

# Brian M. Cicali

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## **Summary**

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- Nine years of research experience and training in multiple disciplines of drug discovery including Structure Activity Characterization, Medical Chemistry, PK/PD, PBPK/PD, Pharmaceutical Outcomes, and Quantitative Systems-Modeling.
- Skilled in a wide variety of laboratory techniques in the fields of Pharmacometrics, Molecular Pharmacology, Medical Chemistry, Toxicology, Computational Science and Data Analytics.
- Skilled in a wide variety of computational techniques including Molecular Modeling and Simulation, Machine Learning Algorithms, Data Mining and Application, Bioinformatics, Data Visualization, and Statistical Characterization.
- Proven project management skills in both academic and industry settings through publication and leadership positions.

## **Education**

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### **PhD in Pharmaceutical Sciences**

University of Florida, College of Pharmacy,  
Center of Pharmacometrics and Systems Pharmacology. Orlando, FL  
Concentration: Pharmacometrics and Systems Pharmacology  
Advisor: Stephan Schmidt, BPharm, PhD, FCP  
Thesis: Physiologically Based Pharmacokinetic/Pharmacodynamic Modeling and  
Pharmacoepidemiologic Applications to Optimizing Macrolide Therapies  
May 2022

### **MS in Computational Science**

Stockton University, School of Natural Sciences and Mathematics. Galloway, NJ  
*Summa Cum Laude* with Program Distinction  
Concentration: Modeling and Simulation  
Advisor: Robert Olsen, PhD  
Thesis: Computational Drug Discovery: An Exploration into Combination Therapies for  
Treatment-Resistant Melanoma  
May 2017

### **BS in Pharmacology and Toxicology**

University of the Sciences, Philadelphia College of Pharmacy. Philadelphia, PA  
Advisor: Adeboye Adejare, PhD  
May 2013

## **Employment/Research Experience**

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**Research Assistant Professor** 2022-Present

Center for Pharmacometrics and Systems Pharmacology  
University of Florida, College of Pharmacy, Department of Pharmaceutics  
Report to: Rodrigo Cristofolletti and Stephan Schmidt

**Editor in Training** 2023-Present

CPT:Pharmacometrics and Systems Pharmacology  
American Society for Clinical Pharmacology and Therapeutics (ASCPT)

**Ruffolo Graduate Education and Research Fellow** 2021 - 2022

University of Florida, College of Pharmacy  
Orlando, FL  
Report To: Stephan Schmidt, B.Pharm, Ph.D., F.C.P., Director & Associate Professor

**Spiegel Graduate Student Fellow** 2019 - 2021

University of Florida, College of Pharmacy, Department of Pharmaceutics.  
Orlando, FL  
Report To: Stephan Schmidt, B.Pharm, Ph.D., F.C.P., Director & Associate Professor

**ORISE FDA Predoctoral Research Fellow** 2019, 2020

Year 1: US Food and Drug Administration, Office of Clinical Pharmacology Division II, Silver Spring, MD

Reported to: Justin Penzenstadler, PharmD, MS, Clinical Pharmacologist

Year 2: US Food and Drug Administration, Office of Clinical Pharmacology Division of Inflammation and Immune Pharmacology, Silver Spring, MD

Reported to: Chandrahas Sahajwalla, Ph.D, F.C.P., Division Director, & Justin Penzenstadler, PharmD, MS, Senior Clinical Pharmacologist

**Graduate Research Assistant** 2018 - 2019

University of Florida, College of Pharmacy, Center of Pharmacometrics and Systems Pharmacology. Orlando, FL  
Reported To: Stephan Schmidt, B.Pharm, Ph.D., F.C.P., Director & Associate Professor

**Pharmacokinetic Research Scientist**

**Lead Data Analyst** 2016 - 2017

Tabula Rasa HealthCare, Carekinesis, Moorestown, NJ  
Reported To: Jacques Turgeon, BPharm, PhD, FCAHS, FNAMF, Chief Scientific Officer

**Distinguished Research Fellow** 2016 - 2017

Stockton University, Galloway, NJ  
Advisor: Robert Olsen, PhD

**Chemist** 2013 - 2015

GlaxoSmithKline Research and Development, Collegeville, PA  
Reported to: Joan Glass

