MATHANGI GOPALAKRISHNAN, M. PHARM, PH.D.

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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
1997-1998	M.Pharmacy Birla Institute of Technology & Science, Pilani Rajasthan, India
1993-1998	B.Pharmacy [Honors] Birla Institute of Technology & Science, Pilani Rajasthan, India

EMPLOYMENT

2024- present	Associate Professor (Tenured) Center for Translational Medicine (CTM) Department of Practice, Sciences, and Health Outcomes Research (PSHOR) University of Maryland, Baltimore (UMB)
2022- present	Graduate Program Director – MS in Pharmacometrics University of Maryland, Baltimore (UMB)
2019-2024	Assistant Professor (Tenure-track) Center for Translational Medicine (CTM) Department of Practice, Sciences, and Health Outcomes Research (PSHOR) University of Maryland, Baltimore (UMB)
2013-2019	Research Assistant Professor Center for Translational Medicine (CTM) Department of Practice, Sciences, and Health Outcomes Research (PSHOR)

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)
PSHOR, UMB

HONORS AND AWARDS

2025 ACCP McKeen Cattell Award

2023 American College of Clinical Pharmacology (ACCP) Fellow

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 & Data science

- Highly proficient in frequentist and Bayesian statistics
- Proficient in artificial intelligence and machine learning methodologies
- 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
- 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
    - Extrapolation of efficacy from adults to pediatrics using similarity of exposure-response relationships between adult and pediatrics
- Experience in Model-Informed Drug Development (MIDD) pathway

- 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

RESEARCH AREAS

My research focusses on two broad areas: Predictive analytics and Clinical trial design.

- Predictive analytics encompasses research in the areas of Pharmacometrics, Precision therapeutics and Clinical decision making. My lab utilizes fundamental principles of clinical pharmacology (pharmacokinetics (PK)/pharmacodynamics (PD)), advanced statistical (frequentist and Bayesian) methods (modeling and simulation) and Artificial Intelligence and machine learning (AI/ML) techniques to inform individualized dosing and improve clinical and therapeutic outcomes for a wide range of patient populations including, pediatrics, pregnant and post-partum women and critically ill patients.
- The trial design research involves applying appropriate statistical principles including Bayesian approaches and AI/ML methods for efficient trial designs for drug development. My lab works in drug development programs on medical counter measures and artificial blood products.

GRANTS AND CONTRACTS

Current grants

Source: FDA – MCERSI
Title: Physiologically Based Pharmacokinetic Modeling Informed Framework to Prioritize Drugs to be Studied in Pregnant Population
Time period: 09/31/2023 - 08/31/2025
Amount: $263,551
Role: PI

Source: DARPA – Defense Advanced Research Projects Agency
Title: CONCERT: Consortium for Optimized Integration of Bio-artificial Blood Components for Adaptive Resuscitation and Therapy
Time period: 01/31/2023 – 01/31/2027
Amount: $46,000,000
Role: Co-I, Computational modeling core lead

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: 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

Source: NIH
Title: Pharmacokinetics (PK) and Pharmacodynamics (PD) Characterization of mTOR Inhibitors in Older Adults
Time period: 09/01/2024 – 08/31/2027
Amount: $897,732
Role: Co-I

Pending grants

FOA: PA-20-184
Title: "The Impact of Cannabidiol on the Pharmacokinetics and Pharmacodynamics of Oral Delta-9-Tetrahydrocannabinol"
Period of Performance: 09/01/2025-08/31/2030

FOA: PA-25-305
Title: "Maternal and Fetal Physiologically Based Pharmacokinetic Model to predict Low Calorie Sweetener Exposure during Pregnancy"
Period of Performance: 12/01/2025-11/30/2029

Completed grants

Source: NIH, 1R21HD105648
Title: Intergenerational Transmission of Low-calorie Sweeteners via the Breast Milk
Time period: 01/01/2022 – 07/31/2024
Amount: $21,305
Role: Co-I and Sub-recipient PI

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 – 03/31/2023
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: 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

Completed Contracts

Source: Partner Therapeutics, Inc
Title: A Meta-analysis of Leukine trials
Time period: 11/25/2020-11/24/2023
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

