Stephan Schmidt, B.Pharm., Ph.D., F.C.P

May 5, 2023

Work Address:

Personal Information:

6550 Sanger Road, Office 464

Place of Birth: Sonneberg, Germany Orlando, FL 32827 Date of Birth: January 4, 1978 Nationality: German

Tel.: (407) 313 7012 Fax: (407) 313 7030

Marital Status: Married, 2009

Email: sschmidt@cop.ufl.edu

Children: 3 (Rosalyn, Hendrik, Johannes)

Present Position:

Certara Professor, Professor, Director Center for Pharmacometrics and

Systems Pharmacology

Department of Pharmaceutics

College of Pharmacy University of Florida

Previous Positions:

2022 - present

Center for Pharmacometrics & Systems Pharmacology

Department of Pharmaceutics

College of Pharmacy University of Florida

2017 - 2022 Associate Professor

Center for Pharmacometrics & Systems Pharmacology

Department of Pharmaceutics

College of Pharmacy University of Florida

2017 - 2018 Associate Chair

Department of Pharmaceutics - Lake Nona

College of Pharmacy University of Florida

2016 - 2019 Associate Director

Center for Pharmacometrics & Systems Pharmacology

Department of Pharmaceutics

College of Pharmacy University of Florida

2012 - 2017 Assistant Professor

Center for Pharmacometrics & Systems Pharmacology

Department of Pharmaceutics

College of Pharmacy University of Florida

Education:

2009 - 2011 Post-doctoral fellowship at the Leiden/Amsterdam Center for Drug Research,

Leiden. The Netherlands

Supervisor: Professor Meindert Danhof, Pharm.D., Ph.D. and Professor

Oscar E. Della Pasqua, Ph.D.

2005 - 2008	Ph.D. Pharmaceutics from the University of Florida, Gainesville, FL, USA Title: "Pharmacokinetics and Pharmacodynamics of Oxazolidinones and Beta-Lactams." Supervisor: Professor Hartmut Derendorf, Ph.D.
2004 - 2005	Pharmaceutical practical training year and received license to practice as a Pharmacist in Germany in February 2005
1999 - 2003	B.S. Pharmacy from the Friedrich-Alexander-University, Erlangen, Germany

Awards and Honors:

Awards and Ho	
2023	University of Florida Research Foundation Professorship Award, April, 2023
2021	Excellence in Academia Award, MIDD+ Scientific Conference,
	SimulationsPlus, March 3-4, 2021
2021	Teacher Service Award, University of Florida, November 12, 2021
2018	Doctoral Dissertation Mentoring Award, College of Pharmacy, University
	of Florida, December 13, 2018
2017	Galenus Support, April 20, 2017
2017	Fellow of the American College of Clinical Pharmacology, February 15,
	2017
2016	Tanabe Young Investigator Award, September 27, 2016
2016	Galenus Support, April 20, 2016
2015	Galenus Support, April 22, 2015
2014	International Educator of the Year (Junior Faculty Category), College of
• • • • • • • • • • • • • • • • • • • •	Pharmacy, University of Florida, November 19, 2014
2014	Galenus Support, April 25, 2014
2013	University of Florida Excellence Award for Assistant Professors, May 13, 2013
2013	Galenus Support, April 30, 2013
2012	University of Florida Clinical and Translational Science Institute Junior
	Faculty Pilot Program Award: Title: "Personalizing Antiplatelet Therapy: Development of a CYP2C19 Genotype-Directed Dosing Algorithm for Clopidogrel", December 20, 2012
2012	Galenus Support, April 30, 2012
2011	American College of Clinical Pharmacology (ACCP) Student/Trainee Abstract Award, Poster Title: "Mathematical Model Reduction: An Innovative Tool for Analyzing Complex Dynamic Systems", September 12, 2011
2011	Galenus Support, April 25, 2011
2010	Paul-Ehrlich Society for Chemotherapy Thesis Award, October 7, 2010
2010	Galenus Support, April 20, 2010
2008	American Society for Microbiology (ASM) Infectious Disease Fellows Travel Grant, August 18, 2008
2008	Annual Research Showcase Poster Competition Winner of the College of Pharmacy at the University of Florida, Poster Title: "Protein Binding – A Source for Many Pitfalls", February 21, 2008.
2007	American College of Clinical Pharmacology (ACCP) Student/Trainee

