

CURRICULUM VITAE

DANIEL GONZALEZ, PHARM.D., PH.D.

CONTACT INFORMATION

Division of Pharmacotherapy and Experimental Therapeutics
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PERSONAL INFORMATION

Place of Birth: Miami, FL
Citizenship: United States of America

EDUCATION AND TRAINING

- 2012-2014 **Post-Doctoral Fellowship, UNC/Duke T32 Post-Doctoral Clinical Pharmacology Training Program**
University of North Carolina at Chapel Hill, UNC Eshelman School of Pharmacy, Chapel Hill, NC, USA and Duke Clinical Research Institute, Duke University Medical Center, Durham, NC, USA
- Co-advisors: Michael Cohen-Wolkowicz, M.D., Ph.D. (major advisor), Daniel K. Benjamin Jr., M.D., Ph.D., M.P.H. and Kim L. R. Brouwer, Pharm.D., Ph.D.
- 2008-2012 **Doctor of Philosophy, Pharmaceutical Sciences, GPA: 3.91/4.00**
University of Florida, College of Pharmacy, Departments of Pharmaceutics and Pharmacotherapy and Translational Research, Gainesville, FL, USA
- Dissertation Title: *Evaluating Sources of Pharmacokinetic Variability Using Breath Testing and Microdialysis*
Major Advisor: Hartmut Derendorf, Ph.D.
- 2004-2008 **Doctor of Pharmacy, *summa cum laude*, GPA: 3.99/4.00, class rank: 1**
University of Florida, College of Pharmacy, Gainesville, FL, USA
- Honors Thesis Title: *Risk of Diabetes Associated with the KCNJ11 E23K Variant in the INVEST Genetic Sub-study*
Co-Advisors: Julie A. Johnson, Pharm.D. and Michael Pacanowski, Pharm.D., M.P.H.
- 2002-2004 **Associate of Arts, Pre-Pharmacy, GPA: 3.86/4.00**
University of Florida, College of Liberal Arts and Sciences, Gainesville, FL, USA

PHARMACY LICENSURE

- 2013-Present **North Carolina (Active, License #23048)**
2008-Present **Florida (Active, License #PS43721)**

PROFESSIONAL EXPERIENCE

- 2020-Present **Associate Professor with Tenure**
Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA

- 2020-Present **Co-Director, UNC-Duke Collaborative Clinical Pharmacology T32 Postdoctoral Training Program**
UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA
- 2016-Present **Adjunct Assistant Professor**
Department of Pediatrics, School of Medicine, University of North Carolina, Chapel Hill, NC, USA
- 2014-2020 **Assistant Professor**
Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA
- 2017-2019 **Division Director of Graduate Studies**
Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA
- 2016-2017 **Division Director of Graduate Admissions**
Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC, USA
- 2008-2012 **Pharmacist (Part-Time)**
CVS/Caremark Corporation, Gainesville, FL, USA
- 2007-2008 **Doctor of Pharmacy Clerkships**
Completed clerkships in drug information; community practice; ambulatory care; hospice; geriatrics; surgery; internal medicine; and clinical research.
- 2006 **Research Internship in Pharmacogenomics**
University of Florida, Center for Pharmacogenomics, Gainesville, FL, USA
Advisors: Julie Johnson, Pharm.D. and Michael Pacanowski, Pharm.D., M.P.H.
- 2002-2006 **Pharmacy Technician (Part-Time over the Holidays)**
Mercy Hospital, Miami, FL, USA
- 2001-2002 **Pharmacy Technician**
Doctors' Hospital at Baptist Health South Florida, Coral Gables, FL, USA

SPECIALIZED TRAINING, WORKSHOPS, AND CERTIFICATES

- 2020 *Faculty Mentor Training for Biomedical Researchers*, Office of Graduate Education, UNC School of Medicine, Chapel Hill, NC, November 20 and December 4
Pediatric Dose Selection, U.S. Food and Drug Administration, Virtual Workshop, October 22-23
- 2019 *Precision Dosing: Defining the Need and Approaches to Deliver Individualized Drug Dosing in the Real-World Setting*, U.S. Food and Drug Administration, Silver Spring, MD August 12
Coaching for Greater Effectiveness, Center for Creative Leadership, Greensboro, NC, June 4-6
Pharmacokinetics and Pharmacodynamics of Protein Therapeutics, University of Tennessee College of Pharmacy, Memphis, TN, April 1-5
- 2018 *The Power of Professional Presence*, UNC Kenan-Flagler Business School Executive Development, Chapel Hill, NC, October 31-November 2
Maximizing Your Leadership Potential, Center for Creative Leadership, Greensboro, NC, October 10-12
Meeting Planning and Facilitation, Center for Faculty Excellence, UNC-Chapel Hill, Chapel Hill, NC, April 12

- Building and Fostering Collaboration*, Center for Faculty Excellence, UNC-Chapel Hill, Chapel Hill, NC, March 29
- 2017 *Bridging PBPK and POPPK for Pediatrics*, Certara/SimCYP, Ft. Lauderdale, FL, October 12
Pediatric Trial Design and Modeling: Moving into the Next Decade, U.S. Food and Drug Administration, Silver Spring, MD, September 8
- 2016 *Borrowing Strength from Accumulating Data*, American Course on Drug Development and Regulatory Sciences (ACDRS) Special Workshop, Webcast, April 21
Quantitative Assessment of Assumptions to Support Extrapolation of Efficacy in Pediatrics, University of Maryland Center of Excellence in Regulatory Science and Innovation, Silver Spring, MD, June 1
Being a Better Faculty Research Mentor, Center for Faculty Excellence, UNC-Chapel Hill, Chapel Hill, NC, June 21, 22, 28, and 29
Pediatric Master Protocols, University of Maryland Center of Excellence in Regulatory Science and Innovation, Silver Spring, MD, September 23
- 2015 *Increasing Openness and Reproducibility in Quantitative Research using OSF and KnitR*, UNC-Chapel Hill, Chapel Hill, NC, October 26
PI Development Series: Financial Compliance, UNC-Chapel Hill, Chapel Hill, NC, October 22
PI Development Series: Roadmap to Research at Carolina, UNC-Chapel Hill, Chapel Hill, NC, September 9
Responsible Conduct of Research, UNC-Chapel Hill, Chapel Hill, NC, July 6-10
Use of Exposure Matching and Exposure-Response for Extrapolation of Efficacy in Pediatric Product Development, University of Maryland Center of Excellence in Regulatory Science and Innovation, Silver Spring, MD, January 22
- 2014 *Scientific Writing from the Reader's Perspective*, UNC-Chapel Hill, Chapel Hill, NC, November 3
Physiologically Based Pharmacokinetic (PBPK) Modeling, Hamner Institute, Research Triangle Park, NC, September 22-23
Optimal Design for Pharmacometrics, Certara, Cary, NC, March 10-13
- 2013 *Scientific Writing from the Reader's Perspective*, Duke University, Durham, NC
Trial Simulator, Pharsight Corporation, Cary, NC, July 16-17
Introduction to Phoenix WinNonlin, Pharsight Corporation, Cary, NC, June 25-26
Principles of Pediatric Clinical Pharmacology, National Institutes of Health, Online Lecture Series, October 3 (2012) – May 29
Model-Based Meta-Analysis to Support Decision Making in Clinical Drug Development, Metrum Institute, Fort Lauderdale, FL, May 16
Mechanistic Modeling of Biologics, Bayer Technology Services GmbH, Fort Lauderdale, FL, USA, May 12
Principles of Clinical Pharmacology, National Institutes of Health, Online Lecture Series, September 6, 2012 – April 25
- 2012 *Model-Based Drug Development: Incorporating Population Variability into Mechanistic Prediction of PK and Modelling of PK-PD*, simCYP Limited, Venice, Italy, June 5
- 2011 Uppsala Pharmacometrics Summer School, Uppsala, Sweden, August 8-19
R for Pharmacometrics, Mango Solutions, San Diego, CA, USA, April 2-3
New and Advanced Features of NONMEM 7 & PDx-Pop 4, Icon Development Solutions, San Diego, CA, USA April 7
- 2008 American Pharmacists Association Pharmacy-Based Immunization Delivery Certification Course

AWARDS AND HONORS

- 2010-12 American Foundation for Pharmaceutical Education Pre-Doctoral Fellowship
- 2009 American College of Clinical Pharmacology Student Abstract Award
- 2008 Biotechnology Education Scholarship
D.W. Ramsaur Award (highest grade point average in graduating pharmacy class of 2008)
Alachua County Association of Pharmacists Scholarship
University of Florida Alumni Fellowship
- 2007 Medco Scholarship
- 2006 University of Florida, NIH-derived research stipend
Inducted into Rho Chi Pharmaceutical Honor Society
- 2004-08 College of Pharmacy Dean's List, University of Florida

PEER-REVIEWED PUBLICATIONS

Published, In Press, or Accepted (*corresponding author; #authors contributed equally to this work)

1. **Gonzalez D***, Sinha J. Pediatric drug-drug interaction evaluation: drug, patient population, and methodological considerations. *J Clin Pharmacol*. 2021. Accepted.
2. Wu YSS, Cohen-Wolkowicz M, Hornik CP, Gerhart JG, Autmizguine J, Cobbaert M, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. External evaluation of two pediatric population pharmacokinetics models of oral trimethoprim and sulfamethoxazole. *Antimicrob Agents Chemother*. 2021;AAC.02149-20.
3. Balevic SJ, Becker ML, **Gonzalez D**, and Funk RS. Low etanercept concentrations in children with obesity and juvenile arthritis. *J Pediatr Pharmacol Ther*. 2021. Accepted.
4. Salerno SN#, Liao Y#, Jackson W, Greenberg RG, McKinzie CJ, McCallister A, Benjamin DK, Laughon MM, Sanderson K, Clark RH, and **Gonzalez D***. Association between nephrotoxic drug combinations and acute kidney injury in the neonatal intensive care unit. *J Pediatr*. 2021;228:213-219.
5. Neely M, Onufrak N, Scheetz MH, Avedissian S, Lakota E, Deitchman AN, and **Gonzalez D**. Supporting precision dosing in drug labeling. *Clin Pharmacol Ther*. 2021;109(1):37-41.
6. Salerno SN, Edginton A, Gerhart JG, Laughon MM, Ambalavanan N, Sokol GM, Hornik CD, Stewart D, Mills M, Martz K, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Physiologically-based pharmacokinetic modeling characterizes the CYP3A-mediated drug-drug interaction between fluconazole and sildenafil in infants. *Clin Pharmacol Ther*. 2021;109(1):253-262.
7. Zhang Y, Sherwin CM, **Gonzalez D**, Zhang Q, Khurana M, Fisher J, Burckart GJ, Wang Y, Yao LP, Ganley CJ, Wang J. Creatinine-based renal function assessment in pediatric drug development: an analysis using clinical data for renally eliminated drugs. *Clin Pharmacol Ther*. 2021;109(1):263-269.
8. Maxfield K, Milligan L, Wang L, **Gonzalez D**, Johnson-Williams B, Liu Q, Madabushi R, Powell R, Wang Y, Zhu H, Zineh I. Proceedings of a workshop: precision dosing: defining the need and approaches to deliver individualized drug dosing in the real-world setting. *Clin Pharmacol Ther*. 2021;109(1):25-28.