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 – 11/30/2021
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. Nyman K, Decker E, Ronan K, **Gopalakrishnan M**, El-Metwally D. Effect of neonatal intensive care unit design on infants with Neonatal Opioid Withdrawal Syndrome. J Neonatal Perinatal Med. 2025 Jan;18(1):46-51. doi: 10.1177/19345798241296324. Epub 2024 Nov 5. PMID: 39973535.
2. Siddiqua TJ, Schulze KJ, Hasan ST, Ahsan KB, Bandyopadhyay S, Zavala E, Ali H, Haque R, Sujan HM, Rahman MH, Baker S, Stephenson KK, Ge X, Gough EK, *Langevin B, Wu LSF, Dyer B, Roy AK, Jubair M, Nishan AA, Rosenblum M, **Gopalakrishnan M**, Kraemer K, Erchick DJ, Ahmed T, Christian P. Micronutrient dose response (MiNDR) study among women of reproductive age and pregnant women in rural Bangladesh: study protocol for double-blind, randomised, controlled trials. BMJ Open. 2025 Jan 4;15(1):e090108. doi: 10.1136/bmjopen-2024-090108. PMID: 39755576; PMCID: PMC11749533.
3. Shah CH, Reed RM, Wastila L, Onukwugha E, **Gopalakrishnan M**, Zafari Z. Comparative effectiveness of olodaterol/tiotropium and vilanterol/umeclidinium among COPD patients: a high-dimensional propensity score matched new user cohort study in a US medicare population. Expert Rev Respir Med. 2024 Dec;18(12):1113-1120. doi: 10.1080/17476348.2024.2446598. Epub 2024 Dec 30. PMID: 39718113.
4. Ruelas Castillo J, Guerrini V, Quijada D, Karanika S, Neupane P, Urbanowski ME, *Shenkoya B, Harris H, Garcia A, Yilma A, Annunziata H, Khan R, **Gopalakrishnan M**, Gennaro ML, Karakousis PC. Pharmacological inhibition of macrophage triglyceride biosynthesis pathways does not improve Mycobacterium tuberculosis control in infected mice. J Infect Dis. 2024 Nov 19:jiae577. doi: 10.1093/infdis/jiae577. Epub ahead of print. PMID: 39560474.
5. Roskes L, *Chamzas A, Ma B, Medina AE, **Gopalakrishnan M**, Viscardi RM, Sundararajan S. Early human milk feeding: Relationship to intestinal barrier maturation and postnatal growth. Pediatr Res. 2024 Oct 14. doi: 10.1038/s41390-024-03622-5. Epub ahead of print. PMID: 39397156.
6. *Shenkoya B, **Gopalakrishnan M**, Eke AC. Physiologically based pharmacokinetic modeling of long-acting extended-release naltrexone in pregnant women with opioid use disorder. CPT Pharmacometrics Syst Pharmacol. 2024 Nov;13(11):1939-1952. doi: 10.1002/psp4.13252. Epub 2024 Oct 9. PMID: 39380562; PMCID: PMC11578127.
7. *Chamzas A, Tellez E, SyBing A, Gobburu JVS, **Gopalakrishnan M**. Optimizing tacrolimus dosing in Hispanic renal transplant patients: insights from real-world data. Front Pharmacol. 2024 Sep 19;15:1443988. doi: 10.3389/fphar.2024.1443988. PMID: 39364052; PMCID: PMC11446860.
8. Sylvetsky AC, Kuttamperoor JT, *Langevin B, Murphy J, Arcaro KF, Smolyak S, et al. Intergenerational transmission of sucralose and acesulfame-potassium from mothers to their infants via human milk: a pharmacokinetic study. Am J Clin Nutr 2024:S0002-9165(24)00657-9. https://doi.org/10.1016/j.ajcnut.2024.08.001.