## Academic Scientist

2013

University of the Sciences, Philadelphia, PA

NeuroPharmacology laboratory ran by Adeboye Adejare, PhD

Reported to: Jason Wallach, PhD

## Research Assistant

2011 - 2013

University of the Sciences, Philadelphia, PA

NeuroPharmacology lab ran by Adeboye Adejare, PhD

## Publications

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### Manuscripts

1. Rodriguez-Vera L, Yin X, Almoslem M, Romahn K, **Cicali B**, Lukacova V, Cristofolletti R, Schmidt S. Comprehensive Physiologically-Based Pharmacokinetic Model to Assess Drug-Drug Interactions of Phenytoin. *Pharmaceutics*. doi:10.3390/pharmaceutics15102486.
2. **Cicali B\***, Kim S\*, Pressly M, Da Silva L, Wendl T, Vozmediano V, Schmidt S, Cristofolletti R. Model-based Analysis of in vivo Release Data of Levonorgestrel Implants: Projecting Long-Term Systemic Exposure. *Pharmaceutics*; 2023, 15(5). <https://doi.org/10.3390/pharmaceutics15051393>. \*co-first author
3. Schmidt S, Vozmediano V, Cristofolletti R, Kim, S, Lin Z, de Morales N, Azeredo F, **Cicali B**, Leuenberger H, Brown J, Jin J, Musante C, Tannenbaum S, Wang Y. Requirements, Expectations, Challenges & Opportunities Associated with Training the Next Generation of Pharmacometricians. *CPT:PSP*, <https://doi.org/10.1002/psp4.12970>
4. **Cicali B**, Da Silva, L, Sarayani A, Lingineni, K, Pressly, M, Kim, S, Wendl T, Hoechel J, Vozmediano V, Winterstein A, Brown J, Cristofolletti R, Schmidt S. Development of an Exposure-Bracketing to Streamline the Development of Contraceptive Products. *CPT*. <https://doi.org/10.1002/cpt.2690>
5. **Cicali B**, Schmidt S, Zeitlinger M, Brown J. Pharmacoepidemiological Evidence for Macrolide Antibiotic Treatment Failure Due to Drug-Drug Interactions and Altered Pharmacokinetics. *Pharmaceutics*; 2022,14,704. <https://doi.org/10.3390/pharmaceutics14040704>
6. Michaud V, Bikmetov R, Smith MK, Dow P, Darakjian L, Deodhar M, **Cicali B**, Bain K, Turgeon J. Use of drug claims data and a medication risk score to assess the impact of drug interactions involving CYP2D6 activities among opioid users: Impact on healthcare costs. *Journal of Personalized Medicine*. <https://doi.org/10.3390/jpm11111174>
7. Lingineni K, Chaturvedula A, **Cicali B**, Cristofolletti R, Wendl T, Hoechel J, Wiesinger H, Vozmediano V, Zhao P, Schmidt S. Determining the Exposure Threshold for Levonorgestrel Efficacy Using Integrated Model-Based Meta-Analysis Approach. *CPT*. <https://doi.org/10.1002/cpt.2457>

8. Long T, Cristofolletti R, **Cicali B**, Michaud V, Dow P, Turgeon J, Schmidt S. Physiologically-based Pharmacokinetic Modeling to Assess the Impact of CYP2D6-Mediated Drug-Drug Interaction on Tramadol and O-Desmethyltramadol Exposures via Allosteric and Competitive Inhibition. *Journal of Clinical Pharmacology*. <https://doi.org/10.1002/jcph.1951>
9. Brown, J., **Cicali, B.**, Henriksen, C., Malaty, I., Okun, M., Armstrong, M. (2021). Balancing post-marketing surveillance of adverse drug events with comparative pharmacovigilance analyses of antipsychotic associated mortality in Parkinson's disease. *Journal of Managed Care and Specialty Pharmacy*. doi:10.18553/jmcp.2021.27.6.785.
10. Sunaga T, **Cicali B**, Schmidt S, Brown J. (2021). Effect of CYP3A4 inducing drug-drug interactions on contraceptive failures stratified by route of administration. *Contraception*. <https://doi.org/10.1016/j.contraception.2020.12.002>
11. Ackley T, McManus D, Topal J, **Cicali B**, Shah S. (2021). A Valid Warning or Clinical Lore: An Evaluation of Safety Outcomes of Remdesivir in Patients with Impaired Renal Function from a Multicenter Matched Cohort. *Antimicrobial Agents and Chemotherapy*. doi:10.1128/AAC.02290-20.
12. **Cicali, B.**, Lingineni, K., Cristofolletti, R., Wendl, T., Hoechel, J., Wiesinger, H., Chaturvedula, A., Vozmediano, V., Schmidt, S. (2021). Quantitative assessment of levonorgestrel enzyme-binding partner interplay and drug-drug interactions using physiologically based pharmacokinetic modeling. *CPT: Pharmacometrics and Systems Pharmacology*. doi:10.1002/psp4.12572 \*\*\***Top-Cited Article in CPT:PSP for 2021 from Wiley**
13. Michaud, V., Dow, P., Rihani, S. B., Deodhar, M., Arwood, M., **Cicali, B.**, & Turgeon, J. (2020). Risk of drug-induced Long QT Syndrome associated with the use of repurposed COVID-19 drugs: A systematic review. *CPT: Clinical and Translational Science*. doi:10.1111/cts.12882
14. Sarayani, A., Brown, J., Goodin, A., Squires, P., Pham, P., **Cicali, B.**, Henriksen, C., Schmidt, S., Winterstein, A. (2020). A Pharmacoepidemiologic Approach to Evaluate Real-world Effectiveness of Hormonal Contraceptives in the Presence of Drug–drug Interactions. *Epidemiology*. doi: 10.1097/EDE.0000000000001302
15. **Cicali, B.\***, Sarayani, A.\*, Henriksen, C. H., & Brown, J. D. (2020). Safety signals for QT prolongation or Torsades de Pointes associated with azithromycin with or without chloroquine or hydroxychloroquine. *Research in Social and Administrative Pharmacy*. doi: 10.1016/j.sapharm.2020.04.016 \*co-first author
16. **Cicali, B.**, Long, T., Kim, S., & Cristofolletti, R. (2020). Assessing the impact of cystic fibrosis on the antipyretic response of ibuprofen in children: physiologically-based modeling as a candle in the dark. *British Journal of Clinical Pharmacology*. doi: 10.1111/bcp.14326 \*\*\***Awarded “Most Informative Scientific Report” by Simcyp Academic Awards 2020**