9. Maharaj A, Wu H, Hornik CP, Balevic SJ, Hornik CD, Smith PB, **Gonzalez D**, Zimmerman KO, Benjamin DK Jr, and Cohen-Wolkowicz M; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Simulated assessment of pharmacokinetically guided pediatric dosing for investigational treatments of pediatric patients with Coronavirus Disease 2019. *JAMA Pediatr.* 2020;174(10):e202422.
10. Konicki R, Weiner D, Patterson JH, **Gonzalez D**, Kashuba A, Cao Y, Gehi AK, Watkins P, Powell JR. Rivaroxaban precision dosing strategy for real world atrial fibrillation patients. *Clin Transl Sci.* 2020;13(4):777-784.
11. Ge S, Mendley SR, Gerhart JG, Melloni C, Hornik CP, Sullivan JE, Atz A, Delmore P, Tremoulet A, Harper B, Payne E, Lin S, Erinjeri J, Cohen-Wolkowicz M, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Population pharmacokinetics of metoclopramide in infants, children, and adolescents. *Clin Transl Sci.* 2020;13(6):1189-1198.
12. Balevic SJ, Hornik CP, Green TP, Clowse MEB, **Gonzalez D**, Maharaj AR, Schanberg LE, Eudy AM, Swamy GK, Hughes BL, and Cohen-Wolkowicz M. Hydroxychloroquine in patients with rheumatic disease complicated by COVID-19: clarifying target exposures and the need for clinical trials. *J Rheumatol.* 2020 May 11 [Epub ahead of print].
13. Tyson RJ, Park CC, Powell JR, Patterson JH, Weiner D, Watkins PB, and **Gonzalez D***. Precision dosing priority criteria: drug, disease, and patient population variables. *Front Pharmacol.* 2020;11:420.
14. Srinivas N, Cottrell M, Maffuid K, Prince H, Nelson J, White N, Sykes C, Dellon E, Madanick R, Shaheen N, **Gonzalez D**, and Kashuba A. A translational approach to predicting the efficacy of maraviroc-based regimens as HIV pre-exposure prophylaxis. *Antimicrob Agents Chemother.* 2020;64(2). pii: e01729-19.
15. McLaughlin J, Minshew L, **Gonzalez D**, Lamb K, Klus NJ, Aubé J, Cox W, and Brouwer KLR. Can they imagine the future? A qualitative study exploring the skills employers seek in pharmaceutical sciences doctoral graduates. *PLoS One.* 2019;14(9):e0222422.
16. **Gonzalez D***, Laughon MM, Smith PB, Ge S, Ambalavanan N, Atz A, Sokol GM, Hornik CD, Stewart D, Mundakel G, Poindexter BB, Gaedigk R, Mills M, Cohen-Wolkowicz M, Martz K, and Hornik CP; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Population pharmacokinetics of sildenafil in extremely premature infants. *Br J Clin Pharmacol.* 2019;85(12):2824-2837.
17. Hornik CP, **Gonzalez D**, Dumond J, Wu H, Graham EM, Hill KD, and Cohen-Wolkowicz M. Population pharmacokinetic/pharmacodynamic modeling of methylprednisolone in neonates undergoing cardiopulmonary bypass. *CPT Pharmacometrics Syst Pharmacol.* 2019;8(12):913-922.
18. Beechinor RJ, Cohen-Wolkowicz M, Jasion T, Hornik CP, Lang JE, Hernandez R, and **Gonzalez D***. A dried blood spot analysis for solithromycin in adolescents, children, and infants: a short communication. *Ther Drug Monit.* 2019;41(6):761-765.
19. Hornik CP, Yogev R, Mourani PM, Watt KM, Sullivan JE, Atz AM, Speicher D, Al-Uzri A, Adu-Darko M, Payne E, Gelber C, Lin S, Harper B, Melloni C, Cohen-Wolkowicz M, and **Gonzalez D**; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Population pharmacokinetics of milrinone in infants, children, and adolescents. *J Clin Pharmacol.* 2019;59(12):1606-1619.

20. Shahin MH, Rouby NE, Conrado DJ, **Gonzalez D**, Gong Y, Lobmeyer MT, Beitelshes AL, Boerwinkle E, Gums JG, Chapman A, Turner ST, Pepine CJ, Cooper-DeHoff RM, and Johnson JA. β 2-adrenergic receptor gene affects the negative chronotropic effects of β -blockers: evidence from 3 clinical studies. *J Clin Pharmacol*. 2019;59(11):1462-1470.
21. Gerhart JG, Watt KM, Edginton A, Wade KC, Salerno SN, Benjamin DK Jr., Smith PB, Hornik CP, Cohen-Wolkowicz M, Duara S, Ross A, Shattuck K, Stewart DL, Neu N, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Physiologically-based pharmacokinetic (PBPK) modeling of fluconazole using plasma and cerebrospinal fluid samples from preterm and term infants. *CPT Pharmacometrics Syst Pharmacol*. 2019;8(7):500-510.
22. Beechinor RJ, Thompson PA, Hwang MF, Vargo RC, Bomgaars LR, Gerhart JG, Dreyer ZE, and **Gonzalez D***. The population pharmacokinetics of high-dose methotrexate in infants with acute lymphoblastic leukemia highlight the need for bedside individualized dose adjustment: a report from the Children’s Oncology Group. *Clin Pharmacokinet*. 2019;58(7):899-910.
23. Salerno SN, Burckart GJ, Huang SM, and **Gonzalez D***. Pediatric drug-drug interaction studies: barriers and opportunities. *Clin Pharmacol Ther*. 2019;105(5):1067-1070.
24. Duan P, Wu F, Moore JN, Fisher J, Crensil V, **Gonzalez D**, Zhang L, Burckart GJ, and Wang J. Assessing CYP2C19 ontogeny in neonates and infants using physiologically-based pharmacokinetic models: impact of enzyme maturation versus inhibition. *CPT Pharmacometrics Syst Pharmacol*. 2019;8(3):158-166.
25. Ku LC, Hornik CP, Beechinor RJ, Chamberlain JM, Guptill JT, Harper B, Capparelli EV, Martz K, Anand R, Cohen-Wolkowicz M, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Population pharmacokinetics and exploratory exposure-response relationship of diazepam in children treated for status epilepticus. *CPT Pharmacometrics Syst Pharmacol*. 2018;7(11):718-727.
26. Puia-Dumitrescu MP, Bretzius OM, Brown N, Fitz-Henley JA, Ssengonzi R, Wechsler CS, Gray KD, Benjamin DK, Smith PB, Clark R, **Gonzalez D**, and Hornik CP. Evaluation of gentamicin exposure in the neonatal intensive care unit and hearing function at discharge. *J Pediatr*. 2018;203:131-136.
27. Sherwin J, Thompson E, Hill KD, Watt K, Lodge AJ, **Gonzalez D**, and Hornik CP. Clinical pharmacology considerations for children supported with ventricular assist devices. *Cardiol Young*. 2018;28(9):1082-90.
28. Ge S, Beechinor RJ, Hornik CP, Standing JF, Zimmerman K, Cohen-Wolkowicz M, Laughon MM, Clark R, and **Gonzalez D***. External evaluation of a gentamicin infant population pharmacokinetic data from a national electronic health record database. *Antimicrob Agents Chemother*. 2018;62(9). pii: e00669-18.
29. **Gonzalez D**, James LP, Yogev R, Al-Uzri A, Bosheva M, Adler-Shohet F, Mendley S, Daudjee M, Bradley J, Espinosa C, Tsonkovak E, Moffett K, Marquez L, Simonsen KA, Stoilov S, Boakye-Agyeman F, Jasion T, Hornik CP, Hernandez R, Benjamin DK Jr., Cohen-Wolkowicz M; on behalf of the SOLI-PEDS program. Population pharmacokinetics and safety of solithromycin following intravenous and oral administration in infants, children, and adolescents. *Antimicrob Agents Chemother*. 2018;62(8). pii:e00692-18.
30. Hornik CP, **Gonzalez D**, van den Anker J, Atz AM, Yogev R, Poindexter B, Ng KC, Delmore P, Harper BL, Melloni C, Lewandowski A, Gelber C, Cohen-Wolkowicz M, and Lee JH; on behalf of the Pediatric Trial Network Steering Committee. Population pharmacokinetics of intramuscular and intravenous ketamine in children. *J Clin Pharmacol*. 2018;58(8):1092-1104.

31. Shahin M, Conrado DJ#, **Gonzalez D**#, Gong Y, Lobmeyer M, Cooper-Dehoff R, Boerwinkle E, Turner ST, Chapman AB, Gums JG, and Johnson JA. Genetic predictors of heart rate response in the Pharmacogenomic Evaluation of Antihypertensives Responses (PEAR) study. *J Am Heart Assoc.* 2018;7(5). pii: e006463.
32. Hornik CP, Onufrak NJ, Smith PB, Cohen-Wolkowicz M, Laughon MM, Clark RH, and **Gonzalez D**. Association between sildenafil dosing, predicted exposure, and systemic hypotension in hospitalized infants. *Cardiol Young.* 2018;28(1):85-92.
33. Maharaj AR, **Gonzalez D**, Cohen-Wolkowicz M, Hornik CP, and Edginton AN. Improving pediatric protein binding estimates: an evaluation of α 1-acid glycoprotein maturation in healthy and sick populations. *Clin Pharmacokinet.* 2018;57(5):577-589.
34. Dong OM, Howard RM, Chruch R, Cottrell M, Forrest A, Innocenti, F, Mosedale M, Kashuba A, **Gonzalez D**, and Wiltshire T. Pharmacy in the era of precision medicine: challenges and solution for future pharmacy practice. *Am J Pharm Educ.* 2018;82(6):6652.
35. Salerno S, Bernhardt J, Laughon MM, Jhaveri R, Massaro M, and **Gonzalez D***. Pharmacokinetics of ceftaroline in a preterm infant with methicillin-resistant *Staphylococcus aureus* pneumonia. *J Pediatric Infect Dis Soc.* 2018;7(4):342-345.
36. Autmizguine J, Melloni C, Hornik CP, Dallefeld S, Harper B, Yogev R, Sullivan JE, Atz AM, Al-Uzri A, Mendley S, Poindexter B, Lewandowski A, Delmore P, Cohen-Wolkowicz M, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Population pharmacokinetics of trimethoprim-sulfamethoxazole in infants and children. *Antimicrob Agents Chemother.* 2017;62(1). pii: e01813-17.
37. Salerno S, Edginton A, Cohen-Wolkowicz M, Hornik CP, Watt KM, Jamieson BD, and **Gonzalez D***. Development of an adult physiologically based pharmacokinetic (PBPK) model of solithromycin in plasma and epithelial lining fluid. *CPT Pharmacometrics Syst Pharmacol.* 2017;6(12):814-822.
38. Hwang MF, Beechinor RJ, Wade KC, Benjamin DJ Jr., Smith PB, Hornik CP, Capparelli EV, Duara S, Kennedy KA, Cohen-Wolkowicz M, and **Gonzalez D***. External evaluation of two fluconazole infant population pharmacokinetic models. *Antimicrob Agents Chemother.* 2017;61(12). pii: e01352-17.
39. **Gonzalez D***, Rao GG, Bailey SC, Brouwer KLR, Cao Y, Crona DJ, Kashuba ADM, Lee CR, Morbitzer K, Patterson JH, Wiltshire T, Easter J, Savage SW, and Powell JR. Precision dosing: public health need, proposed framework, and anticipated impact. *Clin Transl Sci.* 2017;10(6):443-454.
40. Carpenter D, **Gonzalez D**, Retsch-Bogart G, Sleath B, and Wilfond B. Methodological and ethical issues in pediatric medication safety research. *Pediatrics* 2017;140(3). pii: e20170195.
41. Thakkar N, Guptill JT, Aleš K, Jacobus D, Jacobus L, Peloquin C, Cohen-Wolkowicz M, and **Gonzalez D***, for the DAPPER Study Group. Population pharmacokinetics/pharmacodynamics of 3,4-diaminopyridine free base in patients with Lambert-Eaton myasthenia. *CPT Pharmacometrics Syst Pharmacol.* 2017;6(9):625-634.
42. Salerno S, Hornik CP, Cohen-Wolkowicz M, Smith PB, Ku LC, Kelly MS, Clark R, and **Gonzalez D***; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Use of population pharmacokinetics and electronic health records to assess piperacillin-tazobactam safety in infants. *Pediatr Infect Dis J.* 2017;36(9):855-859.