9. Wang X, **Gopalakrishnan M**, Rich B, Gobburu JV, Larsen F, Raoufinia A. Exposure-Response Modeling in Adults and Adolescents With Schizophrenia to Support the Extrapolation of Brexpiprazole Efficacy to Adolescents. J Clin Pharmacol 2024. https://doi.org/10.1002/jcph.2464.
10. **#Gopalakrishnan M**, Amaria RN. Project Optimus Elicits the "Holistic" Benefits of PK/PD Modeling of Immunotherapy. Clin Cancer Res 2024;30:2862–4. https://doi.org/10.1158/1078-0432.CCR-24-0553.
11. Nampota-Nkomba N, Nyirenda OM, Mallewa J, Chimalizeni Y, Dzabala N, Fay MP, et al. DON in pediatric cerebral malaria, a phase I/IIA dose-escalation safety study: study protocol for a clinical trial. Trials 2024;25:87. https://doi.org/10.1186/s13063-023-07808-w.
12. *Langevin B, Singh P, Plett PA, Sampson CH, Masters A, Gibbs A, et al. Pharmacokinetics and Biodistribution of 16,16 dimethyl Prostaglandin E2 in Non-Irradiated and Irradiated Mice and Non-Irradiated Non-Human Primates. Radiat Res 2024;201:7–18. https://doi.org/10.1667/RADE-23-00040.1.
13. *#Langevin B, Gobburu JVS, **Gopalakrishnan M**. Is There a Need for a Dedicated Pharmacokinetic Trial for a Drug in Obese Populations? A Drug Prioritization Decision Tree Framework. J Clin Pharmacol 2023;63 Suppl 2:S48–64. https://doi.org/10.1002/jcph.2304.
14. *Langevin B, **Gopalakrishnan M**, Kuttamperoor J, Van Den Anker J, Murphy J, Arcaro KF, et al. The MILK study: Investigating intergenerational transmission of low-calorie sweeteners in breast milk. Contemp Clin Trials Commun 2023;36:101212. https://doi.org/10.1016/j.conctc.2023.101212.
15. Smolyak D, Humphries EM, Parikh A, **Gopalakrishnan M**, Aycan F, Bjarnadóttir M, et al. Predicting Heterogeneity in Patient Response to Morphine Treatment for Neonatal Opioid Withdrawal Syndrome. Clin Pharmacol Ther 2023;114:1015–22. https://doi.org/10.1002/cpt.3007.
16. *#Salem AM, Dvergsten E, Karovic S, Maitland ML, **Gopalakrishnan M**. Model-based approach to identify predictors of paclitaxel-induced myelosuppression in "real-world" administration. CPT Pharmacometrics Syst Pharmacol 2023;12:929–40. https://doi.org/10.1002/psp4.12963.
17. *#Shenkoya B, Yellepeddi V, Mark K, **Gopalakrishnan M**. Predicting Maternal and Infant Tetrahydrocannabinol Exposure in Lactating Cannabis Users: A Physiologically Based Pharmacokinetic Modeling Approach. Pharmaceutics 2023;15:2467. https://doi.org/10.3390/pharmaceutics15102467.
18. *#Salem AM, Smith T, Wilkes J, Bailly DK, Heyrend C, Profsky M, et al. Pharmacokinetic Modeling Using Real-World Data to Optimize Unfractionated Heparin Dosing in Pediatric Patients on Extracorporeal Membrane Oxygenation and Evaluate Target Achievement-Clinical Outcomes Relationship. J Clin Pharmacol 2023. https://doi.org/10.1002/jcph.2333.
19. Patel M, **Gopalakrishnan M**, Sundararajan S. Impact of Delayed Cord Clamping on Red Blood Cell Transfusion and related outcomes in Very Low Birth Weight Infants. Am J Perinatol. Published online June 22, 2023. doi:10.1055/a-2115-4360.
20. Shah CH, Reed RM, Wastila L, Onukwugha E, **Gopalakrishnan M**, Zafari Z. Direct Medical Costs of COPD in the USA: An Analysis of the Medical Expenditure Panel

Survey 2017-2018. Appl Health Econ Health Policy. Published online June 3, 2023. doi:10.1007/s40258-023-00814-8.

