. Karp, Keith Pratz, and Michelle A. Rudek. "Population Pharmacokinetics and Site of Action Exposures of Veliparib with Topotecan plus Carboplatin in Patients with Hematological Malignancies." *British Journal of Clinical Pharmacology*, February 3, 2017. doi:10.1111/bcp.13253.
37. Ivaturi V, **Gopalakrishnan M**, Gobburu JVS, Zhang W, Liu Y, Heidbreder C, et al. Exposure-Response Analysis after Subcutaneous Administration of RBP-7000, a Once-a-Month Long-Acting Atrigel Formulation of Risperidone. *Br J Clin Pharmacol.* 2017 Jan 30;
38. #*Cacek, Anthony T., Jogarao V. S. Gobburu, and **Mathangi Gopalakrishnan**. "Population Pharmacokinetics of an Intra-Nasally Administered Combination of Oxymetazoline and Tetracaine (K305) in Healthy Volunteers." *Journal of Clinical Pharmacology*, July 19, 2016. doi:10.1002/jcph.799.
39. Creinin MD, Jansen R, Starr RM, Gobburu J, **Gopalakrishnan M**, Olariu A. Levonorgestrel release rates over 5 years with the Liletta® 52-mg intrauterine system. Contraception. 2016 Oct;94(4):353–6.
40. **Mathangi Gopalakrishnan**, Mukul Minocha, Joga Gobburu. Leveraging magnetic resonance imaging-annualized relapse rate to aid early decision making in multiple sclerosis drug development. *Medical Research Archives***,** Vol 2, No 3 (2015): Vol2 N3 (2015)-Oct 15-21.
41. **Mathangi Gopalakrishnan**, Sandra Suarez, Anthony J.Hickey, Jogarao Gobburu. Population pharmacokinetic pharmacodynamic modeling of subcutaneous and pulmonary insulin in rats. *Journal of Pharmacokinetics and Pharmacodynamics*, Vol. 32, Nos. 3–4, August 2005.
42. Roy P. E. Yanong, Eric W. Curtis, Venkatesh Atul Bhattaram**, Mathangi Gopalakrishnan**, Nahal Ketabi, Nelamangala V. Nagaraja, Hartmut Derendorf, Robert Simmons. Pharmacokinetic Studies of Florfenicol in Koi Carp and Threespot Gourami *Trichogaster trichopterus* after Oral and Intramuscular Treatment *Journal of Aquatic Animal Health,* 2005; 17: 129-137

Book Chapters

1. **Mathangi Gopalakrishnan** and Joga Gobburu. Regulatory perspectives on the use of biomarkers and personalized medicine in CNS drug development: The FDA viewpoint. Book Chapter in Translational Medicine in CNS Drug development. Edited by George Nomikos and Doug Feltner: Academic Press, Volume 29 – 1st Edition, 2019.
2. **Mathangi Gopalakrishnan**, Vipul Kumar Gupta, Manish Issar. Relationship between pharmacokinetics and pharmacodynamics. Book Chapter in Applied Biopharmaceutics

and Pharmacokinetics, 7th Edition. Edited by Leon Shargel and Andrew B.C.Yu: McGraw Hill, 2015.

3. Jogarao V.S. Gobburu and **Mathangi Gopalakrishnan**. Optimal dose finding in drug development: Approaches and Regulatory perspectives. Book chapter in Dose Optimization in Drug development. Edited by Rajesh Krishna: Informa Health care, Newyork, 2006.