43. Pierre V, Johnston CK, Ferslew B, Brouwer KLR, and **Gonzalez D***. Population pharmacokinetics of morphine in patients with Non-Alcoholic Steatohepatitis (NASH) and healthy adults. *CPT Pharmacometrics Syst Pharmacol*. 2017;6(5):331-339.
44. Hornik CP, Wu H, Edginton AN, Watt KM, Cohen-Wolkowicz M, and **Gonzalez D**. Development of a pediatric physiologically based pharmacokinetic model of clindamycin using opportunistic pharmacokinetic data. *Clin Pharmacokinet*. 2017;56(11):1343-1353.
45. Smith M, **Gonzalez D**, Goldman J, Yogev R, Sullivan JE, Reed M, Anand R, Berezny K, Smith PB, Cohen-Wolkowicz M, and Watt K; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Pharmacokinetics of clindamycin in obese and nonobese children. *Antimicrob Agents Chemother* 2017;61(4). pii: e02014-16.
46. **Gonzalez D**, Bradley J, Blumer J, Yogev R, Watt KM, James LP, Palazzi DL, Bhatt-Mehta V, Sullivan JE, Zhang L, Murphy J, Ussery XT, Dunne MW, and Cohen-Wolkowicz M. Dalbavancin pharmacokinetics and safety in children 3 months to 11 years of age. *Pediatr Infect Dis J*. 2017;36(7):645-653.
47. Ericson JE, Zimmerman KO, **Gonzalez D**, Melloni C, Guptill JT, Hill KD, Wu H, and Cohen-Wolkowicz M. A systematic literature review approach to estimate the therapeutic index of selected immunosuppressant drugs after renal transplantation. *Ther Drug Monit*. 2017 Feb;39(1):13-20.
48. Wang LA, **Gonzalez D**, Leeder JS, Tyndale RF, Pearce RE, Benjamin DK Jr., Kearns GL, and Cohen-Wolkowicz M; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Metronidazole metabolism in neonates and the interplay between ontogeny and genetic variation. *J Clin Pharmacol*. 2017;57(2):230-234.
49. Thakkar N, Salerno S, Hornik CP, and **Gonzalez D***. Clinical pharmacology studies in critically ill children. *Pharm Res*. 2017;34(1):7-24.
50. **Gonzalez D**, Chamberlain JM, Guptill JT, Cohen-Wolkowicz M, Harper B, Zhao J, and Capparelli EV; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Population pharmacokinetics and exploratory pharmacodynamics of lorazepam in pediatric status epilepticus. *Clin Pharmacokinet*. 2017;56(8):941-951.
51. Ku LC, Wu H, Greenberg RG, Hill KD, **Gonzalez D**, Hornik CP, Berezny A, Guptill JT, Cohen-Wolkowicz M, and Melloni C. Use of therapeutic drug monitoring, pharmacokinetics, and electronic health record data to determine the drug therapeutic index. *Ther Drug Monit*. 2016;38(6):728-737.
52. Onufrak N, Forrest A, and **Gonzalez D***. Pharmacokinetic and pharmacodynamic principles of anti-infective dosing. *Clin Ther*. 2016;38(9):1930-47.
53. Greenberg RG, Melloni C, Wu H, **Gonzalez D**, Ku LC, Hill KD, Hornik CP, Cohen-Wolkowicz M, and Guptill JT. Therapeutic index estimation of antiepileptic drugs: a systematic literature review approach. *Clin Neuropharmacol*. 2016;39(5):232-40.
54. Zimmerman K, Putera M, Hornik C, Cohen-Wolkowicz M, Benjamin DK Jr., Mulugeta Y, Burckart GJ, and **Gonzalez D**. Exposure-matching of pediatric anti-infective drugs: review of FDA submissions. *Clin Ther*. 2016;38(9):1995-2005.
55. Thakkar N, **Gonzalez D**, Cohen-Wolkowicz M, Massaro M, Bernhardt J, Zane N, and Laughon MM. An opportunistic study of sildenafil pharmacokinetics for the treatment of pulmonary hypertension in infants. *J Perinatol*. 2016;36(9):744-7.
56. Zimmerman KO, Wu H, Greenberg R, Hill K, Patel U, **Gonzalez D**, Hornik C, Melloni C, and Cohen-Wolkowicz M. Therapeutic drug monitoring, electronic health records, and pharmacokinetic

- modeling to classify sirolimus as a narrow therapeutic index drug in renal transplant patients. *Ther Drug Monit.* 2016;38(5):600-6.
57. Mulugeta Y, Barrett JS, Nelson R, Eshete AT, Mushtaq A, Yao L, Glasgow N, Mulberg A, **Gonzalez D**, Green D, Florian J, Krudys K, Seo S, Kim I, Chilukuria D, and Burckart GJ. Exposure matching for extrapolation of efficacy in pediatric drug development. *J Clin Pharmacol.* 2016;56(11):1326-1334.
 58. **Gonzalez D**, Delmore P, Bloom BT, Cotton MC, Poindexter BB, McGowan E, Shattuck K, Smith PB, Cohen-Wolkowicz M, Morris M, Lewandowski A, Benjamin DK Jr., Lewis KC, and Laughon MM; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Clindamycin pharmacokinetics and safety in preterm and term infants. *Antimicrob Agents Chemother.* 2016;60(5):2888-94.
 59. **Gonzalez D**, Palazzi D, Bhattacharya-Mithal L, Al-Uzri A, James L, Bradley J, Neu N, Jasion T, Hornik C, Smith PB, Benjamin DK Jr., Keedy K, Fernandes P, and Cohen-Wolkowicz M. Solithromycin pharmacokinetics in plasma and dried blood spots and safety in adolescents. *Antimicrob Agents Chemother.* 2016;60(4):2572-6.
 60. Mase S, Jereb J, **Gonzalez D**, Martin F, Daley C, Fred D, Briand K, Loeffler A, Menon L, Bamrah S, Powell K, Brostrom R, Chorba T, and Peloquin CA. Pharmacokinetics and dosing of levofloxacin in children treated for active or latent multidrug-resistant tuberculosis, Federated States of Micronesia and Republic of the Marshall Islands. *Pediatr Infect Dis J.* 2016;35(4):414-21.
 61. Zimmerman K, **Gonzalez D**, Swamy GK, and Cohen-Wolkowicz M. Pharmacologic studies in vulnerable populations: using the pediatric experience. *Semin Perinatol.* 2015;39(7):532-6.
 62. Watt KM, **Gonzalez D**, Benjamin DK Jr, Brouwer KLR, Wade K, Capparelli EV, Barrett J, and Cohen-Wolkowicz M. Fluconazole population pharmacokinetics and dosing for the prevention and treatment of invasive candidiasis in children supported with extracorporeal membrane oxygenation. *Antimicrob Agents Chemother.* 2015;59(7):3935-43.
 63. **Gonzalez D**, Melloni C, Poindexter BB, Yogev R, Atz AM, Sullivan JE, Mendley SR, Delmore P, Delinsky A, Zimmerman K, Lewandowski A, Harper B, Lewis KC, Benjamin DK Jr., and Cohen-Wolkowicz M; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Administrative Core Committee. Simultaneous determination of trimethoprim and sulfamethoxazole in dried plasma and urine spots. *Bioanalysis* 2015;7(9):1137-49.
 64. **Gonzalez D**, Boggess KA, and Cohen-Wolkowicz M. Lessons learned in pediatric clinical research to evaluate safe and effective use of drugs in pregnancy. *Obstet Gynecol.* 2015;125(4):953-8.
 65. van Ginkel MW, Hill KD, Becker K, Testoni D, Cohen-Wolkowicz M, **Gonzalez D**, Barrett JS, Benjamin DK, Siegel DA, Banks P, and Watt KM, on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Administrative Core Committee. Drug dosing and pharmacokinetics in children with obesity: a systematic review. *JAMA Pediatr.* 2015;169(7):678-85.
 66. **Gonzalez D**, Melloni C, Yogev R, Poindexter BB, Mendley SR, Delmore P, Autmizguine J, Lewandowski A, Harper B, Watt KM, Capparelli EV, Benjamin DK Jr, and Cohen-Wolkowicz M; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Administrative Core Committee. Use of opportunistic clinical data and a population pharmacokinetic model to support dosing of clindamycin for premature infants to adolescents. *Clin Pharmacol Ther.* 2014;96(4):429-37.
 67. Gostelow M, **Gonzalez D**, Smith PB, and Cohen-Wolkowicz M. Pharmacokinetics and safety of recently approved drugs used to treat methicillin-resistant *Staphylococcus aureus* infections in infants, children, and adults. *Expert Rev Clin Pharmacol.* 2014;7(3):327-40.

68. Autmizguine J, Moran C, **Gonzalez D**, Capparelli EV, Smith PB, Benjamin DK Jr, Cohen-Wolkowicz M, and Watt KM. Vancomycin pharmacokinetics and cerebrospinal fluid exposure in children with cerebral ventricular shunt infections. *Pediatr Infect Dis J*. 2014;33(10):e270-2.
69. Hester W, Fry C, **Gonzalez D**, Cohen-Wolkowicz M, Inman BA, and Ortel TL. Thromboprophylaxis with fondaparinux in high-risk post-operative patients with renal insufficiency. *Thromb Res*. 2014;133(4):629-33.
70. Büdingen F, **Gonzalez D**, Tucker AN, and Derendorf H. Relevance of liver failure for anti-infective agents: from pharmacokinetic alterations to dosage adjustments. *Ther Adv Infect Dis*. 2014;2(1):17-42.
71. Folzer E, **Gonzalez D**, Singh R, and Derendorf H. Comparison of skin permeability for three diclofenac topical formulations: an in vitro study. *Pharmazie* 2014;69:27-31.
72. **Gonzalez D**, Schmidt S, and Derendorf H. Importance of relating efficacy measures to unbound drug concentrations for anti-infective agents. *Clin Microbiol Rev*. 2013;26(2):274-88.
73. van der Straten A, Cheng H, Wasdo S, Montgomery L, Smith-McCune K, Booth M, **Gonzalez D**, Derendorf H, Morey TE, and Dennis DM. A novel breath test to directly measure use of vaginal gel and condoms. *AIDS Behav*. 2013;17(6):2211-21.
74. Morey TE, Wasdo S, Wishin J, Quinn B, Booth M, **Gonzalez D**, Derendorf H, McGorray SP, Simoni J, Melker RJ, and Dennis DM. Oral adherence monitoring using a breath test to supplement highly active antiretroviral therapy. *AIDS Behav*. 2013;17(1):298-306.
75. Morey TE, Wasdo S, Wishin J, Quinn B, Van Der Straten A, Booth M, **Gonzalez D**, Derendorf H, Melker RJ, and Dennis DM. Feasibility of a breath test for monitoring adherence to vaginal administration of microbicide gels. *J Clin Pharmacol*. 2013;53(1):103-11.
76. **Gonzalez D**, Conrado DJ, Theuretzbacher U, and Derendorf H. The effect of critical illness on drug distribution. *Curr Pharm Biotechnol*. 2011;12(12):2030-6.
77. Conrado DJ, **Gonzalez D**, and Derendorf H. Role of drug absorption in the pharmacokinetics of therapeutic interventions for stroke. *Ann N Y Acad Sci* 2010;1207:134-42.
78. Schmidt S, **Gonzalez D**, and Derendorf H. Significance of protein binding in pharmacokinetics and pharmacodynamics. *J Pharm Sci*. 2010;99(3):1107-22.
79. **Gonzalez D**, Derendorf H. Ciclesonide in the management of asthma. *Clinical Medicine: Therapeutics* 2009;1:1437-1449.