17. Brown, J., **Cicali, B.**, Pham, P., Schmidt, S., Lip, G.Y.H. (2019) Breaking the Rules for Studies using Real-World Observational Data: The Case of Direct-Acting Anticoagulants and Antiepileptic Drugs. *European Heart Journal- Cardiovascular Pharmacotherapy*. <https://doi.org/10.1093/ehjcvp/pvz053>
18. Kirouac, D.C., **Cicali, B.**, Schmidt, S. (2019) Reproducibility of Quantitative Systems Pharmacology (QSP) Models: Current Challenges and Future Opportunities. *CPT: Pharmacometrics & Systems Pharmacology*. doi:10.1002/psp4.12390 \*\*\***Awarded the CPT:PSP Award for most outstanding paper of 2019**
19. **Cicali, B.**, Michaud, V., Knowlton, C., Turgeon, J. (2018) Application of a Novel Medication-Related Risk Stratification Strategy to a Self-Funded Employer's Population. *Benefits Quarterly*. Q2 2018, Vol. 34:49-55.
20. Wallach, J., Colestock, T., **Cicali, B.**, Elliott, S. P., Kavanagh, P. V., Adejare, A., Dempster, N. M., and Brandt, S. D. (2016) Syntheses and Analytical Characterizations of *N*-alkyl-aryl cyclohexylamines. *Drug Testing and Analysis*, 8: 801–815. doi: 10.1002/dta.1861.

## Patents

1. Turgeon, J., Michaud, V., **Cicali, B.** *Population-Based Medication Risk Stratification and Personalized Medication Risk Score*. Published Oct. 1 2020. US Patent No: US2020/0312434
2. Turgeon, J., Michaud, V., **Cicali, B.** *Population-Based Medication Risk Stratification and Personalized Medication Risk Score*. 2018. WO2019089725. International Application No. PCT/US2018/058405.

## Abstracts

1. Chen H., Chun D., Lingineni K., Guzy S., **Cicali B.**, Cristofolletti R., Vozmediano V., Schmidt S. Applications of Physiologically-based Pharmacokinetic Modeling & Model Based Meta-Analysis in Hormonal Contraceptive Breakthrough Bleeding Analyses. American College of Clinical Pharmacology Annual Meeting. 2023.
2. Chun D., Chen H., Guzy S., **Cicali B.**, Cristofolletti R., Vozmediano V., Schmidt S. Evaluating Clinical Impact of Hormonal Contraceptive Drug-Drug Interactions/Obesity on Ovulation Rate and Pearl Index Using Integrated Physiologically-based Pharmacokinetic Modeling & Model Based Meta-analysis Approach. American College of Clinical Pharmacology Annual Meeting. 2023.
3. **Cicali, B.**, Cristofolletti, R, Pressly, M, Kim, S, Wendl, T, Vozmediano, V, Schmidt, S. Long-acting formulation drug-drug interactions: evaluating the importance of timing using a subcutaneous levonorgestrel PBPK example. PAGE 31, Abstr 10699 [www.page-meeting.org/?abstract=10699]. 2023
4. Rodriguez L, V, Yin, X, Almoslem, M, Romahn, K, **Cicali, B.**, Cristofolletti, R, Schmidt, S. Applying Physiologically-Based Pharmacokinetic (PBPK) Modeling to Assess

- Complex Metabolic-Mediated Drug-Drug Interactions (DDIs). 13<sup>th</sup> American Conference on Pharmacometrics (ACoP13). 2022
5. Da Silva, L, **Cicali, B**, Cristofolletti, R, Schmidt, S. Leveraging Physiologically Based Pharmacokinetic (PBPK) Development and Validation of a Whole-body PBPK Model of Drospirenone for Drug-drug Interaction Studies. 13<sup>th</sup> American Conference on Pharmacometrics (ACoP13). 2022
  6. Hoffert, Y, **Cicali, B**, Cristofolletti, R, Schmidt, S. Leveraging Physiologically Based Pharmacokinetic (PBPK) Modeling to Explore the Role of OCT1 on Tramadol and its Active Metabolite Exposure in Healthy Adults and Children. 13<sup>th</sup> American Conference on Pharmacometrics (ACoP13). 2022
  7. Pressly, M, Kim, S, Cristofolletti, R, **Cicali, B**, Wendl, T, Da Silva, L, Vozmediano, V, Schmidt, S. Development of an etonogestrel disposition model using PK-Sim for application to other dosage forms. American College of Clinical Pharmacology Annual Meeting. 2022.
  8. Da Silva, L, **Cicali, B**, Schmidt, S, Cristofolletti, R. Mechanistic modeling to quantify the influence of BMI on the exposure of drospirenone in women of child-bearing age. American College of Clinical Pharmacology Annual Meeting. 2022. **\*\*\*Awarded Trainee Abstract Award**
  9. **Cicali, B**, Schmidt, S, Zeitlinger, M, Brown J. Macrolide treatment failure due to drug-drug interactions: real-world evidence to evaluate a pharmacological hypothesis. International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE). 2022 **\*\*\*Awarded Spotlight Poster Ribbon**
  10. **Cicali, B**, Cristofolletti, R, Pressly, M, Kim, S, Wendl, T, Vozmediano, V, Schmidt, S. PBPK-based exposure bracketing of subcutaneous levonorgestrel for evaluating drug-drug interactions. 12<sup>th</sup> American Conference on Pharmacometrics (ACoP12). 2021 **\*\*\*Awarded QSP Trainee Blue Ribbon Award**
  11. Pressly, M, Kim, S, Cristofolletti, R, **Cicali, B**, Wendl, T, Vozmediano, V, Schmidt, S. Development of an Etonogestrel disposition model using PK-Sim for application to other dosage forms. 12<sup>th</sup> American Conference on Pharmacometrics (ACoP12). 2021
  12. Da Silva, L, **Cicali, B**, Vozmediano, V, Schmidt, S, Cristofolletti, R. Development of a Physiologically-based Pharmacokinetic Exposure-bracketing Approach to Assess Hormonal Contraceptives Drug-Drug Interactions. American College of Clinical Pharmacology Annual Meeting. Clinical Pharmacology in Drug Development. 2021
  13. Zimmerman, E.S., **Cicali, B**, Cristofolletti, R, Schmidt, S. Physiologically-Based Pharmacokinetic Modelling to describe the tissue distribution of levofloxacin: From rats to humans. American College of Clinical Pharmacology Annual Meeting. Clinical Pharmacology in Drug Development. 2021;093.
  14. **Cicali, B**, Zimmerman, E.S., Cristofolletti, R, Schimdt, S. Target Site Distribution Modeling of Macrolide Antibiotics using a Mechanistic Physiologically-based Approach.