Conference presentations

1. Salem AM, Niu T, Li C, Moffett B, Ivaturi V, Gopalakrishnan M. Reassessing the Pediatric Dose Recommendations for Unfractionated Heparin Through the Pharmacokinetic/Pharmacodynamic Modeling of Real-world Data. American College of Clinical Pharmacology, Virtual Conference, September 13-17, 2021. ** **ACCP/ISoP SIG Student Abstract Award Winner**
2. Parikh AG, Salem AM*, Gopalakrishnan M, Bjarnadottir M, Pay F, Ament S, El-Metwally D, Beitelshees AL. Genetic Factors Impact on Predicting Clinical Outcomes of Neonatal Opioid Withdrawal Syndrome. Pediatric Academic Societies (PAS) 2021 virtual conference. Virtual. April 30th – June 4th, 2021
3. Salem AM*, Jackson IL, Kaytor MD, Serebrenik AA, Vujaskovic Z, Gobburu JV, Gopalakrishnan M. Pharmacokinetic Modeling and Simulation to Inform Dosing Regimen Selection for BIO 300 After Subcutaneous Administration in Irradiated and Non-Irradiated C57BL/6J Mice. American Conference on Pharmacometrics (ACoP). Virtual. November 9-13, 2020
4. Salem AM*, Jackson IL, Kaytor MD, Serebrenik AA, Vujaskovic Z, Gobburu JV, Gopalakrishnan M Interspecies Comparison and Irradiation Effect on Pharmacokinetics of BIO 300, a Nanosuspension of Genistein, Following Different Routes of Administration in C57BL/6J Mice and Non-human Primates. ACCP. Virtual. September 21-23, 2020 ****Student Abstract Award Winner**
5. Wijekoon N, Aduroja O, Biggs JM, El-Metwally D, Gopalakrishnan M. Model based approach to optimize clinical outcomes in neonatal opioid withdrawal syndrome using real world data. FDA-ASA Biopharmaceutical conference, September 2019, Washington DC
6. Wijekoon N, Aduroja O, Biggs JM, El-Metwally D, Gopalakrishnan M. Model based approach to optimize clinical outcomes in neonatal opioid withdrawal syndrome using real world data. American Conference on Pharmacometrics (ACoP), October 2019, Orlando, Florida
7. Calderon J, Gopalakrishnan M, Ivaturi V. Bioequivalence.jl: A suite of routines for bioequivalence (BE) analysis for the Julia language. American Conference on Pharmacometrics, October 2019, Orlando, Florida
8. Kalaria SN, McElroy SL, Gopalakrishnan, M. A Machine Learning Approach to Identify Placebo Responders in Binge Eating Disorder Trials. American Conference on Pharmacometrics, October 2019, Orlando, Florida
9. Parikh AG, Gopalakrishnan M, Beiteshees AL, El-Metwally D. Growth implications in infants with Neonatal Opioid Withdrawal Syndrome undergoing pharmacotherapy. Pediatric Academic Societies meeting, April 2019, Baltimore.

10. Comparison of Vancomycin Trough Attainment in Obese Septic Patients Versus Non-Obese Septic Patients. Society of Critical Care Medicine (SCCM), February 2019, San Diego, CA [Platform]
11. Masich A, Kalaria SN, Heil E, Gonzalez J, Heavner M, Tata A, Gopalakrishnan M. Characterization of vancomycin pharmacokinetics and pharmacodynamics in obese septic shock patients. ACCP Global Conference on Clinical Pharmacy, October 2018, Seattle, WA.
12. Gopalakrishnan M, Hao Zhu, Farchione, T, Mathis MV, Ramana U, Mehta M, Younis I. Shortened PANSS and shortened trial duration for acute schizophrenia registration trials is a feasible option: An analysis from US Food & Drug Administration. Poster presented at American Conference on Pharmacometrics, Annual Conference, San Diego, Oct 2018.
13. Personalized levetiracetam dosing adjustments for patients undergoing continuous venovenous hemofiltration, Poster presented at American Society of Nephrology Annual Conference, Baltimore, Nov 2017. **** Most Promising Research Award**
14. Gopalakrishnan M, Hao Zhu, Farchione, T, Ramana U, Mehta M, Younis I. Shortening the duration of acute schizophrenia registration trials is a possibility. Poster presented at American Conference on Pharmacometrics, Annual Conference, Ft. Lauderdale, Oct 2017.
15. Jones AK, Ngaimisi E, Gopalakrishnan M, Young MA, Laffont CM. Exposure-Response Analyses to support dosing recommendations for RBP-6000 Buprenorphine monthly formulation in subjects with opioid use disorder. Poster presented at American Conference on Pharmacometrics, Annual Conference, Ft. Lauderdale, Oct 2017.
16. Kalaria SN, McElroy SL, Gopalakrishnan, M. Optimizing Binge eating disorder drug development using a quantitative drug-disease trial model. Poster presented at American Conference on Pharmacometrics, Annual Conference, Ft. Lauderdale, Oct 2017
17. Kalaria SN, Armahizer M, Badjatia N, McCarthy P, Gobburu J, Gopalakrishnan M. Individualized dosing adjustments for patients undergoing continuous renal replacement therapy. Poster presented at American college of clinical pharmacology (ACCP), San Diego, Sep 2017.
18. Dahmane E, Gopalakrishnan M, Gobburu J, Ivaturi I. Impact of between-subject, within-subject and between occasion variability on therapeutic success for narrow therapeutic index drugs: a bioequivalence perspective. Poster presented at American Society for Clinical pharmacology and Therapeutics (ASCPT), Virginia, March 2017.
19. Gopalakrishnan M, Hao Zhu, Farchione, T, Mathis MV, Ramana U, Mehta M, Younis I Shortening the duration of acute schizophrenia registration trials is a possibility: Poster presented at Office of Clinical Pharmacology, Science Day, Silverspring, MD, 2016.
20. Kitabi EN, Ivaturi I, Gobburu J, Gopalakrishnan M. A Signal to Noise Ratio Classification System of Drugs to Investigate Generic Drug Ineffectiveness Claims, Poster presented at American college of clinical pharmacology (ACCP), Bethesda, MD, 2016. ****Poster and Podium –Cutting edge abstract submission-Symposium 11**
21. Gopalakrishnan M, Hao Zhu, Farchione, T, Mathis MV, Ramana U, Mehta M, Younis I Increasing placebo response and decreasing treatment effects in schizophrenia trials -the trend continues: an update from us food and drug administration. Poster presented at American Society for Clinical pharmacology and Therapeutics (ASCPT), 2016, San Diego.