21. Ronan K, Hughes Driscoll CA, Decker E, **Gopalakrishnan M**, El-Metwally D. Resource utilization and convalescent care cost in neonatal opioid withdrawal syndrome. Journal of Neonatal-Perinatal Medicine, 2023: 16(1): 49-57. doi: 10.3233/NPM-221060.
22. Gibbs A, Gupta P, Mali B, Poirier Y, **Gopalakrishnan M**, Newman D, et al. A C57L/J Mouse Model of the Delayed Effects of Acute Radiation Exposure in the Context of Evolving Multi-Organ Dysfunction and Failure after Total-Body Irradiation with 2.5% Bone Marrow Sparing. Radiat Res. 2023 Mar 2;
23. Laffont CM, Ngaimisi E, **Gopalakrishnan M**, Ivaturi V, Young M, Greenwald MK, et al. Buprenorphine exposure levels to optimize treatment outcomes in opioid use disorder. Front Pharmacol. 2022;13:1052113.
24. Klasner C, Brown J, **Gopalakrishnan M**, Metwally DE, Besse M, Mark K. Effect of maternal adverse childhood experiences (ACE) and cannabis use on pregnancy outcomes. Arch Womens Ment Health, 2022; 25: 1097-1104.
25. *#Goyal RK, Kalaria SN, McElroy SL, **Gopalakrishnan M**. An exploratory machine learning approach to identify placebo responders in pharmacological binge eating disorder trials. *Clin Transl Sci*. Published online September 20, 2022. doi:10.1111/cts.13406
26. *#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.
27. *#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.
28. *#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.
29. 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.
30. *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.
31. 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.
32. *#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.

33. *#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.
34. 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.
35. *#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.
36. * 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.
37. #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).
38. 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.
39. **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.
40. *#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.
41. 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.
42. **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).
43. 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.
44. *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.

45. *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.
46. * 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.
47. 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.
48. 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.
49. #*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.
50. *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.
51. 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
52. #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.
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56. #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.
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61. #*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.
62. 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;
63. #*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.
64. 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.
65. **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.
66. **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.

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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. Athanasios Chamzas, Kannan Sridharan, **Mathangi Gopalakrishnan.** Patent Ductus Arteriosus in Preterm Infants: Exploring Optimal Acetaminophen Dosing for Oral and Rectal Administration. American Conference on Pharmacometrics (ACoP), Phoenix, Arizona, November 2024.
2. Sooyoung Lee, **Mathangi Gopalakrishnan**. Exploring Appropriate Prior Distributions for Covariance Matrix Estimation in Bayesian Population Pharmacokinetic Analysis. American Conference on Pharmacometrics (ACoP), Phoenix, Arizona, November 2024. **Trainee Quality Award Winner.**
3. Kevin. V. Tobin, Bianca Reginauld, Audra L. Stinchcomb, **Mathangi Gopalakrishnan**. Flux-based IVIVC for predicting oxybutynin exposure with and without occlusion of a transdermal gel. American Conference on Pharmacometrics (ACoP), Phoenix, Arizona, November 2024.
4. Babajide Shenkoya, Ahizechukwu Eke, **Mathangi Gopalakrishnan**. Pharmacokinetics of Long-Acting Naltrexone in Pregnancy: Insights from Physiologically Based Pharmacokinetic Modeling. American Conference on Pharmacometrics (ACoP), Phoenix, Arizona, November 2024.
5. Athanasios Chamzas, **Mathangi Gopalakrishnan**, Osward M. Nyirenda, Nginache Nampota-Nkomba, Jane Mallewa, Rana Rais, Jesse Alt, Matthew Laurens, Douglas G. Postels, Brittany A. Riggle. American College of Clinical Pharmacology (ACCP), Bethesda, MD. September 2024.
6. Babajide Shenkoya, Venkata Yellepeddi, Katrina Mark, **Mathangi Gopalakrishnan.** Modeling THC Pharmacokinetics in Infants Exposed to Breastmilk from Recreational

Cannabis Users. American College of Clinical Pharmacology (ACCP), Bethesda, MD. September 2024.