Under Review

80. **Gonzalez D***, Sinha J. Pediatric drug-drug interaction evaluation: drug, patient population, and methodological considerations.
81. Salerno SN, Carreño FO, Edginton AN, Cohen-Wolkowicz M, and **Gonzalez D***. Leveraging physiologically-based pharmacokinetic (PBPK) modeling and experimental data to guide dosing modification of CYP3A-mediated drug-drug interactions (DDIs) in the pediatric population.
82. Commander SJ, **Gonzalez D**, Kumar KR, Spears T, Cohen-Wolkowicz M, Zimmerman KO, and Hornik CP. The relationship between simulated milrinone exposure and hypotension in children.

OTHER PEER-REVIEWED PUBLICATIONS

83. **Gonzalez D**, Pacanowski MA, and Johnson JA. Important genes in pharmacogenetics and pharmacogenomics: Inwardly rectifying potassium channel (*KCNJ11*). Pharmacogenetics and Pharmacogenomics Knowledge Base (PharmGKB.org), 2006. <https://www.pharmgkb.org/vip/PA166169501>.

NON-PEER REVIEWED PUBLICATIONS

84. Balevic SJ, Hornik, CP, Green TP, Clowse MEB, **Gonzalez D**, Maharaj AR, Schanberg LE, Eudy AM, Swamy GK, Hughes BL, and Cohen-Wolkowicz M. Dr. Balevic, et al., Reply. *J Rheumatol*. 2020;47(10):1587.
85. Beechinor RJ, **Gonzalez D**. Book Review: Introduction to Drug Disposition and Pharmacokinetics. *Clin Pharmacol Ther*. 2017. DOI: 10.1002/cpt.806
86. Wang L, Cohen-Wolkowicz M, and **Gonzalez D**. Advances in pediatric pharmacology, therapeutics, and toxicology. *Adv Pediatr*. 2016;63(1):227-54.
87. **Gonzalez D**, Paul IM, Benjamin DK Jr, and Cohen-Wolkowicz M. Advances in pediatric pharmacology, therapeutics, and toxicology. *Adv Pediatr*. 2014;61(1): 7-31.

ABSTRACTS (presenting author)

1. Zhu J, Wu S, Beechinor R, Kemper R, Bukkems L, Mathot R, Cnossen M, **Gonzalez D**, Chen S, Key N, Crona D. External evaluation and development of a simplified perioperative FVIII population pharmacokinetic model for adult hemophilia A patients undergoing surgeries at UNC Medical Centers. Virtual poster presentation American College of Clinical Pharmacology (ACCP) Annual Meeting on September 21-23, 2020. Poster Number 094. Abstract published in *Clin Pharmacol Drug Dev*. 2020;9(S2):1-75.
2. Konicki R, Weiner D, Cao Y, **Gonzalez D**, Patterson JH, Powell JR. Rivaroxaban precision dosing strategy for real-world atrial fibrillation patients. Accepted for poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting on March 20, 2020. The meeting was canceled due to the COVID-19 pandemic. Abstract published in *Clin Pharmacol Ther*. 2020;107 Suppl 1:S5-S121.
3. Ganguly S, Edginton A, Gerhart JG, Cohen-Wolkowicz M, Greenberg RG, and **Gonzalez D**; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Physiologically-based pharmacokinetic (PBPK) modeling of meropenem in preterm and term Infants. The abstract was accepted for poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Translational and Clinical Pharmacology Advances in Anti-Infective Development pre-conference on March 18, 2020, and the ASCPT Annual Meeting on March 20, 2020. The meeting was canceled due to the COVID-19 pandemic. Abstract published in *Clin Pharmacol Ther*. 2020;107 Suppl 1:S5-S121.
4. Salerno S, Edginton A, Cohen-Wolkowicz M, Hornik CP, Lang JE, and **Gonzalez D**. Evaluation of a pediatric physiologically-based pharmacokinetic (PBPK) model for solithromycin using plasma and dried blood spots (DBS) drug concentrations. The abstract was accepted for poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Translational and Clinical Pharmacology Advances in Anti-Infective Development pre-conference on March 18, 2020, and the ASCPT Annual Meeting on March 19, 2020. The meeting was canceled due to the COVID-19 pandemic. Abstract published in *Clin Pharmacol Ther*. 2020;107 Suppl 1:S5-S121.
5. Salerno S, Liao Y, Jackson W, Greenberg R, McKinzie CJ, McCallister A, Benjamin DK, Laughon MM, Clark R, and **Gonzalez D**. Association between nephrotoxic drug combinations and acute kidney injury in the neonatal intensive care unit. The abstract was accepted for poster presentation at the American

Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting on March 19, 2020. However, the meeting was canceled due to COVID-19. Abstract published in *Clin Pharmacol Ther.* 2020;107 Suppl 1:S5-S121.

6. Gerhart JG, Edginton AE, Watt KM, Cohen-Wolkowicz M, Harper B, Muller W, Delmore P, Atz A, and **Gonzalez D**; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. CYP2B6 genotype affects methadone disposition in children as determined by physiologically-based pharmacokinetic (PBPK) modeling. The abstract was accepted for poster presentation at the 2020 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in Houston, Texas, on March 18 and 19, 2020. However, the meeting was canceled due to the COVID-19 pandemic. Abstract published in *Clin Pharmacol Ther.* 2020;107 Suppl 1:S5-S121.
7. Wu YS, Cohen-Wolkowicz M, Hornik CP, Gerhart JG, Autmizguine J, Cobbaert M, and **Gonzalez D**. External evaluation of population pharmacokinetics (PPK) models of trimethoprim (TMP) and sulfamethoxazole (SMX) developed using opportunistic data in infants and children. The abstract was accepted for poster presentation at the 2020 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in Houston, Texas, on March 19, 2020. However, the meeting was canceled due to the COVID-19 pandemic. Abstract published in *Clin Pharmacol Ther.* 2020;107 Suppl 1:S5-S121.
8. Harris V, Ganguly S, Gerhart J, and **Gonzalez D**. Physiologically-based pharmacokinetic modeling of topiramate in adults. Research-in-progress poster presentation at the American College of Clinical Pharmacy Annual Meeting in New York, NY on October 26, 2019. Poster number 109.
9. Minshew LM, McLaughlin J, Aubé J, Cox W, **Gonzalez D**, Lamb KN, Klus NJ, and Brouwer KLR. What employers want: identifying necessary skills in pharmaceutical science graduates. Poster presentation American Association of Colleges of Pharmacy (AACP) 2019 Annual Meeting in Chicago, Illinois on July 13-17, 2019. The presentation was on July 15, 2019. Poster number 179.
*Selected for a Best Poster Award by the AACP Social and Administrative Sciences SIG.
10. Johnson J, Sanka P, Greenberg RG, **Gonzalez D**, Laughon M, and Jackson W. Methylxanthine use and outcomes in infants with perinatal asphyxia undergoing therapeutic hypothermia. Platform presentation at the 2019 Pediatric Academic Societies (PAS) meeting in Baltimore, Maryland. Presentation on April 30, 2019.
11. Ge S, Mendley S, Gerhart JG, Melloni C, Hornik CP, Sullivan JE, Atz A, Delmore P, Tremoulet A, Poindexter B, Harper B, Payne E, Lin S, Cohen-Wolkowicz M, and **Gonzalez D**; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Population pharmacokinetics of metoclopramide in infants, children, and adolescents. Poster presentation at the 2018 Annual Meeting of the American College of Clinical Pharmacology in Bethesda, MD on September 23-24, 2018. Presentation #018. Published in *Clinical Pharmacology in Drug Development* 2018;7(S1):1-104.
12. Dorcin SM, Beechinor RJ, Gerhart JG, Mendley S, Hornik CP, Sullivan JE, Atz A, Melloni C, Cohen-Wolkowicz M, and **Gonzalez D**. Dried blood spot analysis of metoclopramide in infants, children and adolescents. 2018 Summer Undergraduate Pipeline Research Symposium, UNC-Chapel Hill, Chapel Hill, North Carolina. Poster #38.
*In addition to the presentation at UNC-Chapel Hill, this research was presented as an encore presentation at the March 2019 Student Research Day at Meharry Medical College in Nashville, TN.
13. Hornik CP, Yogev R, Mourani PM, Watt KM, Sullivan JE, Atz AM, Speicher D, Al-Uzri A, Adu-Darko M, Lewandowski A, Gelber C, Lin S, Harper B, Melloni C, Cohen-Wolkowicz M, and **Gonzalez D**. Population pharmacokinetics of milrinone in infants and children. Poster presentation at the 2018 Pediatric Academic Societies (PAS) meeting in Toronto, Canada on May 5-8, 2018. Abstract ID# 2780.2.