	Abstract Award, Poster Title: "Linezolid against MRSA – A New Modeling Approach", September 11, 2007.	
2007	Genentech Podium Award, Presentation Title: "Linezolid against MRSA – A new <i>in vitro</i> Model", September 9, 2007.	
2007	Annual Research Showcase Poster Competition Winner of the College of Pharmacy at the University of Florida, Poster Title: "Linezolid vs. MRSA – A New PK/PD Model", February 19, 2007.	
2007	American Society for Microbiology (ASM) Infectious Disease Fellows Travel Grant, September 17, 2007.	
2006	American Society for Microbiology (ASM) Infectious Disease Fellows Travel Grant, September 27, 2006.	
2006	South East Regional Interdisciplinary Symposium (SERIS) Poster Competition Winner, Poster Title: "Experimental Pitfalls in Protein Binding Measurements", May 21, 2006.	
2006	European Society of Clinical Microbiology and Infectious Diseases (ECCMID) Travel and Registration Scholarship, April 2, 2006.	
Teaching Experience:		
2016 - present	Course coordinator at the University of Florida, Department of Pharmaceutics	
	 PHA5132 (Principles of Drug Therapy Individualization) PHA6131 (Principles and Application of Physiologically-Based Pharmacokinetic Modeling) 	
2014 - 2015	Course coordinator at the University of Florida, Department of Pharmaceutics	
	 PHA5127 (Basic principles of dose optimization I) PHA6935 (Pharmacometrics and Systems Pharmacology) 	
2012 2014	Course co-coordinator at the University of Florida, Department of Pharmaceutics	
	 PHA5127 (Basic principles of dose optimization I) 	
2011	PHA6125 (Advanced Pharmacokinetics and Pharmacodynamics) The Pharmacokinetics and Pharmacodynamics)	
2011	Lecturer at the Dutch Top Institure Pharma's (TI Pharma) Drug Discovery & Development Cycle (DDC)	
	■ Interfacing discovery and development	

- 2009 2011 Teaching Assistant at Leiden University, Department of Pharmacology
 - BFW-2 pharmacology and statistics
 - Systems pharmacology: innovative strategies for disease intervention
- 2005 2008 Teaching Assistant at the University of Florida, College of Pharmacy,

Department of Pharmaceutics

■ PK/PD modeling

- PHA5127 & PHA5128
- Pharmaceutical Skill Laboratory

Professional Affiliations:

2015 - present International Pharmaceutical Federation (Federation Internationale Pharmaceutique, FIP) 2013 - present International Society of Pharmacometrics (ISoP) American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2013 - present 2012 - present American Association of Colleges of Pharmacy (AACP) 2010 - present Paul-Ehrlich Society for Chemotherapy (PEG) 2007 - present American College of Clinical Pharmacology (ACCP) 2006 - 2008 American Society of Microbiology (ASM) student member 2005 - 2018 American Association of Pharmaceutical Scientists (AAPS) **Additional Professional Activities:** Chair of the BPS Special Interest Group on Personalized and Precision 2019 - 2020 Medicine (FIP) 2018 - 2019 Immediate past chair of the Systems Pharmacology Community for the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2017 - present Scientific Advisor to the Editors of JPharmSci 2017 - 2018 Chair of the Systems Pharmacology Community for the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2016 - present Section Editor Eur J Pharm Sci 2016 - present Editorial Board Member J Clin Pharmacol 2016 - 2019 Editorial Board Member CPT Pharmacometrics Syst Pharmacol 2015 - 2017 Vice Chair of the Systems Pharmacology Community for the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2015 - 2019 Chair of the BPS Special Interest Group on PK/PD and Systems Pharmacology (FIP) American College of Clinical Pharmacology (ACCP) 2016 Program 2015 - present Committee Member 2015 20th North American International Society for the Study of Xenobiotics (ISSX) Meeting Co-Chair 2014 - 2015 International Society of Pharmacometrics (ISoP) Quantitative Systems Pharmacology (QSP) Special Interest Group (SIG) Steering Committee Member 2013 - present Founder and faculty advisor for the American College of Clinical Pharmacology (ACCP) student chapter at the University of Florida 2012 - 2018 Founder and faculty advisor for the Personalized Medicine Coalition (PMC) student chapter at the University of Florida

2012 - present Peer reviewer for the Scandinavian Journal of Infectious Diseases
2011 - present Peer reviewer for the British Journal of Pharmacology
2010 - present Peer reviewer for the International Journal of Clinical Pharmacology and Therapeutics
2010 - present Peer reviewer for the British Journal of Clinical Pharmacology
2010 - present Peer reviewer for the European Journal of Pharmaceutical Sciences
2009 - present Peer reviewer for the Journal of Clinical Pharmacology
2008 - 2010 Member of the American Association of Pharmaceutical Scientists microdialysis focus group steering committee
2007 - 2009 American College of Clinical Pharmacology Student Outreach Committee

Grants and Contracts:

Ongoing Research Support - Federal:

Source: NIH

Title: CES1 Genetic Variation Influences Methylphenidate in ADHD

Time period: 7/1/2018- 6/30/2023

Amount: \$3,844,067

Role: co-PI

Source: NIH

Title: "Optimizing Muscular Dystrophy Clinical Trial Designs"

Time period: 09/2021 - 07/2023

Amount: \$190,625

Role: co-PI

Ongoing Research Support – Foundation:

Source: Bill & Melinda Gates Foundation, INV-010213

Title: "Application of physiologically-based pharmacokinetic models to inform dosing recommendations for hormonal contraceptives co-administered with other medications"

Time period: 10/2020-10/2022

Amount: \$1,094,629

Role: PI

Ongoing Research Support - Industry:

Source: Hoffmann-La Roche Ltd.