7. Brooke Langevin, Babajide Shenkoya, Qi Liu, Yuching Yang, Katrina Mark, **Mathangi Gopalakrishnan.** Real-world Insights in to Drug Dosing for Commonly Prescribed Drugs During Pregnancy. American College of Clinical Pharmacology (ACCP), Bethesda, MD. September 2024.
8. *Sooyoung Lee, Alice P. Chen, Keith W. Pratz, Michelle A. Rudek, **Mathangi Gopalakrishnan**. Bayesian Population Pharmacokinetic Modeling for Veliparib Using Sparse Data from a Phase II Clinical Trial in Patients with Hematologic Malignancies. American Conference on Pharmacometrics (ACoP), National Harbour, MD, November 2023.
9. *Babajide Shenkoya, Venkata Yellepeddi, **Mathangi Gopalakrishnan**. Cannabis Smoking and Lactation: A Physiologically-based Pharmacokinetic Model of Breastmilk Exposure in Lactating Recreational Cannabis Users. American Conference on Pharmacometrics (ACoP), National Harbour, MD, November 2023.
10. *Athanasios Chamzas, Eglis Tellez-Corrales, Andrew SyBing, Jogarao Gobburu and **Mathangi Gopalakrishnan**. Optimizing Tacrolimus dosing in Hispanic Renal Transplant Patients Using Population Pharmacokinetic Modeling. American Conference on Pharmacometrics (ACoP), National Harbour, MD, November 2023.
11. *Athanasios Chamzas, Eglis Tellez-Corrales, Andrew SyBing, Jogarao Gobburu and **Mathangi Gopalakrishnan**. Investigating Tacrolimus Population Pharmacokinetics in Adult Hispanic Renal Transplant Patients. American College of Clinical Pharmacology (ACCP), Bellevue, WA. September 2023. **Student Trainee Award Winner.**
12. *Brooke Langevin, Jogarao V.S. Gobburu, Mathangi Gopalakrishnan. Is there a Need for a Dedicated Pharmacokinetic Trial for a Drug in Obese Population. American College of Clinical Pharmacology (ACCP), Bellevue, WA. September 2023. **Student Trainee Award Winner.**
13. *Brooke Langevin, Allison C. Sylvetsky, Janae Kuttamperoor, Peter Walter, Hongyi Cai, John Van Den Anker, Jeanne Murphy, Kathleen F. Arcaro, **Mathangi Gopalakrishnan**. The MILK Study: Investigating Intergenerational Transmission of Low Calorie Sweetener in Breast Milk. American College of Clinical Pharmacology (ACCP), Bellevue, WA. September 2023.
14. Salem AM*, Smit T, Wilkes J, Bailly D, Yellepeddi V, **Gopalakrishnan M**. Population Pharmacokinetic Modeling to Guide the Optimal Dosing for Unfractionated Heparin in Pediatrics Requiring Extracorporeal Membrane Oxygenation. American Society of Clinical Pharmacology and Therapeutics (ASCPT), Atlanta, GA, March 2023. **Presidential Trainee Award Winner**.
15. Langevin B*, El-Metwally D, **Gopalakrishnan M**. External Evaluation of Neonatal Opioid Withdrawal Syndrome Clinical Decision Support Systems. American Conference on Pharmacometrics (ACoP), Denver, CO, November 2022.
16. Goyal RK*, McManus J, **Gopalakrishnan, M**. Unsupervised Hierarchical Clustering Analysis for the Characterization of Sequence of Pancytopenia in Male and Female Non-human Primates Post Total Body Irradiation. Conference on Pharmacometrics (ACoP), Denver, CO, November 2022.
17. Goyal RK*, McManus J, **Gopalakrishnan, M**. Application of Machine Learning Analysis to Inform Medical Countermeasure Development – A Case Study Using

Random Forest Ensemble to Identify Predictive Biomarkers of Mortality for Hematopoietic Acute Radiation Syndrome and Confirmation of Benefit with Leukine® Across Myeloid Lineages. Conference on Pharmacometrics (ACoP), Denver, CO, November 2022.