American College of Clinical Pharmacology Annual Meeting. Clinical Pharmacology in Drug Development. 2021;095.

15. Sarayani, A, Winterstein, A, **Cicali, B**, Schmidt, S, Brown, J. Oral Contraceptive Failures in the Presence of Drug-drug Interaction- Does Progestin Type Matter? International Conference of Pharmacoepidemiology (ICPE) 2021. **\*\*\*Awarded Best Poster by the Drug-drug Interaction SIG**
16. Pham, P, Albogami, Y, **Cicali, B**, Squires, P, Sarayani, A, Thai, T, Reams, V, Rhew, K, Gooddin, A, Schmidt, S, Winterstein, AG, Brown, J. *Risk of thromboembolic events associated with concomitant use of oral hormonal contraceptives and selective serotonin reuptake inhibitors*. 36th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. Pharmacoepidemiology and Drug Safety. 2020: 29, 613-614.
17. **Cicali, B**, Lingineni, K, Cristofolletti, R, Wendl, T, Hoechel, J, Wiesinger, H, Chaturvedula, A., Vozmediano, V, Schmidt, S. *Development and Verification of a Levonorgestrel PBPK Model for Enzyme-Mediated Drug Interaction Studies*. 11<sup>th</sup> American conference on Pharmacometrics (ACoP11). 2020; TUE-010
18. Brown, J, **Cicali, B**, Henriksen, C, Malaty, I, Okun, M, Armstrong, M. *Comparative pharmacovigilance analyses of pimavanserin and mortality in Parkinson's Disease*. International Conference on Pharmacoepidemiology and Therapeutic Risk Management. Pharmacoepidemiology and Drug Safety. 2020: 29, 478-479
19. Sarayani A, Brown JD, Goodin AJ, **Cicali B**, Henriksen C, Schmidt S, Winterstein AG. *Effect of enzyme-inducing antiepileptic drugs on failure of oral low-dose hormonal contraceptives*. International Society of Pharmacoepidemiology All Access. Pharmacoepidemiology and Drug Safety. 2020: 29, 638-639.
20. Lingineni, K, **Cicali, B**, Chaturvedula, A, Cristofolletti, R, Wendl, T, Hoechel, J, Wiesinger, H, Vozmediano, V, Zhao, P, Schmidt, S. *Quantitative Evaluation of Levonorgestrel Efficacy in Drug-Drug Interaction (DDI) Scenarios in Healthy and Obese Women: Applications of Integrated Physiologically-based Pharmacokinetic (PBPK) Modeling & Model Based Meta Analysis (MBMA)*. American College of Clinical Pharmacology Annual Meeting. Clinical Pharmacology in Drug Development. 2020. **\*\*\*Awarded Trainee Abstract Award & Wayne A. Colburn Memorial Award**
21. Liu, T, Penzenstadler, J, **Cicali, B**, Zemskova, M, S, Vaidyanathan, J, Sahajwalla, C. *Evaluation of IGF-1 as a Biomarker to Inform Phase 3 Clinical Trial Design and Dose Selection in Patients Born Small for Gestational Age who Fail to Demonstrate Catch-Up Growth by Ages 2-4 Years*. Journal of Endocrine Society 2020: 4, S94.
22. **Cicali, B**, Cristofolletti, R, Wendl, T, Lingineni, K, Hoechel, J, Wiesinger, H, Vozmediano, V, Schmidt, S. *Expansion of a Levonorgestrel Physiologically-Based Pharmacokinetic Model (PBPK) to Evaluate the Pharmacokinetic/Pharmacodynamic (PKPD) Effects of SHBG Protein Binding*. International Federation of Pharmaceuticals: 6<sup>th</sup> Pharmaceutical Sciences World Congress. Montreal, Canada. 2020. (Meeting cancelled due to COVID-19 pandemic)
23. **Cicali, B**, Cristofolletti, R, Wendl, T, Lingineni, K, Hoechel, J, Wiesinger, H, Vozmediano, V, Schmidt, S. *Development and Verification of a Levonorgestrel PBPK Model for Enzyme-Mediated Drug Interaction Studies*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. Clinical Pharmacology & Therapeutics 2020: 107, S64-S64. (Meeting cancelled due to COVID-19 pandemic)