Title: Physiologically Based Biopharmaceutics Modeling and Virtual Bioequivalence

Assessment During the Development Process

Time Period: 06/01/2022 - 05/31/2025

Amount: \$750,000

Role: co-PI

Source: Takeda

Title: Takeda Research Agreement Time period: 03/30/21-03/31/23

Amount: \$250,000

Source: Simulations Plus

Title: Using Physiologically-Based Pharmacokinetic (PBPK) Simul

Time period: 04/01/21-09/30/22

Amount: \$100,000

Role: PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 09/01/21-08/31/22

Amount: \$82,178

Role: PI

Source: Simulations Plus

Title: Novel physiologically based absorption modeling to predict

Time period: 07/01/21-12/31/22

Amount: \$135,000

Role: co-PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 08/01/22-07/31/23

Amount: \$88,400

Role: PI

Ongoing Research Support - Other:

None

Completed Research Support – Federal:

Source: NIAID, 1P01AI123036-01

Title: "Optimizing Combination Therapy to Accelerate Clinical Cure of Tuberculosis"

Time period: 08/2016 - 07/2022

Amount: \$11,987,633

Role: Head of the mathematical modeling core (20%)

Source: FDA, Center for Drug Evaluation Research - Office of Generic Drugs, U01 RFA-

FD-14-024

Title: "Pharmacokinetic and pharmacodynamic (PK-PD) studies of cardiovascular drugs"

Time period: 09/2014 - 09/2018

Amount: \$2,209,415 Role: I (10%, 15%, 20%)

Source: FDA, Center for Drug Evaluation Research - Office of Generic Drugs,

5U01FD005210 - 04

Title: "A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to

Generic Substitution"

Time period: 09/2014 - 09/2018

Amount: \$1,000,000

Role: PI since December 2018 and co-PI prior to that (20%)

Source: FDA, Office of Women's Health

Title: "Disease Systems Analysis: Towards a Generic Framework for Characterizing Disease

Progression and Treatment Effects in Osteoporosis"

Time period: 04/30/2014 - 05/01/2016

Amount: \$180,000

Role: PI

Source: FDA

Title: "Using Drug-Drug Interactions to Identify Pharmacogenomic Opportunities"

Time period: 02/01/2014 - 08/01/2014

Amount: \$36,000

Role: co-PI

Source: FDA

Title: "PBPK training"

Time period: 09/2012 - 08/30/2013

Funding Requested: \$90,000

Role: PI

<u>Complete Research Support – Foundation:</u>

Source: Bill & Melinda Gates Foundation, OPP1185454

Title: "Application of physiologically-based pharmacokinetic models to inform dosing recommendations for hormonal contraceptives co-administered with other medications"

Time period: 11/17-10/20 Amount: \$1,499,992

Role: PI

Source: Thrasher Foundation

Title: "Genotype-tailored treatment of symptomatic acid-reflux in children with uncontrolled

asthma"

Time period: 03/01/18-02/28/21

Amount: \$374,897

Role: co-PI

Completed Research Support - Industry:

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 08/01/21-07/31/22

Amount: \$97,021

Role: PI

Source: Millennium Pharmaceuticals, Inc.

Title: Development of a Mechanism-Based Drug Disease Trial Model for Parkinson's disease

(PD)

Time period: 11/1/2018-08/31/2021

Amount: \$220,000.00

Role: co-PI

Source: ARS Pharmaceuticals

Title: Development of a Physiologically based Pharmacokinetic Model (PBPK) to Inform the

Development of a New Nasal Formulation of Epinephrine

Time period: 06/01/2020-09/30/2021

Amount: \$106,550

Role: co-PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 07/01/20-07/30/21

Amount: \$82,535

Role: PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 09/01/20-08/30/21

Amount: \$91,582

Role: PI

Source: Tabula Rasa HealthCare

Title: "Pharmacometrics modeling and simulation of the probe drug tramadol administered

alone or while subjected to competitive enzyme inhibition"

Time period: 08/05/2019-08/04/2020

Amount: \$142,085

Role: PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 07/01/18-06/30/20

Amount: \$159,284

Role: PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 07/2018-04/2019

Amount: \$86,819

Role: PI

Source: Eli Lilly

Title: Development and qualification of an expanded Diabetes model

Time period: 7/6/2018-7/5/2020

Amount: \$120,488

Role: PI

Source: Biomedical Advanced Res & Development Author Title: "Microdialysis study of Lipo680 in the animal model"

Time period: 07/2019-06/2020

Amount: \$80,215

Source: Biomedical Advanced Res & Development Author Title: "Microdialysis study of Lipo680 in the animal model"

Time period: 07/2019-06/2020

Amount: \$301,213

Role: PI

Source: Hoffmann-La Roche Ltd.

Title: "Improved Pediatric Dose Selection through Physiologically Based Pharmacokinetic

Modeling"

Time period: 01/2017-01/2019

Amount: \$278,331

Role: PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 07/2016-12/2018

Amount: \$246,217

Role: PI

Source: GlaxoSmithKline

Title: Research fellowship program for pharmacokinetics pharmacodynamics

Time period: 07/01/18-06/30/19

Amount: \$80,215

Role: PI

Source: Translation Research Institute for Metabolism and Diabetes Title: Translational Research Institute for Metabolism and Diab

Time period: 10/2015-10/2018

Amount: \$32,747

Role: PI

Source: Janssen Research and Development

Title: "In Silico Clinical Trial Qualification of Successful Biomarker Measurements Related

to Monoclonal Antibody Drug Development" Time period: 04/30/2015 - 02/28/2017

Amount: \$197,428

Role: PI

Source: AstraZeneca

Title: "Systems Pharmacology Based Modeling as a Platform"