18. Salem AM*, Moffett B, **Gopalakrishnan M**. A Full Bayesian Approach for Population Pharmacokinetic/Pharmacodynamic Modeling of Unfractionated Heparin in Pediatrics. American Conference on Pharmacometrics (ACoP), Denver, Co, November 2022.
19. Pigarev SE, Fedoros E, Engelholm SA, Meineke V, Dainiak N, Shapiro A, Kane M, Zalesak-Kravec S, **Gopalakrishnan M**, Chen D, Doyle-Eisele M, Weber W, Brower J. BP-C2: Radiomitigative Potential in CRI-ARS Study in Yorkshire Swine. Radiation Research Society, Hawaii, October 2022.
20. Goyal RK*, McManus J, **Gopalakrishnan, M** . Application of Machine Learning Analysis to Inform Medical Countermeasure Development – A Case Study Using Machine Learning to Identify Predictive Biomarkers of Mortality for Hematopoietic Acute Radiation Syndrome and Confirmation of Benefit with Leukine® Across Myeloid Lineages. Radiation Research Society, Hawaii, October 2022.
21. Goyal RK*, McManus J, **Gopalakrishnan, M.** Machine Learning-based Meta-Analysis of H-ARS Studies in NHPs: Hematologic Myeloid Predictors & Confirmation of Leukine® Benefit Across Myeloid Lineages. Radiation Injury Treatment Network, Alexandra, VA, August 2022.
22. Raja K, **Gopalakrishnan M**, Hussey-Gardner B, Sundararajan, S. Association of Platelet Transfusion and Severe Intraventricular Hemorrhage in Very Low Birth Weight Infants. Joint ESPR/AFMR 1st Annual Eastern Medical Research Conference, Virtual, March 2022.
23. Salem AM*, Karovic S, Dvergsten E, Maitland M**, Gopalakrishnan M.** Model-Based Approach to Identify Predictors for Weekly Paclitaxel-Induced Myelosuppression Using Real-World Data. American Conference on Pharmacometrics (ACoP), Virtual, November 2021.
24. Patel M, **Gopalakrishnan M,** Sundararajan, S. Impact of Delayed Cord Clamping on Red Blood Cell Transfusion in Very Low Birthweight Infants. American Academy of Pediatrics (AAP), Virtual, October 2021.
25. 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**
26. 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 4^{th,} 2021
27. 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

28. 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**
29. 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. ****Student Abstract Award Winner**
30. 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
31. 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
32. 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
33. 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.
34. Masich A, Kalaria SN*, Heil E, Gonzalez J, Heavner M, Tata A, **Gopalakrishnan M** 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]
35. 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.
36. **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.
37. Kalaria SN*, Armahizer M, Badjatia N, McCarthy P, Gobburu J, **Gopalakrishnan M**. 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**
38. **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.
39. 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.

40. 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
41. 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.
42. 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.
43. **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.
44. 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**
45. **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.
46. 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.
47. 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.
48. **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.
49. **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.
50. 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.
51. Cacek AT, Gobburu J, **Gopalakrishnan M**. Population Pharmacokinetics of an intra-nasally administered combination of Oxymetazoline and Tetracaine (Kovacaine Mist^{TM})

in Healthy volunteers. Poster presented at American College of Clinical Pharmacology (ACCP), 2014, Atlanta.

52. Ivaturi V, **Gopalakrishnan M**, Sergei. Evaluation of bias and precision of QRPEM algorithm for discrete data models. Poster presented at PAGE, 2014, Alicante Spain.
53. **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.
54. **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.
55. **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
56. **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. *Invited Speaker:* Precision Therapeutics Guided by Pharmacometrics in Lactating Women. 13th Annual Indiana CTSI. Disease and Therapeutic Response Modeling Symposium. February 2024.

2. Gopalakrishnan M. *Invited Speaker*: Innovative Data Analytics to Inform Pharmacokinetics and Dosing in Pregnancy. FDA-MCERSI PK Evaluation in Pregnancy – Public Workshop. Virtual. May 2022.