24. **Cicali, B**, Schmidt, S, Brown, J. *Novel Application of Pharmacoepidemiology for Examination of Possible Pharmacokinetic/Pharmacodynamic Mechanisms of Macrolide Antibiotic Resistance*. American College of Clinical Pharmacology Annual Meeting. *Clinical Pharmacology in Drug Development* 2019; 8(S1):78.
25. **Cicali, B**, Penzenstadler, J, Sahajwalla, C, *Towards a Better Prediction of Hepatic Impairment Effect on Drug Exposure: Applications of Statistical Modeling*. FDA 2019 Summer Research Showcase. Internal
26. **Cicali, B**, Penzenstadler, J, Liu, T, *Comparison of Efficacy Biomarkers for Growth-Hormone Therapy in Small-for-Gestational-Age (SGA) Patients*. FDA 2019 Summer Research Showcase. Internal
27. **Cicali, B**, Schmidt, S, Kirouac D.C. *Developing a Quantitative Systems Pharmacology Model Repository for CPT-PSP: Challenges and Future Opportunities*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. *Clinical Pharmacology & Therapeutics* 2019; 105; S54. \*\*\***Awarded the Best QSP Preconference Poster**
28. **Cicali, B**, Collin, A,J, Vega, A, Raghunandan, S, Schmidt, S. *Bridging the Gap of Macrolide Resistance Mechanisms and Clinical Application through PK/PD Modeling and Pharmacovigilance Analyses*. American Conference on Pharmacometrics 9. *Journal of Pharmacokinetics and Pharmacodynamics* 2018; 45:S12.
29. **Cicali, B**, Turgeon, J, Verzicco, J, Knowlton, C.H., Michaud, V. *Increased Risk of Medication-Related Problems due to Concomitant Administration of CYP2D6-Dependent Opioids and CYP2D6 Interacting Drugs*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. *Clinical Pharmacology & Therapeutics* 2018; 103; S63.
30. Michaud, V, **Cicali, B**, Verzicco, J, Knowlton, C.H, Turgeon, J. *Yearly medical expenditure in patients treated with CYP2D6-dependent opioids and impact of concomitant treatment with CYP2D6 substrate or inhibitor drugs*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. *Clinical Pharmacology & Therapeutics* 2018; 103; S80.
31. **Cicali, B.**, Olsen, R. *Presentation of an In Silico and In Vitro Exploration into Combining FDA-Approved Therapies for Treatment-Resistant Melanoma*. International Federation of Pharmaceuticals: 6<sup>th</sup> Pharmaceutical Sciences World Congress. Stockholm, Sweden. 2017: PSWC-1269.
32. **Cicali, B.**, Badea, G., Steffen, L., Bain, K.T., Schwartz, E., Knowlton, C.H., Turgeon J. *The application of a novel medication risk stratification tool to identify high risk patients within a large population*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. *Clinical Pharmacology & Therapeutics* 2017;101:S60.
33. **Cicali, B.**, Badea, G., Bain, K.T., Knowlton, C.H., Turgeon J. *Visualization technique for FAERS-based adverse event prediction*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. *Clinical Pharmacology & Therapeutics* 2017;101:S25.
34. **Cicali, B.**, Olsen, R. *Presentation of a Simplified Method for Modeling Protein and Drug Interactions using Open-Source Software*. American Society for Clinical Pharmacology and Therapeutics Annual Meeting. *Clinical Pharmacology & Therapeutics* 2017;101:S60.
35. Steffen, L.E., Badea, G., **Cicali, B.**, Knowlton, C.H., Turgeon, J. *Medication-Specific Long QT-JT Index And Patient-Specific Long QT-JT Score For Assessing Risk Of Torsade De Pointes: Validation In An Ambulatory Population*. American Society for

Clinical Pharmacology and Therapeutics Annual Meeting. Clinical Pharmacology & Therapeutics 2017;101:S48

36. **Cicali, B.**, Olsen, R. *Computational Drug Discovery: An In Silico and In Vitro Exploration into Combining Established Therapies for Treatment-Resistant Melanoma*. Rocky 2016 Bioinformatics: International Society of Computational Biology.2016: P14.
37. Wallach, J., **Cicali, B.**, Haigh, B., Sun, S., Adejare, A. *Arylbicloheptylamines: Novel conformationally restricted uncompetitive NMDA receptor antagonists*. The Pharmacologist 2013. 55:4:D-3.

### Other Articles

1. **Cicali, B.**, Savant, N., Isaksson, R., Han, S. (2021) 20 Years of YPG Celebration Report; Chapter 11: New Generation of Pharmaceutical Scientists. *International Pharmaceutical Federation*
2. Savant, N., **Cicali, B.**, Lee Y.Z., Yau, E. (2020) Inspiring the Future: Highlighting the Impact of BPS Support of YPG. Editorial for the *International Pharmaceutical Federation*. <https://fipyypg.medium.com/>

### Invited Oral Presentations

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1. **Brian Cicali**. (2023). "Model-informed Evidence Approach for Paediatric and Neonate Dosing of Tramadol." FIP 81<sup>st</sup> Pharmacy and Pharmaceutical Scientist World Congress. Brisbane, Australia.
2. Amir Sarayani, **Brian Cicali**. (2022). "A Translational Approach to Study Drug-drug Interaction with Hormonal Contraceptives: From Pharmacoepidemiology to Mechanistic Modeling". 38<sup>th</sup> International Conference on Pharmacoepidemiology and Therapeutic Risk Management. Copenhagen, Denmark.
3. **Brian Cicali**, Phaikyeoung Cheah, Jass Liew. (2021) "Strategies for a Successful Career Change". International Federation of Pharmaceuticals webinar hosted by the Young Pharmacist Group (YPG).
4. **Brian Cicali**. (2021) "Assessing the Impact of Cystic Fibrosis on the Antipyretic Response of Ibuprofen in Children". Lake Nona Leadership Council Virtual Meeting.
5. **Brian Cicali**. (2020) "Insights and Experiences of an FDA Intern/Fellow". Virtual Seminar to the AAPS Student Chapters at Kent State University and University of Health Sciences and Pharmacy in St. Louis.
6. **Brian Cicali**. (2020) "Assessing the impact of cystic fibrosis on the antipyretic response of ibuprofen in children: physiologically-based modeling as a candle in the dark". Simcyp Virtual Seminar.
7. **Brian Cicali**. (2020) "Optimizing Our Understanding of Hepatic Dysfunction's Role on Drug Exposure: A Statistical Characterization and Comparison of Current Hepatic Function Assessment Scales". OCP Science Week 2020. US Food and Drug Administration, Silver Spring, MD.
8. Lingineni, K, **Cicali, B**, Chaturvedula, A, Cristofolletti, R, Wendl, T, Hoechel, J, Wiesinger, H, Vozmediano, V, Zhao, P, Schmidt, S. (2020) "Quantitative Evaluation of Levonorgestrel Efficacy in Drug-Drug Interaction (DDI) Scenarios in Healthy and Obese Women: Applications of Integrated Physiologically-based Pharmacokinetic (PBPK)