Time period: 04/2015-10/2017

Amount: \$247,523

Role: PI

Source: Pinnacle Laboratory Services & Florida High Tech Corridor (FHTC) Title: "Pharmacogenomics of Oxycodone in Chronic Pain Management"

Time period: 04/01/2015 - 03/31/2017

Amount: \$150,000

Role: co-PI

Source: Eli Lilly and Company

Title: "In Silico Modeling of Biomarkers and Surrogate Endpoints of Diabetes III"

Time period: 04/16/2014 - 12/31/2016

Amount: \$98,376 Role: PI (10%)

Source: GlaxoSmithKline LLC

Title: "Research Fellowship Program for Pharmacokinetics Pharmacodynamics"

Time Period: 11/01/2015 - 10/31/2016

Amount: \$ 151,663

Role: PI

Source: Bayer Business and Technology Services LLC

Title: "Establishment of a Pediatric PBPK Model for Large Molecules in PK-Sim®"

Time Period: 06/15/2015 - 08/30/2016

Amount: \$48,000

Role: PI

Source: Pfizer II

Time period: 12/2013 - 12/2015Post-doctoral fellow support

Amount: \$120,000

Role: co-PI

Source: Daiichi Sankyo Post-doctoral fellow support

Time period: 04/09/2013 - 04/09/2016

Amount: \$150,000

Role: co-PI

Source: Eli Lilly and Company

Title: "In Silico Modeling of Biomarkers and Surrogate Endpoints of Diabetes III"

Time period: 04/16/2014 - 04/16/2015

Amount: \$87,000 Role: PI (10%)

Source: Sprout Pharmaceuticals, Inc.

Title: "Determination of the Relationship between Flibanserin Exposure and Adverse Drug

Events"

Time Period: 03/16/2015 - 06/30/2015

Amount: \$25,000

Role: PI

Source: Aegerion

Title: "Population Pharmacokinetic Assessment of Lomitapide exposure in Subjects Following Administration of Development and Commercial Lomitapide Capsules (BMS-

CV145-003, AEGR-733-005, 733-015, 733-017, 733-018, 733-023)"

Time period: 01/01/2014 - 12/31/2014

Amount: \$23,116.50 (5%)

Source: Simulations Plus, Inc.

Title: "Parameterization and qualification of physiologically based pharmacokinetic models

in children for implementation in GastroPlus"

Time period: 09/01/2013 - 08/31/2014

Amount: \$58,750 Role: PI (5%)

Source: Amgen

Title: "Modeling of Antibody-Based Therapeutic Proteins in Pediatrics"

Project Date: 6/22/2012 – 6/2014

Amount: \$120,000

Role: PI

Source: Eli Lilly and Company

Title: "In Silico Modeling of Biomarkers and Surrogate Endpoints of Diabetes"

Time period: 04/16/2013 - 04/15/2014

Amount: \$40,000

Role: PI

Source: Bayer Business and Technology Services

Title: "Pharmacokinetic modeling of oral drug absorption in preterm neonates"

Time period: 08/01/2013 - 12/31/2013

Amount: \$26,000

Role: PI

Source: Aegerion

Title: "Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulation of

Lomitapide Exposure with Co-Administration of CYP3A4 Inhibitors"

Time period: 09/17/2012 - 11/30/2012

Amount: \$62,500

Role: PI

Source: Aegerion

Title: "Lomitapide Pediatric Trial Dose Selections Using Two Approaches: Allometric

Scaling and Physiologically-Based Pharmacokinetic (PBPK) Modeling"

Time period: 12/01/2012 - 06/30/2013

Amount: \$15,000

Role: PI

Source: Aegerion

Title: "Evaluation of race effects on the systemic exposure of lomitapide"

Time period: 08/14/2013 - 12/31/2013

Amount: \$18,750

Role: PI

Agency: Pfizer I

Post-doctoral fellow support Project Date: 12/2011 – 12/2013

Amount: \$120,000

Completed Research Support – Other:

Source: University of Florida Center for Research to Investigate Substance use and Pain (UF-CRISP)

Title: "Etiology and Mechanisms of Opioid Overdoses – A Pilot Study of Interactions of Pain and Substance Use in a New Era of Reduced Access to Prescription Opioids and Increasing Overdose Rates"

Time period: 06/2019 - 05/2020

Amount: \$72,558

Role: co-I

Source: CTSI Junior Faculty Pilot Program Award

Title: "Personalizing antiplatelet therapy: development of a CYP2C19 genotype-directed

dosing algorithm for clopidogrel"

Time period: 01/01/2013 - 12/31/2013

Amount: \$20,000

Role: PI

Source: Rio Grande do Sul State Support to Research Agency

Title: "PBPK modeling as a translational tool to investigate oral antidiabetics"

Time period: 07/01/2014 – 12/31/2015 Amount: R\$ 90,000 (USD \$40,266)

Role: co-PI

Professional Courses and Trainings:

2017	American Association of Colleges of Pharmacy (AACP) Catalyst:
	Accelerating Research Leadership Program, USA
2017	Department Chairs Workshop, Howey-in-the-Hills, USA, June 4-7, 2017
2016	Managing Emotions under Pressure, Orlando, USA, October 18, 2016
2016	Dealing with Difficult People, Orlando, USA, March 31, 2016
2015	Implementing Transformational Philanthropy for Academic Leaders,
	Gainesville, USA, August 20, 2015
2014	Population analysis and modeling with Monolix and Mlxtran, Alicante,
	Spain, June 9-10, 2014
2014	Training Grant Workshop, Gainesville, FL, USA, March 31, 2014
2014	Introductory GastroPlus TM Simulation and Modeling Workshop, Princeton,
	NJ, USA, March 10-12, 2014
2014	Hands-on SimBiology Workshop for Pharmacokinetic and Mechanistic
	Modeling, Lake Nona (Orlando), USA, February 25-26, 2014
2014	MATLAB Technical Seminars at University of Florida, Lake Nona
	(Orlando), USA, February 24, 2014
2013	Mechanistic Modeling of Biologics, Fort Lauderdale, USA, May 12, 2013
2013	Pharmacokinetics & Pharmacodynamics of Protein Therapeutics – Concepts
	and Hands-on Modeling and Simulation, Memphis, USA, April 15-19, 2013
2013	Grantsmanship Writing Workshop, Gainesville, USA, February 4, 2013
2012	Teaching Excellence Workshop, Gainesville, USA, April 6, 2012
2010	Quality by Design, TI PHARMA, Leiden, The Netherlands, November 10,
	2010
2010	PKPD modeling of Continuous and Categorical data in NONMEM 7,
	Uppsala University, Berlin, Germany, June 6-8, 2010

2010	Pharmacokinetic and Pharmacodynamic Modeling and Simulation in R ,
	Leiden/Amsterdam Center for Drug Research, Leiden, The Netherlands,
	March 18, 2010
2010	Time-to-Event course, Leiden/Amsterdam Center for Drug Research, Leiden,
	The Netherlands, February 3, 2010
2009	Intellectual Property, TI PHARMA, Utrecht, The Netherlands, November
	25, 2009
2009	New and Advanced Features of NONMEM 7 workshop, GSK, Greenford,
	UK, October 22-23, 2009
2009	Drug Discovery Simulation, TI PHARMA, Sint-Michielsgestel, The
	Netherlands, September 14-18, 2009
2009	Binary and categorical data modeling, analysis and simulation using
	NONMEM, TI PHARMA, Leiden, The Netherlands, June 3-4, 2009
2009	NONMEM workshop, EMF-consulting, Aix en Provence, France, May 4-8,
	2009
2009	Introduction to Bayesian analysis using WinBUGS, MRC Biostatistics Unit,
	Cambridge, UK, February 25-26, 2009

List of Publications:

- 1. Subhani S, Lukacova V, Kim C, Rodriguez-Vera L, Muniz P, Rodriguez M, Cristofoletti R, Van Os S, Suarez E, **Schmidt S**, Vozmediano V. Leveraging physiologically based modeling to provide insight on the absorption of paliperidone extended release formulation under fed and fasted conditions. *MDPI*. 2023. 15(2): 629.
- 2. Pressly MA, Peletier LA, Zheng S, Sharma VD, Lien YT, Wang W, Zhou H, **Schmidt S.** The quest for balance between capturing data and model complexity: a quantitative clinical pharmacology approach applied to monoclonal antibodies. *CPT: Pharmacometrics & Systems Pharmacology*. 2023.
- 3. Sarayani A, Winterstein A, Cristofoletti R, Vozmediano V, **Schmidt S**, Brown J. Real-World Effect of a Potential Drug-Drug Interaction Between Topiramate and Oral Contraceptives on Unintended Pregnancy Outcomes. *Elsevier*. 2023.
- 4. Abdelmageed M, de Moraes N, **Schmidt S**, Vozmediano V, Rochani A, Kraft W, Boelig RC. Application of population modeling to characterize the effect of pregnancy on aspirin pharmacokinetics. *Elsevier*. 2023. 228(1): S180.
- 5. de-Lima Moreira F, de-Barros Tarozzo MM, Balthazar Nardotto GH, Saraiva Gonçalves JC, **Schmidt S**, Valadares de-Moraes N. Assessing the contribution of UGT isoforms on raltegravir drug disposition through PBPK modeling. *European Journal of Pharmaceutical Sciences*. 2023.
- 6. Caballero U, Eraso E, Quindos G, Vozmediano V, **Schmidt S**, Jauregizar N. PK/PD modelling and simulation of the in vitro activity of the combinations of isavuconazole with echinocandins against Candida auris. *CPT: Pharmacometrics & Systems Pharmacology*. 2023.
- 7. Michelet R, Aullin L, Borghart J, Dalla Costa T, Denti P, Ibara M, Ma G, Meibohm B, Oillai G, Henning S, Kloft C, **Schmidt S.** Barriers to global pharmacometrics; educational challenges and opportunities across the globe. *CPT:Pharmacometrics & Systems Pharmacology*. 2023.
- 8. Guinn D, Pressly MA, Liu Z, Ceresa C, Samuels S, Wang Y, Madabushi R 1, **Schmidt S**, Fletcher EP. Exploring the knowledge gaps in infant drug exposure from human milk: A clinical pharmacology perspective. *Journal of Clinical Pharmacology*. 2022. 63(3): 273-276.