14. Beechinor RJ, Thompson PA, Hwang MF, Vargo RC, Bomgaars LR, and **Gonzalez D**. A population pharmacokinetic study of high dose methotrexate treatment in infants with acute lymphoblastic leukemia: An evaluation of inter-occasion variability across treatment cycles. [Abstract]. Poster presentation at the Population Approach Group in Europe (PAGE) 2018 Meeting on May 29-June 1, 2018 in Montreaux, Switzerland.
15. **Gonzalez D**, Laughon MM, Smith PB, Ge S, Ambalavanan N, Atz A, Sokol GM, Hornik CD, Stewart D, Mundakel G, Mills M, Cohen-Wolkowicz M, Martz K, and Hornik CP; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network. Population pharmacokinetics and safety of sildenafil in premature infants. Poster presentation at the 2018 Pediatric Academic Societies (PAS) meeting in Toronto, Canada on May 5-8, 2018. Abstract ID #2800.5.
16. Shahin MH, Conrado DJ, **Gonzalez D**, Gong Y, Lobmeyer MT, Beitelshees AL, Boerwinkle E, Gums JG, Chapman A, Turner ST, Cooper-DeHoff RM, and Johnson JA. Genome-wide meta-analyses reveal novel predictors of heart rate response to β -blockers in the Pharmacogenomic Evaluation of Antihypertensive Responses (PEAR) studies. Poster presentation at the 2018 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in Orlando, Florida. Published in *Clin Pharmacol Ther*. 2018;103: S15. Poster #PI-001.
17. Shahin MH, Conrado DJ, **Gonzalez D**, Gong Y, Lobmeyer MT, Beitelshees AL, Boerwinkle E, Gums JG, Chapman A, Turner ST, Cooper-DeHoff RM, and Johnson JA. β 2-adrenergic receptor gene affects the negative chronotropic effects to β -blockers in the PEAR and PEAR2 studies. Poster presentation at the 2018 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in Orlando, Florida on March 21-24, 2018. Published in *Clin Pharmacol Ther*. 2018;103: S15. Poster #PI-002.
18. Burnham J, **Gonzalez D**, Hwang MF, Green D, Ye J, Madabushi R, Zahurak M, Rosner G, and Burckart GJ. Pediatric clinical trial simulations (CTS) in drug development: argatroban. Poster presentation at the 2018 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in Orlando, Florida on March 21-24, 2018. Published in *Clin Pharmacol Ther*. 2018; 103: S15. Poster #PI-045.
**Top poster award at the 2018 ASCPT meeting.*
19. Gerhart JG, Watt KM, Edginton A, Wade KC, Benjamin DK Jr., Smith PB, Hornik CP, Cohen-Wolkowicz M, Duara S, Ross AS, Shattuck K, Stewart DL, Neu N, and **Gonzalez D**. Physiologically-based pharmacokinetic (PBPK) modeling of fluconazole using plasma and cerebrospinal fluid (CSF) samples collected from preterm and term infants. Poster presentation at the 2018 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in Orlando, Florida on March 21-24, 2018. Published in *Clin Pharmacol Ther*. 2018; 103: S15. Presentation #PWI-001 and poster #PT-009.
**Recipient of a 2018 ASCPT Presidential Trainee Award.*
20. Hwang MF, Beechinor RJ, Wade KC, Benjamin DK Jr., Smith PB, Hornik CP, Duara S, Kennedy KA, Cohen-Wolkowicz M, and **Gonzalez D**. External validation of two fluconazole infant population pharmacokinetic models. Poster presentation at the 2017 American College of Clinical Pharmacology (ACCP) Annual Meeting in San Diego, CA on September 17-19, 2017.
**Student Abstract Award winner.*
21. **Gonzalez D**, Blumer J, James L, Yogev R, Al-Uzri A, Bosheva M, Mendley S, Bradley J, Espinosa C, Moffett K, Simonsen KA, Boakye-Agyeman F, Hornik CP, Jasion T, Hernandez R, Jamieson BD, Cohen-Wolkowicz M; on behalf of the SOLI-PEDS program. Pharmacokinetics and safety of solithromycin following intravenous and oral administration in children. Poster presentation at the Pediatric Academic Societies (PAS) 2017 Annual Meeting in San Francisco, CA on May 6-9, 2017. Publication #2695961.

22. Dumitrescu MP, Benjamin DK, Smith PB, Clark R, **Gonzalez D**, and Hornik CP. Evaluation of gentamicin-induced ototoxicity in hospitalized infants. Platform presentation at the Pediatric Academic Societies (PAS) 2017 Annual Meeting in San Francisco, CA on May 6-7, 2017.
23. Autmizguine J, Melloni C, Hornik CP, Dallafeld S, Harper B, Yogev R, Sullivan J, Atz AM, Al-Uzri A, Mendley S, Poindexter B, Lewandowski A, Delmore P, Cohen-Wolkowicz M, and **Gonzalez D**; on behalf of the Best Pharmaceuticals for Children Act-Pediatric Trials Network Steering Committee. Population pharmacokinetics of trimethoprim-sulfamethoxazole in infants and children. Platform presentation at the Pediatric Academic Societies (PAS) 2017 Annual Meeting in San Francisco, CA on May 6-9, 2017. Publication #2660250.
24. Salerno S, Edginton A, Cohen-Wolkowicz M, Hornik C, Jamieson B, Fernandes P, and **Gonzalez D**. Development of an Adult Physiologically based pharmacokinetic (PBPK) model of solithromycin in plasma and epithelial lining fluid. Poster presentation at ASCPT Annual Meeting in Washington, DC on March 15-18, 2017.
**In addition to the ASCPT Annual Meeting presentation, this research was presented as an encore presentation at the 2017 Chapel Hill Pharmaceutical Sciences Conference, where it was selected for the best poster award.*
25. **Gonzalez D**, Bradley JS, Blumer J, Yogev R; Watt KM, James LP, Palazzi DL, Bhatt-Mehta V, Sullivan JE, Zhang L, Murphy J, Ussery XT, Puttagunta S, Dunne MW, and Cohen-Wolkowicz M. Dalbavancin pharmacokinetics and safety in children 3 months to 11 years of age. Poster presentation at IDWeek in New Orleans, LA on October 26-30, 2016.
26. Shahin MH[#], Conrado DJ[#], **Gonzalez D**[#], Gong Y, Lobmeyer M, Beitelshes AL, Cooper-DeHoff RM, Boerwinkle E, Turner ST, Chapman A, Gums JG, and Johnson JA. Identifying novel genetic predictors associated with heart rate response to beta-blockers. Presented at the 2016 American College of Clinical Pharmacy (ACCP) Annual Meeting in Hollywood, FL, on October 23-26, 2016. Poster #244,
[#]Authors contributed equally to this work.
27. Guptill JT, Thakkar N, Peloquin C, Aleš K, Jacobus D, Jacobus L, Cohen-Wolkowicz M, and **Gonzalez D** for the DAPPER Study Team. PK/PD modeling and simulation of 3,4-diaminopyridine base in patients with Lambert–Eaton myasthenia. Poster and podium presentation at the 2016 American Association of Neuromuscular & Electrodiagnostic Medicine Annual Meeting in New Orleans, LA. Presentation on September 15. Poster #6.
**Selected for the President’s Research Award.*
28. Salerno S, Hornik CP, Cohen-Wolkowicz M, Smith PB, Clark R, and **Gonzalez D**; on behalf of the Best Pharmaceuticals for Children Act – Pediatric Trials Network Steering Committee. Using population pharmacokinetics and electronic health records to assess piperacillin safety in infants. Poster presentation at the Pediatric Academic Societies (PAS) 2016 Annual Meeting in Baltimore, MD on April 30 – May 3. Publication #4151.409.
**In addition to the presentation at PAS, this research was presented as an encore presentation at the 2016 Chapel Hill Pharmaceutical Sciences Conference.*
29. **Gonzalez D**, Al-Uzri A, Bradley J, James L, Adler-Shohet F, Mendley S, Moffett K, Daudjee M, Dehority W, Bosheva M, Tsonkova E, Cinoman M, Hernandez R, Hornik C, Fernandes P, and Cohen-Wolkowicz M. 2016. Pharmacokinetics and safety of intravenous solithromycin in children ≥ 6 years of age. E-poster presentation at the European Society for Pediatric Infectious Diseases meeting in Brighton, UK on May 10-14, 2016. Abstract ID# ESP16-0193.
30. Guptill J, Greenberg RG, Melloni C, Wu H, **Gonzalez D**, Ku L, Hill K, Honrik C, Zheng N, Jiang W, and Cohen-Wolkowicz M. Narrow therapeutic index classification of antiepileptic drugs using a comprehensive literature search. Poster presentation at the 2016 American Academy of Neurology Annual Meeting in Vancouver, BC.

31. Thakkar N, Peloquin C, Aleš K, Jacobus D, Cohen-Wolkowicz M, Guptill JT, and **Gonzalez D**; for the DAPPER Study Group. Population pharmacokinetics/pharmacodynamics of 3,4-diaminopyridine free base in patients with Lambert-Eaton myasthenic syndrome (LEMS). Poster presentation at the 2016 American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in San Diego, CA. Presentation on March 10, 2016. Poster # PI-091.
32. Pierre V, Johnston CK, Ferslew B, Brouwer KL, and **Gonzalez D**. Population pharmacokinetics of morphine in patients with non-alcoholic steatohepatitis (NASH) and healthy adults. Poster presentation at the American Conference for Pharmacometrics (ACoP). Poster presentation on October 6, 2015, in Crystal City, VA.
33. **Gonzalez D**, Palazzi D, Bhattacharya-Mithal L, Al-Uzri A, James L, Bradley J, Neu N, Jasion T, Benjamin DK Jr., Rosiak C, Oh R, Keedy K, Fernandes P, and Cohen-Wolkowicz M. Pharmacokinetics and safety of solithromycin in adolescents with suspected or confirmed bacterial infection. Poster presentation at the Pediatric Academic Societies (PAS) 2015 Annual Meeting in San Diego, CA. Presentation on April 25, 2015. Publication #1545.340.
34. Smith M, **Gonzalez D**, Goldman J, Yogev R, Sullivan JE, Reed M, Anand R, Berezny K, Smith PB, Cohen-Wolkowicz M, and Watt K. Pharmacokinetics of multiple-dose intravenous clindamycin in obese children. Poster presentation at the Pediatric Academic Societies (PAS) 2015 Annual Meeting in San Diego, CA. Presentation on April 25, 2015. Publication #4194.689.
35. **Gonzalez D**, Palazzi D, Bhattacharya-Mithal L, Al-Uzri A, James L, Bradley J, Neu N, Jasion T, Hornik C, Smith PB, Benjamin DK Jr., Rosiak C, Oh R, Keedy K, Fernandes P, and Cohen-Wolkowicz M. Solithromycin concentrations measured in dried blood spots collected from adolescents. Poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2015 Annual Meeting in New Orleans, LA. Presentation on March 5, 2015. Late-Breaking Abstract ID #963.
36. **Gonzalez D**, Melloni C, Yogev R, Watt KM, Poindexter B, Mendley S, Delmore P, Autmizguine J, Lewandowski A, Harper B, Capparelli EV, Benjamin DK Jr, and Cohen-Wolkowicz M, Best Pharmaceuticals for Children Act-Pediatric Trials Network. Developmental pharmacokinetics of clindamycin from premature infants to adolescents. Poster presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2014 Annual Meeting in Atlanta, GA. Late-Breaking Abstract ID #743.
37. Falcao NMS, Singh R, **Gonzalez D**, Pieper S, and Derendorf H. In-vitro uses of microdialysis to measure unbound drug concentrations. Presentation at the International Symposium on Microdialysis in Poitiers, France, May 2013.
38. **Gonzalez D**, Mase S, Jereb J, Martin F, Daley C, Fred D, Briand K, Loeffler A, Chorba T, and Peloquin C. Population pharmacokinetics of levofloxacin in children treated for, or exposed to, multidrug resistant tuberculosis in the federated states of Micronesia and Republic of Marshall Islands. Presented at the American Conference for Pharmacometrics (ACoP) in Fort Lauderdale, FL, in May 2013. Published in *J Pharmacokinet Pharmacodyn*. 2013;40 Suppl 1:15-149.
39. **Gonzalez D**, Morey TE, Wasdo S, Wishin J, Quinn B, Booth M, Derendorf H, Melker RJ, and Dennis DM. Population pharmacokinetics of two volatile markers used for assessment of definitive adherence. Abstract accepted for poster presentation at the Population Approach Group in Europe (PAGE) Meeting in Venice, Italy, June 2012.
40. **Gonzalez D**, van der Straten A, Morey TE, Wasdo S, Wishin J, Quinn B, Booth M, Melker RJ, Derendorf H, and Dennis DM. Pharmacokinetic analysis of two flavorants used in a novel breath-based system (SMART™) designed to assess use of vaginally applied products. Presented at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting in National Harbor, Maryland, March 2012. Published in *Clin Pharmacol Ther*. 2012;91 Suppl 1:S1-149.