Modeling & Model Based Meta Analysis (MBMA).” American College of Clinical Pharmacology Annual Meeting.

9. Tao Liu, **Brian Cicali**, Justin Penzenstadler, Jaya Vaidyanathan, Chandrahas Sahajwala (2020). “Evaluation of IGF-1 as a biomarker to inform Phase 3 clinical trial design and dose selection in small for gestational age patients”. OCP Science Week 2020. US Food and Drug Administration, Silver Spring, MD.
10. **Brian Cicali** & Yi Ting (Kayla) Lien (2020). “ACCP Early-Stage Professional Interview”. Interview with Dr Oliver Grundmann for the American College of Clinical Pharmacology (ACCP). <https://www.youtube.com/watch?v=Jzc10tDcl7A&t=41s>
11. Lawrence J. Lesko (2019). Regulatory Guidance vs Clinical Guidance on Drug Interactions with Combined Hormonal Contraception. Marbach DDI Workshop. Marbach, Germany. (Foreword acknowledgement for in-depth DDI database analyses and slide development).
12. Yi Ting (Kayla) Lien, Brett Fleisher, **Brian Cicali**, and Tamara King (2018). “Introduction and Background of ISoP and Florida Local Chapter.” Inaugural Florida-ISoP Local Event. Orlando, FL
13. **Brian Cicali** (2017) “The Development and Application of a Novel Risk Stratification Tool”. 25-minute oral presentation at Intracon 2017. Moorestown, NJ
14. **Brian Cicali** (2017) “Computational Drug Discovery: A Novel Comparative Study using MAPK-Specific Melanoma Therapies”. Oral presentation delivered at Stockton University’s Spring17 Graduate Research Symposium. Galloway, NJ
15. Jacques Turgeon and **Brian Cicali** (2017) “Tabula Rasa Medication Risk Stratification”. 3-hour presentation to the Strategic Advisory Board of Tabula Rasa HealthCare. Moorestown, NJ
16. **Brian Cicali** (2017) “Application of a Novel Risk Stratification Tool for Client Development”. 30-minute presentation to Tabula Rasa HealthCare’s business and client development departments. Moorestown, NJ
17. **Brian Cicali** (2016) “Modeling the Pharmacokinetic Properties of Crestor using Computational Estimation and Simulation Processing”. Stockton University’s Fall’16 Graduate Research Symposium. Galloway, NJ
18. **Brian Cicali** (2016) “Computational Modeling: Implementing Collaborative Work through Simplified Biochemical Modeling Techniques.” Short oral presentation to select students and faculty of the biological sciences department at Stockton University. Galloway, NJ
19. Jason Wallach and **Brian Cicali** (2014) “Arylbicycloheptylamines: Novel Conformationally Restricted Uncompetitive NMDA Receptor Antagonists.” Oral Presentation at the Mid-Atlantic Pharmacology Society (MAPS) Annual Meeting. Philadelphia, PA

## **Research Funding**

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### **On-going:**

#### Federal

NA

#### Foundation

Bill & Melinda Gates Foundation

Title: "Characterizing efficacy and safety of hormonal contraceptives by combining pharmacometrics and RWE"

Time period: 11/2022 – 11/2024

Amount: \$1,316,795

Role: Co-PI

### Industry

Amryt Pharma

Title: "Pooled population analysis of lomitapide"

Time period: 12/2023 – 3/2024

Amount: \$25,000

Role: PI

TEVA Pharmaceuticals

Title: "Physiologically-based pharmacokinetic (PBPK) modeling of drug-drug interactions for TEV-56268"

Time period: 5/2023 – 7/2023

Amount: \$60,000

Role: Co-I

### Other:

FIP Foundation and Early Career Pharmaceutical Group Innovation Research Grant

Title: "Model-informed evidence approach for pediatric and neonate dosing of tramadol"

Time period: 1/2023 – 4/2024

Amount: \$5,000

Role: PI

### **Completed:**

Amryt Pharma

Title: "Pediatric population analysis of lomitapide"

Time period: 5/2023 – 7/2023

Amount: \$25,000

Role: PI

### **Awards**

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**FIP Early Career in Pharmaceutical Science Recognition Award (Honorable Mention)**

FIP- Board of Pharmaceutical Sciences

2023

**Early Career Pharmaceutical Group Innovative Research Award**

International Pharmaceutical Federation (FIP)