- 9. Vouri CM, Morris EJ, Jiang X, Hofer A, **Schmidt S,** Pepine C, Winterstein AG, Smith SM. Evaluation of a Beta-Blocker–Edema–Loop Diuretic Prescribing Cascade: A Prescription Sequence Symmetry Analysis. *American Journal of Hypertension*. 2022. 35(7):601-609.
- 10. Yamada W, Kim S, Almoslem M, Kim S, Myrick J, Nole J, Duncanson B, Louie A, Peloquin CA, **Schmidt S**, Drusano GL, Neely M. Combination therapy to kill Mycobacterium tuberculosis in its non-replicating persister phenotype. *Antimicrobial Agents and Chemotherapy*. 2022. 66(10): e00695-22.
- 11. Morales JF, Muse R, Podichetty J, Burton J, David S, Martin F, Atkinson MA, Haller MJ, Campbell-Thompson M, Romero K, O'doherty I, **Schmidt S**, Kim S. A Model-Based Clinical Trial Simulation Tool to Optimize Clinical Trial Designs for Type 1 Diabetes Prevention Studies. *Diabetes*. 2022.71(Supplement_1):63-OR
- 12. Cicali B, **Schmidt S**, Zeitlinger M, Brown JD. Macrolide Treatment Failure due to Drug–Drug Interactions: Real-World Evidence to Evaluate a Pharmacological Hypothesis. *Pharmaceutics*. 2022. 14(4):704.
- 13. Vouri SM, Morris EJ, Jiang X, Hofer A, **Schmidt S**, Pepine C, Winterstein AG, Smith SM. Evaluation of a Beta-Blocker–Edema–Loop Diuretic Prescribing Cascade: A Prescription Sequence Symmetry Analysis. *American Journal of Hypertension*. 2022. 35(7):601-609.
- 14. Subhani S, Kim C, Muniz P, Rodriguez M, Van Os S, Suarez E, Cristofoletti R, **Schmidt S**, Vozmediano V. Application of Physiologically Based Absorption and Pharmacokinetic Modeling in the development process of oral modified release generic products. *European Journal of Pharmaceutics and Biopharmaceutics*. 2022. 176:87-94
- 15. Cicali B, Da Silva L, Sarayani A, Lingineni K, Pressly M, Kim S, Wendl T, Hoechel J, Vozmediano V, Winterstein AG, Brown JD, **Schmidt S**, Cristofoletti R. Development of a Translational Exposure-Bracketing Approach to Streamline the Development of Hormonal Contraceptive Drug Products. *Clinical Pharmacology & Therapeutics*. 2022. doi.org/10.1002/cpt.2690.
- 16. Soldatos TG, Kim S, **Schmidt S**, Lesko LJ, Jackson DB. Advancing drug safety science by integrating molecular knowledge with post-marketing adverse event reports. *CPT: Pharmacometrics & Systems Pharmacology.* 2022. 11(5):540-555.
- 17. Lingineni K, Chaturvedula A, Cicali B, Cristofoletti R, Wendl T, Hoechel J, Brown JD, Vozmediano V, **Schmidt S**. Determining the Exposure Threshold for Levonorgestrel Efficacy Using an Integrated Model Based Meta-Analysis (MBMA) Approach. Clin Pharmacol Ther. 2022. 111(2):509-518.
- 18. Kim S, Louie A, Drusano GL, Almoslem M, Kim S, Myrick J, Nole J, Duncanson B, Peloquin CA, Scanga CA, Yamada W, Neely M, **Schmidt S**. Evaluating the effect of clofazimine against Mycobacterium tuberculosis when given alone or in combination with pretomanid, bedaquiline or linezolid. Int J Antimicrob Agents. 2022. 59(2):106509.
- Lingineni K, Aggarwal V, Morales JF, Conrado DJ, Corey D, Vong C, Burton J, Larkindale J, Romero K, Schmidt S, Kim S. Development of a Model-based Clinical Trial Simulation Platform to Optimize the Design of Clinical Trials for Duchenne Muscular Dystrophy. Pharmacometrics & Systems Pharmacology. 2022. 11(3):318-332.
- 20. Mosley SA, Kim S, El Rouby N, Lingineni K, Vozmediano Esteban V, Gong Y, Chen Y, Estores D, Feng K, Kim H, Kinjo M, Langaee T, Li Z, Schmidt SOF, Johnson JA, Frye RF, Fang L, Zhao L, Binkley PF, **Schmidt S**, Cavallari LH. A Randomized, Cross-over Trial of Metoprolol Succinate Formulations to Evaluate PK and PD Endpoints for Therapeutic Equivalence. Clinical and Translational Science. 2022.