41. **Gonzalez D**, Schmidt S, and Derendorf H. Effects of plasma protein binding on half-life of elimination. Presented at the American College of Clinical Pharmacology (ACCP) Annual Meeting in San Antonio, TX, September 2009. Published in *J Clin Pharmacol*. 2009;49:1091-1130.

ORAL PRESENTATIONS

- 2021 *Application of Pharmacometrics to Inform Drug Dosing in Neonates and Infants*, St. Jude Children's Research Hospital, March 11.
- 2020 *Application of Pharmacometrics to Inform Drug Dosing in Neonates and Infants*, Unified Program for Therapeutics in Children (UPTiC) Colloquium, UNC School of Medicine Children's Research Institute, Virtual Meeting, November 3.
- Evaluation of Drug-Drug Interactions and Their Influence on Drug Dosing in the Pediatric Population*, Presentation at a 'Pediatric Dose Selection' workshop. U.S. Food and Drug Administration, Virtual Meeting, October 23.
- Pharmacokinetics/Pharmacodynamics and Drug Dosing in Pediatric Patients*, Innovations and Transformations in Pharmaceutical Sciences Virtual Meeting, UNC-Chapel Hill, July 27.
- Pharmacokinetics and Drug Dosing in Children and Adolescents with Obesity*, Center for Gastrointestinal Biology and Disease (CGIBD), UNC-Chapel Hill, Chapel Hill, NC, March 26.
- Application of Pharmacometrics to Inform Drug Dosing in Neonates and Infants*, Department of Clinical Pharmacy, University of Michigan College of Pharmacy, Ann Arbor, MI, March 9.
- 2019 *Application of Pharmacometrics to Inform Drug Dosing in Pediatric Drug Development: Considerations for Neonates and Infants*, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, September 10.
- Pharmacometric Strategy and Tools in the Design of Precision Dosing for the Electronic Patient Care Environment*. Presentation at a workshop titled 'Precision Dosing: Defining the Need and Approaches to Deliver Individualized Drug Dosing in the Real-World Setting.' U.S. Food and Drug Administration, Silver Spring, MD, August 12.
- Population Pharmacokinetics and Dosing of Clindamycin in Preterm and Term Infants*. Presentation at a Research Symposium Honoring Prof. Hartmut Derendorf, College of Pharmacy, University of Florida, March 11.
- 2018 *Application of Pharmacometrics to Inform Drug Dosing and Clinical Trial Design in Pediatric Drug Development*. Presentation to the Office of Clinical Pharmacology staff, U.S. Food and Drug Administration, Silver Spring, MD, September 27.
- 2017 *Drug Efficacy Determinants*. Presentation at a conference titled 'Defining Precision Medicine at UNC: Charting the Path to Better Health Care,' UNC-Chapel Hill, Chapel Hill, NC, October 31.
- Clinical Trial Simulations (CTS) as a Tool to Guide Pediatric Drug Development*. Symposium at the American College of Clinical Pharmacology (ACCP) Annual Meeting titled 'Clinical Trial Simulations in Pediatric Drug Development.' San Diego, CA, September 17.
- Panel Discussion Member. Students, Trainees & Young Professionals event at American College of Clinical Pharmacology (ACCP) Annual Meeting, San Diego, CA, September 17.
- Panel Discussion Member. A workshop titled 'Pediatric Trial Design and Modeling: Moving into the Next Decade.' U.S. Food and Drug Administration Public Workshop, Silver Spring, MD, September 8.

- 2016 *Pharmacokinetic and Pharmacodynamic Studies in the Pediatric Population*. Department of Pediatrics Grand Rounds, UNC School of Medicine, September 1.
- Early Phase Studies in Children and Infants: Challenges and Opportunities*. Chapel Hill Pharmaceutical Sciences Conference, May 13, Chapel Hill, NC.
- K Award Day Panel Discussion, Duke University, Durham NC, January 14.
- 2015 *The Pediatric Trials Network: Experience with Matching Drug Exposure in Infants and Neonates to Adult Drug Exposure*. A workshop titled 'Pediatric Drug Development: Use of Exposure Matching and Exposure-Response for Extrapolation of Efficacy in Pediatric Product Development.' U.S. Food and Drug Administration, Silver Spring, MD, January 22.
- 2014 *Early Phase Studies in Children and Infants: Challenges and Opportunities*. UNC Eshelman School of Pharmacy, Board of Visitors meeting, Chapel Hill, NC, November 19.
- 'Antimicrobial Drug Development in Adults and Children: Applications of PK/PD Modeling.' Division of Pharmacotherapy and Experimental Therapeutics, UNC Eshelman School of Pharmacy, Chapel Hill, NC, March 25.
- 2012 *Breath Testing to Assess Definitive Adherence to Oral and Vaginal Medications*. Globalization of Pharmaceutics Education Network (GPEN) meeting in Melbourne, Australia on November 30.
- Use of Microdialysis for the Evaluation of Topical Bioequivalence*. Department of Pharmacotherapy and Translational Research Seminar Series, University of Florida, Gainesville, FL, March 30. ACPE continuing education credit was provided.
- 2010 *Incorporating Pharmacogenomic Data in Pharmacometric Analyses: A Path Towards a Complete Picture*. Department of Pharmacotherapy and Translational Research Seminar Series, University of Florida, Gainesville, FL, USA, November 12. ACPE continuing education credit was provided.
- 2009 *Significance of Protein Binding in Pharmacokinetics and Pharmacodynamics*. Department of Pharmacotherapy and Translational Research seminar series, University of Florida, Gainesville, FL, October 30.

RESEARCH FUNDING

Active

5R01HD096435

Title: Physiologically-Based Pharmacokinetic Modeling to Guide Drug Dosing in Children with Obesity

Sponsor: National Institute of Child Health and Human Development (NICHD)

Project period: 9/1/18 – 7/31/23

Total Direct Costs: \$1,684,853 (Years 1-5); \$444,798 (Year 3)

Effort: 30%

Role: Principal Investigator

1R01HD102949-01A1

Title: Application of Physiologically-Based Pharmacokinetic Modeling to Characterize Drug-Drug Interactions in Infants

Sponsor: National Institute of Child Health and Human Development (NICHD)

Project period: 5/1/21 – 4/30/26

Total Direct Costs: \$1,907,945 (Years 1-5); \$392,685 (Year 1)

Effort: 30%
Role: Principal Investigator

HHSN27500004, Pediatric Trials Network (PTN Contract # HHSN2752018000031)

Title: BPCA Data Closeout and Dissemination
Sponsor: Duke University (Prime Sponsor: NICHD)
Project period: 9/14/20 – 9/13/21
Total Direct Costs: \$38,534
Effort: 14%
Role: Subcontract Principal Investigator (Prime Principal Investigator: Daniel K. Benjamin Jr.)

HHSN27500039, Pediatric Trials Network (PTN Contract # HHSN2752018000031)

Title: Physiologically-Based Pharmacokinetic Modeling of Sildenafil in Infants
Sponsor: Duke University (Prime Sponsor: NICHD)
Project period: 3/1/20 – 9/30/21
Total Direct Costs: \$25,557
Effort: 26% for 3 months (3/1/2020-5/31/2020); 0% (6/1/2020-Present)
Role: Subcontract Principal Investigator (Prime Principal Investigator: Daniel K. Benjamin Jr.)

AFPE Fred Eshelman Pre-Doctoral Fellowship

Title: Application of Physiologically-Based Pharmacokinetic (PBPK) Modeling to Understand Drug Disposition in Children with Obesity
Sponsor: American Foundation for Pharmaceutical Education (AFPE)
Project period: 9/1/20 – 8/31/21
Total Direct Costs: \$10,000
Effort: 0%
Role: Major advisor (PI: Jacqueline G. Gerhart)

ZTI-01-100

Title: A Phase 1, Non-comparative, Open-Label Study of Pharmacokinetics and Safety of a Single-Dose of ZTI-01 (Fosfomycin for Injection) in Pediatric Subjects (Less than 12 Years of Age) Receiving Standard of Care Antibiotic Therapy for Proven or Suspected Infection or for Peri-operative Prophylaxis.
Sponsor: Nabriva Therapeutics
Project period: 12/1/2020- 11/30/2022
Total Costs: \$45,899
Effort: 2.75%
Role: Principal Investigator

Pending

RFA-HD-21-025

Title: Maternal and Pediatric Precision in Therapeutics (MPRINT) Knowledge and Research Coordination Center (KRCC) - Pharmacometrics and Clinical Trial Design Core
Sponsor: Duke University (Prime Sponsor: NICHD)
Project period: 7/1/2021 – 6/30/2026
Total Direct Costs: \$298,470 (Years 1-5); \$56,580 (Year 1)
Effort: 10%
Role: Subcontract Principal Investigator (Prime Principal Investigator: Michael Cohen-Wolkowicz)

RFA-HD-21-025

Title: Maternal and Pediatric Precision in Therapeutics (MPRINT) Knowledge and Research Coordination Center (KRCC) - Outreach, Dissemination, and Training Core
Sponsor: Duke University (Prime Sponsor: NICHD)
Project period: 7/1/2021 – 6/30/2026
Total Direct Costs: \$370,811 (Years 1-5); \$76,985 (Year 1)
Effort: 10%

Role: Subcontract Principal Investigator (Prime Principal Investigator: Michael Cohen-Wolkowicz)

RFA-HD-21-026

Title: Maternal and Pediatric Precision in Therapeutics (MPRINT) Knowledge and Research Coordination Center (KRCC) - Translational Technology Support Core

Sponsor: Duke University (Prime Sponsor: NICHD)

Project period: 7/1/2021 – 6/30/2026

Total Direct Costs: \$2,686 (Year 1)

Effort: 1%

Role: Subcontract Principal Investigator (Prime Principal Investigator: Christoph P. Hornik)

RFA-HD-21-026

Title: Maternal and Pediatric Precision in Therapeutics (MPRINT) Knowledge and Research Coordination Center (KRCC) - Clinical Project

Sponsor: Duke University (Prime Sponsor: NICHD)

Project period: 7/1/2021 – 6/30/2026

Total Direct Costs: \$34,266 (Year 1)

Effort: 5%

Role: Co-Investigator (Prime Principal Investigator: Christoph P. Hornik)

RFA-HD-21-026

Title: Maternal and Pediatric Precision in Therapeutics (MPRINT) Knowledge and Research Coordination Center (KRCC) - Translational Research Project

Sponsor: Duke University (Prime Sponsor: NICHD)

Project period: 7/1/2021 – 6/30/2026

Total Direct Costs: \$34,266 (Year 1)

Effort: 5%

Role: Co-Investigator (Prime Principal Investigator: Christoph P. Hornik)

NAB-BC-3781-1202

Title: A Phase 1, Open-Label, Two-Part Study to Evaluate the Pharmacokinetics, Safety, and Tolerability, of a Single Dose of Intravenous Lefamulin in Hospitalized Pediatric Subjects Receiving Standard of Care Antibiotic Therapy for Confirmed or Suspected Infection

Sponsor: Nabriva Therapeutics

Project period: 12/1/2020- 11/30/2023

Total Costs: \$111,284

Effort: 5%

Role: Principal Investigator

Completed

5K23HD083465

Title: Use of Physiologically-Based PK/PD Models to Streamline Drug Approvals

Sponsor: National Institute of Child Health and Human Development (NICHD)

Project period: 4/15/15 – 2/29/20

Total Direct Costs: \$678,820 (Years 1-5)

Effort: 55% (Years 4 and 5); 75% (Years 1-3)

Role: Principal Investigator

HHSN27500004, Pediatric Trials Network (PTN Contract # HHSN2752018000031)

Title: BPCA Data Closeout and Dissemination

Sponsor: Duke University (Prime Sponsor: NICHD)

Project period: 3/1/20 – 9/13/20

Total Direct Costs: \$9,152

Effort: 10%

Role: Subcontract Principal Investigator (Prime Principal Investigator: Daniel K. Benjamin Jr.)