3. Gopalakrishnan, M. *Invited Speaker and Session Co-Chair*: A predictive clinical decision support system for precision dosing of Morphine to Improve Clinical Outcomes in Neonatal Opioid Withdrawal Syndrome using Real World Data. American Society of Clinical Pharmacology and Therapeutics (ASCPT). Virtual. March 2022.

4. Gopalakrishnan M. *Invited Panelist*: FDA-M CERSI: Advancing the Development of Pediatric Therapeutics Complex Innovative Trial Design Public Workshop. Virtual. September 2021.

5. Gopalakrishnan M. *Invited Speaker*: 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 (ASCPT). Virtual. March 2021.

6. Gopalakrishnan M. *Invited Panelist*: Innovative Analytical Approaches and Study Designs for Efficient and Feasible Pediatric Drug Development, Biotechnology Innovative Organization (BIO), Washington DC, Oct 2018.

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

8. Gopalakrishnan M. *Invited Panelist:* Regulatory science advance precision medicine forum-participant, PhRMA Foundation, Washington DC, Sep 2017.

9. Gopalakrishnan M. *Invited Speaker*: Bayesian Methodologies for Pediatric extrapolation based on exposure-response relationship. Joint Statistical Meetings (JSM). Baltimore, July 2017.

10. Gopalakrishnan M. *Invited Speaker*: Math Awareness Week, Baltimore County Community College, April 2017

11. Gopalakrishnan M. *Course moderator and presenter:* Dose Response Trials Course Lecture, American College of Clinical Pharmacology (ACCP), 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. and Masters Students – Primary Advisor

Student Name	**Degree type**	**Thesis Title**	**Years**	**Current Status / Professional Position**
Athanasios Chamzas	PhD		2023-present	
Babajide Shenkoya	PhD		2022-present	
Brooke Langevin	PhD		2021-2025	Assistant Professor, PSHOR, UMSOP
Ahmed Salem	PhD	Pharmacometric Model-Based Real-World Data Driven Framework to Refine Unfractionated Heparin Dosing in Pediatric Population	2019-2024	Senior Scientist, Astra Zeneca
Shamir Kalaria	PhD	From Data to Decisions: Utilizing Pharmacometrics to Optimize Clinical Therapeutics and Drug Development in Neuropsychiatry	2015-2020	Clinical Reviewer, Division of Psychiatry Products, Office of New Drugs, Center for Drug Evaluation & Research (CDER), FDA
Yali Liang	Masters	Model based meta analysis to rank order efficacy of PD-L1 therapeutics	2020	Clinical Pharmacologist, Jazz Pharmaceuticals
Tao Niu	Masters	Pharmacokinetic-Pharmacodynamic modeling of Unfractionated Heparin in Pediatric Subjects	2019	Associate Director, Modeling & Simulation, Vertex Pharmaceuticals
Chao LI	Masters	Pharmacokinetic-Pharmacodynamic modeling of	2019	Head of Clinical Pharmacology, Startup

		Unfractionated Heparin in Pediatric Subjects		
Ritu Chadda	Masters	Population pharmacokinetic modeling to assess drug-drug interactions	2019	Clinical Pharmacology Reviewer, FDA
Aburough Abegesah	Masters	Population pharmacokinetic modeling to assess drug-drug interactions	2019	Senior Scientist, AstraZeneca
Vatsala Nageshwaran	Masters	Population pharmacokinetic modeling of ophthalmic suspension to scale drug exposure from preclinical models to humans	2019	Vice President, Head of Business Development, Pharmaron
Bindu Murthy	Masters	PK-PD modeling to inform dose selection	2018	Executive Director, Clinical Pharmacology & Pharmacometrics Bristol Myers Squibb
Martine Allard	Masters	Population PK modeling of estrogen to inform dose selection	2017	Director Clinical Pharmacology & Pharmacometrics, Telios Pharma
Nagaraju Poola	Masters	Population PK modeling of Veliparib in hematological malignancies	2017	Clinical Pharmacologist, Otsuka Pharmaceuticals
Arash Raoufinia	Masters	Population pharmacokinetic modeling to assess adherence	2017	VP, Head of Early Phase Development and Translational Medicine, Otsuka Pharmaceuticals
Shabnam Sani	Masters	Population PK modeling and IVIVC Correlation	2017	Associate Director, Clinical Pharmacology, Mersana Therapeutics
Neha Mehta	Masters	Population PK modeling of Veliparib in hematological malignancies	2017	Reviewer, FDA
Soujanya Sunkaraneni	Masters	Exposure-Response modeling and simulation to inform Phase 2 dose selection for a psoriatic agent	2016	Senior Director Syndax Pharmaceuticals
Jihye Ahn	Masters	Does gastric bypass surgery affect bioavailability of orally	2016	Pharmacometrics Reviewer, FDA