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Books:

- 1. Derendorf H and **Schmidt S** (ed.) *Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications*. Fifth Edition. Wolters Kluwer, Alphen aan den Rijn, Netherlands, 2019, 1-939.
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Book Chapters:

- 1. Ait-Oudhia S, Lien YT, Basu S, Lesko LJ, **Schmidt S**. Quantitative Pharmacology and Individualized Therapy Strategies in Development of Therapeutic Proteins for Immune-Mediated Inflammatory Diseases in Application of Pharmacometrics and Systems Pharmacology to Current and Emerging Biologics in Inflammatory Bowel Disease. John Wiley & Sons, Inc., 2018.
- 2. Berkhout J, Madrasi K, Li F, Li L, Kim MJ, Wang Y, Samant S, Post T, **Schmidt S**. Academic, industry and regulatory application of quantitative pharmacometric approaches in osteoporosis disease and treatment characterization. accepted for publication in *Pharmacometrics*, 2nd edition. John Wiley & Sons, Inc. Hoboken, New Jersey.
- 3. Schlender JF, Golden AG, Samant TS, Lagishetty CV, **Schmidt S**. The personalization of Drug Therapy for Elderly Patients. Accepted In: Stegemann S (ed.) *Developing drugs for the older patient*. Springer, NY, 2016: 589-611.
- 4. Gaitonde P, Miller S, Trame MN, **Schmidt S**. Quantitative Approaches in Translational Research: An Overview. In: Krentz A, Heinemann L, Hompesch (ed). *Translational research methods for diabetes, obesity, and cardiometabolic drug development*, Springer, New York, NY, 2015: 243-264.
- 5. Garhyan P, Topp BG, Chien JY, Sinha VP, Danhof M, **Schmidt S**. Drug-disease model-based development of therapeutic agents for treatment of diabetes. In: **Schmidt S** and Derendorf H (ed.) *Applied pharmacometrics*. Springer, New York, NY, 2014: 139-159.
- 6. **Schmidt S**, Post TM, Boroujerdi M, van Kesteren C, Ploeger BA, Della Pasqua OE, Danhof M. Disease progression analysis: towards mechanism-based models. In: Kimko H and Peck C (ed). *Clinical trial simulations applications and trends*. Springer, New York, NY; 2010: 437-60.

List of Oral Presentations:

- **1. Schmidt S.** Seminar. Challenges and Opportunities for Translational Research: The Power of Data Integration. Department of Mathematics, University of Florida. Orlando, FL. February 23, 2023.
- **2. Schmidt S.,** Gupta C, Vozmediano V. Poster. QSP approach for α-synuclein pathology in Parkinson's Disease. 36th UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 6, 2023.

- **3. Schmidt S.** Poster. Optimizing the Safety Profile of Ropivacaine Administered via Erector Spinae Plane Blocks. 36th UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 6, 2023.
- **4. Schmidt S.** Poster. Dosing optimization for voriconazole in critically ill patients diagnosed with aspergillosis. 36th UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 6, 2023.
- **5. Schmidt S.** Poster. Integrating Operational Model of Agonist in Model Based Meta-Analysis for Assessing Inhibition of Ovulation Rate by Different Progestins. 36th UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 6, 2023.
- **6. Schmidt S.** Poster. Leveraging PBPK DDI application between Phenytoin and Omeprazole in special populations. 36th UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 6, 2023.
- 7. Schmidt S. Poster. A Physiological Based Pharmacokinetic Modeling Approach to Interpret Nonlinear Behavior of Carbamazepine and its DDI Potential on CYP3A4 and CYP2C9. 36th UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 6, 2023.
- **8. Schmidt S.** Seminar. Empowering Translational Research Through Data Integration. University of Florida, Department of Medicine, Division of Pulmonary, Critical Care, and Sleep Medicine, Laboratory for Systems Medicine. Gainesville, FL. January 31, 2023.
- **9. Schmidt S.** Seminar. Empowering Translational Research Through Data Integration. Universitaet Bonn. Virtual. December 5, 2022.
- **10. Schmidt S.** Seminar. The Next Frontier in Quantitative Clinical Pharmacology: A Personal Perspective. Department of Environmental and Global Health, University of Florida. Virtual. November 2, 2022.
- **11. Schmidt S.** Seminar. A Combined Pharmacometrics and Real-World Data Analysis Approach to Understanding Drug-Drug Interactions for Hormonal Contraceptives. Bayer AG, Berlin Germany. October 19, 2022.
- **12. Schmidt S.** Lecture. Model-Informed Drug Development: Application to Post-Menopausal Osteoporosis. Peking University Third Hospital. Virtual. October 12, 2022.
- **13. Schmidt S.** Seminar. Empowering Translational Research Through Data Integration. Genentech, San Francisco. October 4, 2022.
- **14. Schmidt S.** Symposium. Pharmacometrics, PBPK, QSP, What's Next? Uppsala University, Uppsala, Sweden. September 14, 2022.
- **15. Schmidt S.** Seminar. Empowering Translational Research Through Data Integration. Freie Universitaet Berlin. Berlin, Germany. September 7, 2022.
- **16. Schmidt S.** Lecture. Model-Informed Drug Development: Concepts and Applications. Freie Universitaet Berlin. Berlin, Germany. August 5, 2022.
- **17. Schmidt S.** Seminar. When An Opportunity Arises, Don't Pull Down The Shutter. Freie Universitaet Berlin. Berlin, Germany. July 20, 2022.
- **18. Schmidt S.** Workshop. Understanding Contraceptive DDIs through Combining Pharmacology Models and RWDA. March DDI Workshop. Marbach, Germany. May 30, 2022.
- **19. Schmidt S.** Workshop. PK-Sim/Systems Pharmacology Overview. Bill & Melinda Gates Foundation. Seattle. May 16, 2022.
- **20. Schmidt S.** Symposium. Setting the Scene Why, How and Hurdles? Arbeitsgemeinschaft für Angewandte Humanpharmakologie e.V. Saarbruecken, Germany. April 29, 2022.
- **21. Schmidt S.** Symposium. How much complexity do we need? Quantitative Systems Pharmacology Conference 2022. Leiden, The Netherlands. April 20, 2022.