22. Desrochers J, Klein-Schwartz W, Gobburu J Gopalakrishnan M. To antidote-or not: Population Pharmacokinetic Modeling and Bayesian Forecasting as a Tool to Predict the Need for Antidote in Acute Acetaminophen Overdose. Poster presented at American Conference on Pharmacometrics (ACoP), 2015, Crystal City, Virginia.
23. Singh R, Mehrotra S, Gopalakrishnan M, Gojo I, Karp J, Greer J, Chen A, Rudek M. Pharmacokinetic/pharmacodynamic characteristics of veliparib with and without temozolomide in patients with hematological malignancies. Poster presented at American Conference on Pharmacometrics (ACoP), 2015, Crystal City, Virginia.
24. Gopalakrishnan M. Leveraging Biomarkers, Clinical Endpoints, and Exposure-Response Modeling and Simulation to optimize Phase 3 Dose Selection. Poster presented at American Conference on Pharmacometrics (ACoP), 2015, Crystal City, Virginia.
25. Gopalakrishnan M, Creinin MD, Jansen R, Starr RM, Gobburu J, Olariu A. Levonorgestrel release rates with LNG20, a new levonorgestrel intrauterine system. Poster presented at American Congress of Obstetricians and Gynecologists (ACOG), 2015, SanFrancisco.
26. Minocha M, Gopalakrishnan M, Gobburu J. Leveraging biomarker-outcome relationship to aid early decision making in multiple sclerosis clinical development. Poster presented at American Conference on Pharmacometrics (ACoP), 2014, Las Vegas.
27. Cacek AT, Gobburu J, Gopalakrishnan M. Population Pharmacokinetics of an intra-nasally administered combination of Oxymetazoline and Tetracaine (Kovacaine Mist™) in Healthy volunteers. Poster presented at American College of Clinical Pharmacology (ACCP), 2014, Atlanta.
28. Ivaturi V, Gopalakrishnan M, Sergei. Evaluation of bias and precision of QRPEM algorithm for discrete data models. Poster presented at PAGE, 2014, Alicante Spain.
29. Gopalakrishnan M, Roy A. Validation of Surrogate Endpoints by Bayesian Equivalence testing. Oral Poster presentation at Joint Statistical Meetings (JSM), at SanDiego, July-August 2012.
30. Gopalakrishnan M, Guo-Linag Tian. Non-iterative Bayesian Sampling for analyzing Zero-Inflated Count Data. Poster presentation at Workshop on Contemporary Statistical Methods in Biostatistics, UMBC, at Baltimore, 2011.
31. Gopalakrishnan M, Suarez S, Hickey Anthony, Gobburu J. A Pharmacokinetic-Pharmacodynamic model for insulin to guide in optimal drug delivery. Poster podium presented at American Association of Pharmaceutical Scientists (AAPS), Baltimore, 2004
32. Gopalakrishnan M, Jadhav P, Gobburu J. A Web-based Pharmacometrics learning resource. Poster presented at American College of Clinical Pharmacology (ACCP), 2004 at Phoenix, Arizona

INVITED LECTURES

1. Gopalakrishnan M. A Quantitative Model-Based Framework to Improve Clinical Outcomes in Neonatal Opioid Withdrawal Syndrome using Real World Data, American Society of Clinical Pharmacology and Therapeutics. Virtual. March 2021.

2. Gopalakrishnan M. Innovative Analytical Approaches and Study Designs for Efficient and Feasible Pediatric Drug Development, Biotechnology Innovative Organization, Oct 2018

3. Gopalakrishnan M. Modeling and simulation to support development and approval of complex products. 4th Annual Development of Generics & 505 b(2) Symposium, New Jersey, Sep 2017

4. Gopalakrishnan M. Regulatory science advance precision medicine forum-participant, PhRMA Foundation, Washington DC, Sep 2017.

5. Gopalakrishnan M. Bayesian Methodologies for Pediatric extrapolation based on exposure-response relationship. Joint Statistical Meetings. Baltimore, July 2017.