T32GM122741 - UNC Certificate Program in Translational Medicine

Title: Application of Physiologically-Based Pharmacokinetic (PBPK) Modeling to Understand Drug Disposition in Children with Obesity

Sponsor: National Institute of General Medical Sciences (NIGMS)

Project period: 8/1/19 – 6/30/20

Total Direct Costs: \$24,816 (stipend support)

Effort: 0%

Role: Major advisor (PI: Jacqueline G. Gerhart)

Tier 3 Pilot Grant

Title: Precision Dosing of Direct Oral Anticoagulants

Sponsor: Eshelman Institute for Innovation (EII)

Project period: 12/1/19 – 11/30/20

Total Direct Costs: \$250,523

Effort: 5% (cost sharing)

Role: Co-Investigator

Tier 3 Pilot Grant

Title: Precision Dosing of Direct Oral Anticoagulants

Sponsor: Eshelman Institute for Innovation (EII)

Project period: 12/1/18 – 11/30/19

Total Direct Costs: \$250,523

Effort: 10% (cost sharing)

Role: Co-Innovator

Boehringer Ingelheim Pharmaceuticals, Inc. Travel Grant

Title: Travel Grant to Present at Boehringer Ingelheim Pharmaceuticals, Inc.

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc.

Project period: 12/11/18 – 12/10/19

Total Direct Costs: \$675

Effort: 0%

Role: Principal Investigator

BARDA HHSO100201300009C

Title: Solithromycin Pediatric Development Program (Phase II/III Trials)

Sponsor: Duke University (Prime Sponsor: BARDA)

Dates: 12/1/15 – 9/30/18

Direct Costs: \$13,018 (Fellow/graduate student support)

Effort: Concurrent with K23

Role: Subcontract Principal Investigator (Prime Principal Investigator: Michael Cohen-Wolkowicz)

Thrasher Early Career Award

Title: Use of Physiologically-Based Pharmacokinetic Models to Streamline Drug Approvals

Sponsor: Thrasher Research Fund

Budget Period: 1/1/15 – 6/31/17

Direct Costs: \$25,000

Effort: 4%

Role: Principal Investigator

Jacobus Pharmaceutical Company, Inc.

Title: Pharmacometric Analyses of 3,4- Diaminopyridine in Patients with Lambert-Eaton Myasthenic Syndrome

Sponsor: Jacobus Pharmaceutical Company, Inc.

Budget Period: 6/1/16 – 6/31/17

Direct Costs: \$6,442

Effort: 1%
Role: Principal Investigator

HHSN27500014, Pediatric Trials Network (PTN Contract #HHSN201000003I)

Title: Pharmacokinetics of Sildenafil in Premature Infants
Sponsor: Duke University (Prime Sponsor: NICHD)
Budget Period: 8/13/15 – 8/26/16
Direct Costs: \$21,961 (Post-doctoral fellow support)
Effort: Concurrent effort with K23
Role: Subcontract Principal Investigator (Prime Principal Investigator: Daniel K. Benjamin Jr.)

BARDA HHSO100201300009C

Title: A Phase 1, Open-Label, Multi-Center Study to Determine the Pharmacokinetics and Safety of Solithromycin as Add-On Therapy in Adolescents and Children with Suspected or Confirmed Bacterial Infection
Sponsor: Duke University (Prime Sponsor: BARDA)
Budget Period: 11/1/14 – 11/30/16
Direct Costs: \$28,250
Effort: 20% (11/1/14 -04/14/15); concurrent effort with K23 (04/15/15-11/30/16)
Role: Subcontract Principal Investigator (Prime Principal Investigator: Michael Cohen-Wolkowicz)

Jacobus Pharmaceutical Company, Inc.

Title: Pharmacometric Analyses of 3,4- Diaminopyridine in Patients with Lambert-Eaton Myasthenic Syndrome
Sponsor: Jacobus Pharmaceutical Company, Inc.
Budget Period: 8/1/14 – 07/31/16
Direct Costs: \$17,525
Effort: 1%
Role: Principal Investigator

NC TraCS DUR11410

Title: Sildenafil Exposure and Safety in Premature Infants.
Sponsor: North Carolina Translational and Clinical Sciences (Duke/UNC-CH CTSA Consortium Collaborative Translational Research Pilot Grants)
Budget Period: 5/1/15 – 4/30/16
Direct Costs: \$25,000 (Post-doctoral fellow support)
Effort: Concurrent effort with K23
Role: Co-Principal Investigator

HHSN27500013, Pediatric Trials Network (PTN Contract #HHSN201000003I)

Title: Pharmacokinetics of Antistaphylococcal Antibiotics in Infants (Staph Trio) Trial
Sponsor: Duke University (Prime Sponsor: NICHD)
Budget Period: 9/1/14 – 3/31/15
Direct Costs: \$7,320
Effort: 5%
Role: Subcontract Principal Investigator (Prime Principal Investigator: Daniel K. Benjamin Jr.)

HHSN27500018, Pediatric Trials Network (PTN Contract #HHSN201000003I)

Title: Pharmacokinetics of Clindamycin in Pediatric Subjects with BMI > 85th Percentile
Sponsor: Duke University (Prime Sponsor: NICHD)
Budget Period: 9/1/14 – 3/31/15
Direct Costs: \$3,660
Effort: 2.5%
Role: Subcontract Principal Investigator (Prime Principal Investigator: Daniel K. Benjamin Jr.)

DOD 5042657

Title: UNC-BioGears® Partnership
Sponsor: Applied Research Associates, Inc. (Prime Sponsor: U.S. Department of Defense)
Budget Period: 9/15/14 – 12/15/15
Direct Costs: \$230,263
Effort: 18% (9/15/14 -04/14/15); 0% (04/15/15-12/15/2015)
Role: Subcontract Co-Investigator (Subcontract Principal Investigator: Alexander Tropsha)

HHSN27500019, Pediatric Trials Network (PTN Contract #HHSN201000003I)

Title: Sedation, Status Epilepticus Lab Reanalysis.
Sponsor: Duke University (Prime Sponsor: NICHD)
Budget Period: 9/28/14 – 3/31/15
Direct Costs: \$3,762
Effort: 3.5%
Role: Subcontract Principal Investigator

BARDA HHSO100201300009C

Title: A Phase 1, Open-Label, Multi-Center Study to Determine the Pharmacokinetics and Safety of Solithromycin as Add-On Therapy in Adolescents with Suspected or Confirmed Bacterial Infection
Sponsor: Duke University (Prime Sponsor: BARDA)
Budget Period: 6/1/14 – 12/31/14
Direct Costs: \$17,479
Effort: 20%
Role: Subcontract Principal Investigator (Prime Principal Investigator: Michael Cohen-Wolkowicz)

5T32GM086330

Title: UNC-Duke Collaborative Clinical Pharmacology Postdoctoral Training Program.
Sponsor: National Institute for General Medical Sciences
Funding period: 12/1/12 – 5/31/14
Effort: 100%
Role: Trainee (MPI: Kim Brouwer, Daniel K. Benjamin Jr., and Paul Watkins)

TEACHING EXPERIENCE

Professional Pharm.D. Courses – Lecturer and Discussion Leader

UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill

- 2021 Research Career Paths in Pharmacy, PHCY 624: Research and Scholarship in Pharmacy 1, April 21
- 2020 Journal Club, PHCY 504: Evidence-Based Pharmacy, November 11
Pharmacokinetics and Drug Dosing in Pediatric Patients, PHCY 611: Applied Clinical Pharmacology, November 5
Research Career Paths in Pharmacy, PHCY 624: Research and Scholarship in Pharmacy 1, February 26 and April 22
- 2019 *Pharmacokinetics and Drug Dosing in Pediatric Patients*, PHCY 611: Applied Clinical Pharmacology, October 29
Research Career Paths in Pharmacy, PHCY 624: Research and Scholarship in Pharmacy 1, February 27 and April 24
- 2018 *Pharmacokinetics and Drug Dosing in Pediatric Patients*, PHCY 611: Applied Clinical Pharmacology, October 13

- Research Career Paths in Pharmacy*, PHCY 624: Research and Scholarship in Pharmacy 1, February 23 and April 27
- 2017 *Pharmacokinetics and Drug Dosing in Pediatric Patients*, PHCY 611: Applied Clinical Pharmacology, October 13
Research Career Paths in Pharmacy, PHCY 624: Research and Scholarship in Pharmacy 1, February 17 and April 28
Mini case on Drug-Drug Interactions, PHCY 510: Foundations in Clinical Pharmacology, February 6
- 2016 *Pharmacokinetics and Dosing in Pediatric Patients*, PHCY 611: Applied Clinical Pharmacology, October 13
Pharmacokinetics in Neonates and Infants, PHCY 414: Applied Pharmacokinetics, April 12
Time Course of Drug Action & Drug-Drug Interactions, PHCY 510: Foundations in Clinical Pharmacology, January 29
- 2015 *Arthritis & Inflammation Recitation Case*, PHCY 442: Pharmacotherapy I – Introduction to Pharmacy Care, April 9
Pharmacokinetics in Neonates and Infants, PHCY 414: Applied Pharmacokinetics, April 2

College of Pharmacy, University of Florida (Teaching Assistant)

- 2011-12 Pharmacotherapy II and III
- 2008-10 Pharmaceutical Skills Laboratory I
Pharmaceutical Skills Laboratory II
Dosage Forms II

Graduate Courses – Lecturer and Discussion Leader

UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill

- 2020 *Adaptive Design Trials*, DPET 833: Experimental Design Considerations in Clinical Research, October 28
Population Pharmacokinetic Analysis Theory, Covariate Selection, and Population Pharmacokinetic/Pharmacodynamic Modeling in NONMEM, DPET 857: Population Pharmacokinetic/Pharmacodynamic Analysis, January 9, January 14, January 16, January 21, February 25, and February 27
- 2019 *Adaptive Design Trials*, DPET 833: Experimental Design Considerations in Clinical Research, November 6
- 2018 *Peer Review, Publication, and Open Access*, PHRS 801: Foundations for Cross-Disciplinary Training in the Pharmaceutical Sciences, November 15
Adaptive Design Trials, DPET 833: Experimental Design Considerations in Clinical Research, November 14
Population Pharmacokinetic Analysis Theory, Covariate Selection, and Population Pharmacokinetic/Pharmacodynamic Modeling in NONMEM, DPET 857: Population Pharmacokinetic/Pharmacodynamic Analysis, January 22, January 24, January 29, February 26, and February 28
- 2017 *Adaptive Design Trials*, DPET833: Experimental Design Considerations in Clinical Research, November 15
Introduction to Pharmacodynamic and Pharmacokinetic/Pharmacodynamic Modeling, DPET854: Pharmacodynamic Concepts and Applications, October 25