		administered darunavir? A physiologically based pharmacokinetic modeling approach		
Julie Desrochers	Masters	To antidote-or not: Population Pharmacokinetic Modeling and Bayesian Forecasting as a Tool to Predict the Need for Antidote in Acute Acetaminophen Overdose	2015	Principal Modeling Scientist, Novo Nordisk
Renu Singh	Masters	Pharmacokinetic/pharmacodynamic characteristics of veliparib with and without temozolomide in patients with hematological malignancies	2015	Director, Clinical Pharmacology, Gilead Sciences
Tim Cacek	Masters	Population Pharmacokinetics of an intra-nasal combination anesthetic	2014	Contract Services Pharmacometrician, Self Employed

Ph.D. Students – Committee Member

Student Name	Years Under Supervision	Thesis type and Status
Onyeka		
Udim		
Rahul Goyal	2022-2024	PhD, Graduated
Dawoon Jung	2022-2024	PhD, Graduated
Tsung-Ying Lee	2023-2024	PhD, Graduated
Chintal Shah	2021-2023	PhD, Graduated
Nadeesri Wijekoon	2018 - 2021	PhD, Graduated Current position: Visiting Associate, Office of Biostatistics, FDA
O'Mareen Spence	2019-2020	PhD, Graduated
Shailly Mehrotra	2014-2017	PhD, Graduated Current position: Associate Scientific Director, Quantitative Clinical Pharmacology, Takeda
Mina Hosseini	2017	PhD at UMBC, Graduated

Fellow, Post-Doctoral Trainee

	Name: Kevin Tobin
	Name: Sree Ojili
Mentor	Name: Sooyoung Lee, PhD Year: 2023 – present Primary project title: Application of Pharmacometrics for optimal therapeutics.
	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

PROFESSIONAL COMMITTEES

National

2025 - 2026	Mental Health and Addiction Community American Society of Clinical Pharmacology & Therapeutics (ASCPT) Role: Chair
2024 – 2025	Mental Health and Addiction Community American Society of Clinical Pharmacology & Therapeutics (ASCPT) Role: Vice Chair
2024 - present	Education Committee American College of Clinical Pharmacology (ACCP) Role: Member
2021- present	Mental Health and Addiction Community American Society of Clinical Pharmacology & Therapeutics (ASCPT) Role: Steering committee member
2022 – 2024	Publications Committee American College of Clinical Pharmacology (ACCP)

	Role: Member
2018 - 2022	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 - 2022	Bayesian Scientific Working Group Drug Information Association Role: Member

School

2025 - present	Faculty Affairs Committee
2025 - present	PSC PhD Steering Committee
2024 – 2025	PSC Progression and Academic Affairs Committee School of Pharmacy, UMB Role: Member
2024 – 2025	Assessment Committee School of Pharmacy, UMB Role: Member
2020 - present	Graduate Council Graduate school, UMB Role: Member
2015 - present	Clinical Research Consulting Unit (CRCU) Department of Pharmacy Practice & Science, UMB Role: Director
2018, 2023	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
2021-2022	Student Affairs Committee School of Pharmacy, UMB Role: Chair

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

Editorial Board Member

2022 – present	Cancer Chemotherapy & Pharmacology

Peer-reviewer 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

CONSULTING

1 Data and Safety Monitoring Board Member

Consulting type: Advisory Committee
Organization: The Emmes Company, LLC (Contract with NICHD)
Location: National
Paid for service: Yes
Date: 03/01/2023 – 05/31/2027