2023

**Leadership Development Program Award**

American College of Clinical Pharmacology	2022
<b>Young Leader in Pharmacy</b> Canadian Health Network, Pharmacy U	2022
<b>Robert and Stephany Ruffolo Graduate Education and Research Fellowship</b> University of Florida, College of Pharmacy Amount: \$35,000 (estimated)	2021
<b>Dr. Allen J. Spiegel Endowed Graduate Fellowship</b> University of Florida, Department of Pharmaceutics Amount: \$55,000 (estimated)	2019
<b>College of Pharmacy Scholarship</b> University of Florida Amount: \$3,948	2019
<b>Best Poster Award for QSP-Preconference</b> American Society for Clinical Pharmacology and Therapeutics Amount: \$75	2019
<b>Charlotte M. Liberty Scholarship Award</b> University of Florida Amount: \$338	2018
<b>College of Pharmacy Scholarship</b> University of Florida Amount: \$2,059	2018
<b>Distinguished Research Fellowship</b> Stockton University Grant Amount: \$2,945	2016, 2017
<b>Graduate Student Travel Award</b> Stockton University Amount: \$700	2017
<b>Stockton University Foundation Award</b> Stockton University Amount: \$1,000	2016
<b>Supervisor Leadership Award</b> GlaxoSmithKline / Sodexo	2015
<b>Academic Achievement Award</b> University of the Sciences, Upsilon Sigma Phi	2013

## **Achievement of Success**

University of the Sciences, 10<sup>th</sup> Annual Research Day

2013

## **Professional Memberships**

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American College of Clinical Pharmacology (ACCP)	2018 - present
American Society for Clinical Pharmacology and Therapeutics (ASCPT)	2016 - present
International Pharmaceutical Federation (FIP)	2016 - present
International Society of Pharmacometrics (ISoP)	2016 - present
Golden Key International Honour Society	2016 - present
American Association of Pharmaceutical Scientists (AAPS)	2016 - 2018
Upsilon Sigma Phi (USP) Professional Pharmacy Fraternity	2013 - present

## **Leadership/Service Positions**

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### International

<b>Chair – FIP New Generation of Pharmaceutical Scientists SIG</b>	2023-present
<b>Editorial Board Member- European Journal of Pharmaceutical Sciences</b>	2021-present
<b>Member- ISoP Influence Working Group</b>	2021-present
<b>Chair - ISoP Student Community (elect, acting, past)</b>	2020-2023
<b>Vice-Chair- FIP New Generation of Pharmaceutical Scientists (NGPS) SIG</b>	2019-2023
<b>Member- ISoP Student Community Steering Committee</b>	2018-2023
<b>Member- ISoP Internationalization Working Group</b>	2019-2021
<b>Member- FIP-YPG Working Group for the Promotion of Pharmaceutical Sciences</b>	2020
<b>Liaison- FIP-BPS: PK/PD &amp; Systems Pharmacology</b>	2017-2019

### National

<b>Member- ACoP Scientific Programing Committee</b>	2023-present
<b>Member- ACCP STEP Committee</b>	2023-present
<b>Chair- Translational Informatics Community (elect, acting, past)- ASCPT</b>	2023-present
<b>Steering Committee - Translational Informatics Community- ASCPT</b>	2022-present
<b>New Member Ambassador- ACCP</b>	2021-present
<b>Member- ACCP Membership Committee</b>	2020-2023
<b>Chairman of the Board- USP Alumni Association Executive Committee</b>	2019-2022
<b>Chair- ACoP Planning Committee Student (elect, acting, past)</b>	2019-2022
<b>Member-ASCPT PGx Programming Steering Committee</b>	2019-2021
<b>Founding Member- ISoP Local Southeast Chapter</b>	2018

### University

<b>Mentor- Graduate Student Mentor Program- UF College of Pharmacy</b>	2020, 2021
<b>Member- Exam and Quiz Procter Team- UF College of Pharmacy</b>	2019-2021
<b>Chair- ACCP UF-Student Chapter (elect, chair, past)</b>	2019-2021
<b>Member- PhD Internship Policy Task Force- UF College of Pharmacy</b>	2019

### Scientific Review

<b>Journal- Pharmaceutical Research</b>	2023-present
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<b>Journal-Biopharmaceutics and Drug Disposition</b>	2022-present
<b>Journal-Pharmaceutics</b>	2022-present
<b>Journal-Journal of Personalized Medicine</b>	2022-present
<b>Journal-CPT: Pharmacometrics and Systems Pharmacology</b>	2021-present
<b>Journal-Research in Social and Administrative Pharmacy</b>	2020-present
<b>Program Proposals-ASCPT</b>	2020-present
<b>Abstracts-FIP</b>	2020
<b>Abstracts-ASCPT, ACoP</b>	2019-present
<b>Journal-European Journal of Pharmaceutical Sciences</b>	2019-present

### **Other Scientific Contributions**

Chair and Panelist- Annual ASCPT Network and Community Event “Unlocking the Potential of Translational Informatics”	2023
Expert Panelist- FIP 2030 Workforce Symposium “Early Career Development: Are we paying enough attention to early career development and scope of practice?”	2023
Moderator- ASCPT Journal Webinar “Hallmarks of Neurodegenerative Disease: A Systems Pharmacology Perspective”, hosted by ASCPT. Speaker: Peter Bloomingdale	2022
Session Chair – ASCPT Annual Meeting “Trainee Communication Showdown” Session highlighting trainee communication education and science, as well as a training bootcamp.	2022
Webinar Chair – FIP- New Generation of Pharmaceutical Sciences SIG “The Role of Pharmaceutical Scientists in a Government Body” International Webinar hosted by FIP. Speakers: Renata de Lima Soares, Justin Penzenstadler	2021
Session Chair – 11 <sup>th</sup> American Conference on Pharmacometrics (ACoP11) “First in Human Dose Determinations: From Small Molecules to Cell-Therapies. A trainee-focused workshop” Speakers: Daren Austin, Tim Hart.	2020
Session Chair – 11 <sup>th</sup> American Conference on Pharmacometrics (ACoP11) “Trainee Mentoring Session” Speakers: Stacey Tannenbaum, Ben Weber, Hartmut Derendorf, Pete Bonate, Rajanikanth Madabushi, Kelly Mahar, Emmanuel (Mannie) Chigutsa, Ayyappa Chaturvedula, Rajendra Singh, Bela Patel, Kyle Baron.	2020
Contributor/Reviewer – FIP YPG Career Development Guidance “Career Develop Toolkit for Early Career Pharmacists and Pharmaceutical Scientists”	2020
Session Chair – 7 <sup>th</sup> Pharmaceutical Sciences World Congress (PSWC)	2020