- Basic Concepts and Graphical Evaluation of Pharmacodynamic Data*, DPET 854: Pharmacodynamic Concepts and Applications, October 23
- 2016 *Adaptive Design Trials*, DPET 833: Experimental Design Considerations in Clinical Research, November 9
Basic Population Pharmacokinetic Concepts, DPET 900: Introduction to Translational Research, August 29
Population Pharmacokinetics using NONMEM, DPET 856: Advanced Pharmacokinetics/ Pharmacodynamics, March 21 and 23
- 2015 *Population Pharmacokinetics I and II*, DPET 855: Principles of Pharmacokinetics, November 30 and December 2
Article Critique, DPET 855: Principles of Pharmacokinetics, November 23
Drug Metabolism in Pediatrics and Other Special Populations: Clinical Implications, T32 Clinical Pharmacology Training Program Fellows Forum, November 16
Drug Metabolism in Pediatrics and Other Special Populations: Clinical Implications, MOPH 810: Drug Metabolism, November 12
Model Development by Laplace Transformation, DPET 855: Principles of Pharmacokinetics, August 24
- 2014 *Drug Metabolism in Pediatrics and Other Special Populations: Clinical Implications*, MOPH 810: Drug Metabolism, November 18
- 2013 *Introduction to R*, DPET855: Principles of Pharmacokinetics, December 4
Introduction to Nonlinear Mixed Effects Modeling, DPET 855: Principles of Pharmacokinetics, December 2

UNC School of Medicine, University of North Carolina at Chapel Hill

- 2020 *Clindamycin Pharmacokinetics and Safety in Preterm and Term Infants*, Post-Baccalaureate Research Education Program (PREP) Journal Club, June 19
- 2019 *Clindamycin Pharmacokinetics and Safety in Preterm and Term Infants*, Post-Baccalaureate Research Education Program (PREP) Journal Club, June 24
- 2018 *Clindamycin Pharmacokinetics and Safety in Preterm and Term Infants*, Post-Baccalaureate Research Education Program (PREP) Journal Club, June 18

North Carolina State University, College of Veterinary Medicine

- 2014 *Introduction to Nonlinear Mixed Effects Modeling*, CBS 787: Pharmacokinetics, November 12

University of Florida, College of Pharmacy

- 2012 *Pirana Software Training*, PHA 6125: Advanced Pharmacokinetics, March 30

Graduate Courses – Course Director

- 2020 DPET857: Population Pharmacokinetic/Pharmacodynamic Analysis, Spring 2020, Course Director
- 2018 DPET857: Population Pharmacokinetic/Pharmacodynamic Analysis, Spring 2018, Course Co-Director

Innovations and Transformations in Pharmaceutical Sciences Summer Program – Lecturer and Discussion Leader

UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill

2019 Division of Pharmacotherapy and Experimental Therapeutics Overview, July 30

Journal Club

UNC Eshelman School of Pharmacy, University of North Carolina at Chapel Hill

2015 – Present Pharmacokinetics/Pharmacodynamics Journal Club, Co-Coordinator

MENTORSHIP

Current Group Members

Graduate Students (Doctor of Philosophy)

2019-Present Stephen Balevic, M.D., M.H.S.
2017-Present Jacqueline G. Gerhart, M.S.

Academic Post-Doctoral Fellows

2020-Present Jennifer Ford, Ph.D.

Industry-Sponsored Post-Doctoral Fellows

2020-Present Eleni Caratzas, Ph.D.

Pharm.D. Candidates Enrolled in Research and Scholarship in Pharmacy (RASP)

2021-Present Katie Brandecker, B.S.

Alumni

Graduate Students (Doctor of Philosophy)

2015-2020 Sara N. Salerno, Pharm.D., Ph.D.
2015-2019 Christoph P. Hornik, M.D., Ph.D., M.P.H.

Academic Post-Doctoral Fellows

2019-2021 Jaydeep Sinha, Ph.D.
2018-2020 Samit Ganguly, Ph.D.
2017-2018 Shufan Ge, Ph.D.
2015-2017 Nikolas Onufrak, Pharm.D. (Co-mentored with Dr. Alan Forrest)
2015-2016 Nilay Thakkar, Ph.D.

UNC/Duke Collaborative T32 Clinical Pharmacology Fellows

2016-2018 Ryan J. Beechinor, Pharm.D., BCPS, BCOP

Industry-Sponsored Post-Doctoral Fellows

2019-2021 Fernando Carreño, Ph.D.
2018-2020 Shirley Wu, Pharm.D.
2017-2019 Sherif Sharaby, Pharm.D. (Co-mentored with Dr. Julie Dumond)

2016-2018 Michael Hwang, Pharm.D.
2014-2016 Vadryn Pierre, Pharm.D. (Co-mentored with Dr. Kim L. R. Brouwer)

Summer of Learning and Research (SOLAR) Program

2018 Shanna Dorcin, M.H.S. (M.D. Candidate at Meharry Medical College)

Undergraduate Students

2019 Sonam Shah (B.S. student in Neuroscience, UNC-Chapel Hill)
2019 Rima Patel (B.S. student in Biomedical Engineering, UNC-Chapel Hill)

Dissertation Committee Member

2021-Present Talisa Kinsale, B.S., Committee Chair
2020-Present Shekhar Yeshwante, B.S., Committee Chair
2015-2019 Christine Lee, M.S., Committee Member
2018-2019 Lawrence Ku, M.D., Committee Member
2015-2018 Cen Guo, M.S., Committee Member

Fellowship Mentoring Committee

UNC-Duke Collaborative Clinical Pharmacology T32 Postdoctoral Training Program

2018-2020 Kathleen Marulanda, M.D., M.S. (co-mentored with Melina Kibbe, M.D., Nick D. Tsihlis, Ph.D., Sean E. Mclean, M.D., and Matthew M. Laughon, M.D., M.P.H.)
2017-2019 Kate Westmoreland, M.D. (co-mentored with Satish Gopal, M.D. and Patrick Thompson, M.D.)

Department of Pediatrics, UNC School of Medicine

2018-Present Wesley Jackson, M.D. (co-mentored with Matthew M. Laughon, M.D., M.P.H., Rebecca Fry, Ph.D., and Melissa S. Bauserman, M.D., M.P.H.)

UNC Eshelman School of Pharmacy Teaching Certificate Program

2016-17 Emma Stafford, Pharm.D.
2015-16 Erin Brewer, Pharm.D.
2014-15 Rachel Lebovic, Pharm.D.

PROFESSIONAL SERVICE

The University of North Carolina at Chapel Hill

2021 Campbell Mentoring Program Discussion Leader
Scholastic Achievement and Progression Committee (Chair: Patterson)

2020 UNC Eshelman School of Pharmacy Strategic Planning Advisory Committee Meeting
(Co-Chairs: Gonzalez and McLaughlin)
PharmD Candidates' Days, September 18
Scholastic Achievement and Progression Committee (Chair: Patterson)
Program for Precision Medicine in Health Care Genetics and Genomics Governance
Committee (Chair: Berg)

2019 Clinical Assistant/Associate/Full Professor Search Committee (Chair: Williams)
Research Assistant Professor Search Committee (Chair: Laughon)

- Neonatal Medicine Research Coordinator Search Committee (Chair: Laughon)
Biostatistician Search Committee (Chair: Laughon)
Program for Precision Medicine in Health Care Genetics and Genomics Governance
Committee (Chair: Berg)
Graduate Education Committee (Chair: Jarstfer)[through 3/2019]
- 2018 Clinical Assistant/Associate/Full Professor Search Committee (Chair: Williams)
Graduate Education Committee (Chair: Jarstfer)
Graduate Program Visionary Committee (Chair: Brouwer)
Committee to Optimize Graduate Student Selection (Chair: Ainslie)
Board of Directors (University Appointee), Victory Village Day Care Center
- 2017 Graduate Education Committee (Chair: Hawke)
Graduate Program Visionary Committee (Chair: Brouwer)
Chapel Hill Pharmaceutical Sciences Conference (Co-Chairs: Gonzalez/Wiltshire)
Research Professor Search Committee (Chair: Patterson)
DPET Graduate Program Coordinator Search Committee (Chair: Bishop)
Research Assistant Professor Search Committee (Chair: Forrest)
Board of Directors (University Appointee), Victory Village Day Care Center
- 2016 Graduate Education Committee (Chair: Hawke)
Chapel Hill Pharmaceutical Sciences Conference (Co-Chairs: Gonzalez/Wiltshire)
Faculty Search Committee (Chair: Brouwer), Research Assistant Professor
Graduate Program Self-Study Committee (Chair: Patterson)
Post-Doctoral Research Associate Search Committee (Chair: Cao)
Board of Directors (University Appointee), Victory Village Day Care Center
Research Specialist Search Committee (Chair: Crona)
Staff Scientist Search Committee (Chair: Gonzalez)
Staff Scientist Search Committee (Chair: Forrest)
Research Technician Search Committee (Chair: Lee)
Faculty Search Committee, Drug Metabolism Research Faculty (Chair: Thakker)
Clinical Assistant Professor Search Committee (Chair: Williams)
PharmD Candidates' Days, February 5
- 2015 Faculty Search Committee (Chair: Forrest), Infectious Disease Research Faculty
Faculty Search Committee (Chair: Thakker), Drug Metabolism Research Faculty
Faculty Search Committee (Chair: Brouwer), Research Assistant Professor
PharmD Candidates' Days, February 6 and December 14
Assured Admission Interview Day, March 20
- 2014 Hematology/Oncology Translational Research Faculty Search Committee (Chair:
Zamboni)
PharmD Candidates' Days, November 14 & December 15

University of Florida

- 2005-07 College of Pharmacy Curriculum Committee
2005-06 College of Pharmacy First-Year Student Orientation

American Association of Pharmaceutical Scientists (AAPS)

- 2011 – 2012 Academic Subcommittee
2011 – 2012 University of Florida Student Chapter President

American College of Clinical Pharmacology (ACCP)

2016 - 2019 Honors & Awards Committee
2014 Annual Meeting Planning Committee
2011 – 2016 Student Outreach Committee
2011 – 2013 Education Committee

American Conference on Pharmacometrics (ACoP)

2018-Present Abstract Review Committee
2011 Annual Meeting Student Planning Committee

National Institutes of Health (NIH)

2021 Co-Leader of the PK Modeling to Inform Drug Dosing Working Group
2020 Best Pharmaceuticals for Children Act (BPCA) Stakeholders Meeting Breakout Group
Co-Leader
Organizing Committee for 9th Annual Meeting of T32 Trainees in Pediatric Clinical
Pharmacology
2019 Pediatric Critical Care Conferences Initiative (R13) Special Emphasis Panel (ZHD1
DSR-A (50))
2018 NICHD Strategic Planning Working Group
2018 Early Career Reviewer, Xenobiotic and Nutrient Disposition and Action Study Section

JOURNAL REVIEWER

Antimicrobial Agents and Chemotherapy
British Journal of Clinical Pharmacology
Clinical Pharmacokinetics
Clinical Pharmacology & Therapeutics
JAMA Pediatrics
Journal of Antimicrobial Chemotherapy
Journal of Clinical Pharmacology

EDITORIAL BOARD MEMBER

2013 – 2015 Pharmacology Research & Perspectives

PROFESSIONAL AFFILITATIONS

2017 – Present	Member	American Society of Microbiology
2014 – Present	Member	American Association of Colleges of Pharmacy
2011 – Present	Member	International Society of Pharmacometrics
2008 – Present	Member	American Society for Clinical Pharmacology and Therapeutics
2008 – Present	Member	American College of Clinical Pharmacology
2008 – 2018	Member	American Association of Pharmaceutical Scientists
2006 – Present	Member	American College of Clinical Pharmacy