6. Gopalakrishnan M. Math Awareness Week, Baltimore County Community College, April 2017

7. Gopalakrishnan M. Dose Response Trials Course Lecture, American College of Clinical Pharmacology, Sep 2014.

TEACHING/MENTORING EXPERIENCE

Teaching

2012 - present	**Course Manager – MS in Pharmacometrics program** PHMX 663 – Statistics for Pharmacometricians – I PHMX 759 – Statistics for Pharmacometricians-II
2019-present	**Course Manager – PharmD program** PHAR 556 –Pharmacokinetics
2021- present	**Course Manager – PhD in Palliative Care program** PALC 652 – Statistical for Palliative care
2014 - present	**Lecturer** Courses: PHAR 615 (Select topics in the Ethics & Biostatistics) PHAR 506 (Select topics in Principles of drug action) PHAR 556 (Pharmacokinetics – Taught in Fall 2014, 2015)
2020- present	**Guest Lecturer** Department of Pharmaceutical Health and Research Course: PHSR 702 – Research Methods-II
2020	**Preceptor** University of Maryland School of Medicine Course: Pharmacokinetics
2012-2013	**Graduate Instructor** Department of Mathematics and Statistics University of Maryland, Baltimore County (UMBC)

Course: STAT 350: Statistics for Life sciences

2009-2011 **Graduate Teaching Assistant**
Department of Mathematics and Statistics
University of Maryland, Baltimore County (UMBC)

Mentoring

Ph.D. Students

Primary Advisor

Name: Shamir Kalaria, Pharm.D.
Years under supervision: Fall 2015 – Spring 2020
Thesis title: From Data to Decisions: Utilizing Pharmacometrics to Optimize Clinical Therapeutics and Drug Development in Neuropsychiatry
Current position: Clinical Reviewer, Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation & Research (CDER), FDA

Name: Ahmed Salem, M.S.
Years under supervision Fall 2019 – present

Name: Brooke Langevin
Years under supervision: Fall 2021- present

Committee member

Name: Nadeesri Wijekoon (UMBC)
Year: 2018-present

Name: O'Mareen Spence
Year: 2019-2020

Name: Shailly Mehrotra
Year: 2014-2017

Name: Mina Hosseini (UMBC)
Year: 2017

Fellow, Post-Doctoral Trainee

Mentor

Name: Pawan Gupta, PhD
Year: Spring 2020 - present
Primary project title: Application of Model Informed Drug Development strategies

Name: Eliford Ngaimisi Kitabi, PhD.
Year: 2015 – 2018

Primary project title: Pharmacometric modeling and simulation for generic drug substitutability and post-marketing risk assessment
Current Position: Pharmacometrics Reviewer, US Food and Drug Administration

Pharmacometrics Masters Students Advised

1. Tim Cacek, 2014
2. Julie Desrochers, 2015
3. Renu singh, 2016
4. Arash Roufinia, 2017
5. Nagaraju Poola, 2017
6. Martine Allard, 2017
7. Bindu Murthy, 2018
8. Vatsala Nageshwaran, 2019
9. Aburough Abegesah, 2019
10. Ritu Chadda, 2019
11. Chao Li, 2019
12. Tao Niu, 2019
13. Yali Liang, 2020

PROFESSIONAL COMMITTEES

National

2018-present	Awards and Honors Committee American College of Clinical Pharmacology (ACCP) Role: Member
2013-2018	Public Policy Committee American College of Clinical Pharmacology Role: Member
2015 - present	Bayesian Scientific Working Group Drug Information Association Role: Member

School

2015-present	Clinical Research Consulting Unit (CRCU) Department of Pharmacy Practice & Science, UMB Role: Director
2018	Faculty Search Committee Department of Pharmacy Practice & Science, UMB Role: Chair

2014-2017	Admissions Committee School of Pharmacy, UMB Role: Member
2018-2019	Student Affairs Committee School of Pharmacy, UMB Role: Member
2020-2021	Student Affairs Committee School of Pharmacy, UMB Role: Co-Chair
2021-present	Student Affairs Committee School of Pharmacy, UMB Role: Chair
2020-present	Graduate Council Graduate school, UMB Role: Member

PROFESSIONAL MEMBERSHIP

2015-present	American Society of Clinical Pharmacology & Therapeutics
2015-present	International Society of Pharmacometrics
2013-present	American College of Clinical Pharmacology
2008-2021	American Statistical Association

ADDITIONAL PROFESSIONAL ACTIVITIES

2017-present	Peer reviewer for Journal of Clinical Pharmacology
2017-present	Peer reviewer for British Journal of Clinical Pharmacology
2018-present	Peer reviewer for Clinical Cancer Research
2018-present	Peer reviewer for Cancer Chemotherapy & Pharmacology
2020-present	Peer reviewer for European Journal of Clinical Pharmacology
2020-present	Peer reviewer for Clinical Pharmacokinetics
2020-present	Peer reviewer for Drug design development and therapy
2020-present	Peer reviewer for Pharmaceutical Research
2022-present	Peer reviewer for Frontiers in Pharmacology – Drug Metabolism