“Targeting Networks: Systems Pharmacology Approaches to Develop Disease-modifying Therapies.” Speakers: Hiroshi Suzuki, Coen van Hasselt, Stephan Schimdt, Oscar della Pasqua. (Conference Postponed due to COVID-19)

## **Teaching Experience**

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### **Academic:**

PHA6131: Physiologically Based Modeling, Spring 2023  
University of Florida, College of Pharmacy

PHA6418: Introduction to Model-Informed Drug Discovery, Fall 2022  
University of Florida, College of Pharmacy  
Lecture(s): Introduction to PBPK, Drug-Drug Interactions, Active Learning Session Support

PHA6894: Introduction to Graduate Studies, Spring 2021  
University of Florida, College of Pharmacy  
Lecture(s): Communication and Presentation Skills III: Manuscripts

PHA5930: Seminars in Pharmacy Research, Fall 2020  
University of Florida, College of Pharmacy  
Lecture(s): Active Learning Session #6

PP-541-01: Pharmacogenomics: Bioinformatics and Model Systems, Spring 2017  
University of the Sciences, Philadelphia College of Pharmacy  
Lecture(s): Bioinformatics and Model Systems

CPLS-5800: Biological Systems Modeling with Python, Spring 2016  
Stockton University, School of Natural Sciences and Mathematics  
Lecture(s): Basics of Biomolecular Modeling

### **CE Accredited:**

Risk Stratification Strategies. April 2017, July 2017  
MedWiseAdvisor Specialty Pharmacy Training, Tabula Rasa HealthCare  
Accreditor: University of the Sciences, Creighton University

Adverse Event Prediction Tool. December 2016  
Medication Risk Mitigation Certificate Training, Tabula Rasa HealthCare  
Accreditor: Creighton University

## **Certifications**

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Achieve High Performance Program Completion  
2022- The Achieve Institute

Certificate of Completion for NONMEM Applications  
2019- Cognigen

Certificate of Completion for Protecting Human Research Participants  
2019 - PHRP Training LLC

Certificate in the Clinical Application of Pharmacogenomics  
2018- University of Florida

Certificate of Completion for GastroPlus PBPK Modeling and Simulation Training  
2018- Simulations Plus

## **Technical Skills**

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### **Pharmacometrics and Systems Pharmacology:**

QSP: Systems modeling and simulation with PK-Sim/MoBi, Matlab/Simbiology, and R.

PK/PD: Various compartmental and noncompartmental PK modeling in R, Excel, Phoenix/Winnonlin, Monolix, NONMEM, Matlab/Simbiology, and SAS. Various PD modeling in R, and Matlab/Simbiology.

PBPK: Whole-body and minimal PBPK model development and simulation in PK-Sim/MoBi, Simcyp, Gastroplus, and Simbiology.

### **Pharmacology and Toxicology:**

In Vitro: Radio-ligand binding studies, tissue analyses for toxicology mechanisms, assay experimentation with HeLA, Mouse Melanoma, iCell Neurons, and BRCA cell lines.

In Vivo: Experimentation using rats for pharmacokinetic pathway analyses, behavioral analysis for anti-convulsion toxicity screening, experimentation using mice for sedation studies.

In Silico: Ligand docking screening, binding pocket analyses, biological systems modeling, PK/PD analyses.

Assays: Apoptotic, Cell-Survival (DNA and Protein), ELISA, Phosphorylation assays, Tritiated-ligand assays, HPLC-coupled PK analyses.

Molecular biology: real time PCR, RNA and DNA isolation, Protein extraction and purification, Western Blot and SDS-Page Electrophoresis.

### **Computational Science:**

Computer Language and Software: Skilled to Proficient in the following languages: Unix, Python, R, SQL, SAS, JavaScript, HTML5, and XML. Skilled with various windows-based tools including Microsoft Office, Graphpad Prism, ChemDraw, SAS Studio, R-Studio, MySQL workbench, DB Forge.

Computer Programming: Biological modeling, machine-learning algorithms, data mining and analysis, drug-alternative prediction tools, string-search tool creation, statistical characterization and analyses, data visualization techniques, parameter estimation techniques.

Biological Modeling: Python-based pharmacological modeling and simulation, SAS model Procedures, R, BioNetGen, NONMEM, PK-Sim/MoBi.

Bioinformatics: GenBank BLAST techniques, ExPASy protein sequence analysis, String-Match Algorithm designs, FAERS database analyses.

**Medical Chemistry:**

Synthesis: Aryl-cycloamines and Aryl-bicycloamines expertise, Solvent and reagent optimization.

Analytics: Skilled in the following analytical characterization techniques: GC-MS, HPLC,  $^1\text{H}$ ,  $^{13}\text{C}$  NMR, TLC, LC-MS and IR techniques.