- **22. Schmidt S.,** Cicali B, Cristofoletti R, Pressly M, Kim S, Wendl T, Vozmediano V. Poster. PBPK-based Exposure Bracketing of Subcutaneous Levonorgestrel for Evaluating Drug-Drug Interactions. American Conference on Pharmacometrics. Virtual. November 11, 2021.
- **23. Schmidt S.,** Tatipalli M, Siripuram VK, Long T, Shuster D, Bernstein G, Martineau P, Cook KA, Cristofoletti R, Vozmediano V. Poster. A model informed dose extrapolation of a new spironolactone liquid formulation. American Conference on Pharmacometrics. Virtual. October 24, 2021.
- **24. Schmidt S.,** Morales JF, Lingineni K, Thomas M, Lang P, Podichetty J, Burton J, David S, Dunne J, Atkinson MA, Haller MJ, Romero K, O'Doherty I, Kim S. Modeling Longitudinal Glucose Dynamics to Inform Type 1 Diabetes Prevention Clinical Trial Studies. American Conference on Pharmacometrics. Virtual. October 4, 2021.
- **25. Schmidt S.,** Morales JF, Lingineni K, Thomas M, Lang P, Podichetty J, Burton J, David S, Dunne J, Atkinson MA, Haller MJ, Romero K, O'Doherty I, Kim S. Quantifying heterogeneity contributing to risk of type 1 diabetes diagnosis. University of Florida College of Pharmacy Research Showcase 34th held virtually. April 13, 2021.
- **26. Schmidt S.,** Morales JF. Quantifying heterogeneity contributing to risk of type 1 diabetes. University of Florida, Center for Pharmacometrics & Systems Pharmacology, Lake Nona Leadership Council Virtual Meeting. April 7, 2021.
- **27. Schmidt S.** Poster. A Systems based model to understand progression of Parkinson's disease. ASCPT virtual meeting. March 12, 2021.
- **28. Schmidt S.** Poster. CYP2D6-Mediated Drug-Drug Interaction (DDI) between Tramadol, O-Desmethyltramadol and Quinidine via Allosteric Inhibition using Physiologically-based Pharmacokinetic (PBPK) Modeling and Simulation. ASCPT Annual Virtual Meeting. March 8, 2021.
- **29. Schmidt S.** Poster. Physiologically-based Pharmacokinetic (PBPK) Modeling to Assess CYP2D6-Mediated Drug-Drug Interaction (DDI) between Tramadol and Metoprolol due to Competitive Inhibition. ASCPT Annual Virtual Meeting. March 8, 2021.
- **30. Schmidt S.** Speech. CYP2D6-Mediated Drug-Drug Interaction (DDI) between Tramadol, O-Desmethyltramadol and Quinidine via Allosteric Inhibition using Physiologically-based Pharmacokinetic (PBPK) Modeling and Simulation. ASCPT DUO Community Meeting-oral presentation, virtual. February 9, 2021.
- **31. Schmidt S.** Symposium. Bridging the Gap Between in Vitro, Animal, and Human via Modeling and Simulation. American Association of Pharmaceutical Scientists. Virtual. Oct 29, 2020.
- **32. Schmidt S.** Keynote. Model-Informed Drug Development: Challenges and Opportunities. Gulf Coast Consortium. Virtual. Oct 22, 2020.
- **33. Schmidt S.**, Long T, Cristofoletti R, Turgeon J, Michaud V, Galiano L, Farhan N. Poster. Physiologically-based Pharmacokinetic (PBPK) Modeling to Assess the Impact of Cytochrome P450 2D6 Activity on Tramadol and O-Desmethyltramadol Exposure. The 11th American Conference on Pharmacometrics. Virtual. October 4, 2020.
- **34. Schmidt S.,** Lingineni K, Morales JF, Conrado DJ, Vong C, Hanan N, Corey D, Burton J, Larkindale J, Romero K, Kim S. Poster. Towards Achieving Regulatory Endorsement of a Disease Progression Model-Based Clinical Trial Simulation Tool for Duchenne Muscular Dystrophy Models of Progression of Timed Motor Function Tests. The 11th American Conference on Pharmacometrics. Virtual. October 4, 2020

- **35. Schmidt S.,** Vozmediano V, Cicali B, Lingineni K, Cristofoletti R, Wendl T, Hoechel J, Wiesinger H, Wiesinger H. Poster. Development and Verification of a Levonorgestrel PBPK Model for Enzyme-Mediated Drug Interaction Studies. The 11th American Conference on Pharmacometrics. Virtual. October 4, 2020
- **36.** Schmidt S., Cicali B, Cristofoletti R, Wendl T, Lingineni K, Hoechel J, Wiesinger H, Vozmediano V. Poster. Expansion of a Levonorgestrel Physiologically-Based Pharmacokinetic Model (PBPK) to Evaluate the Pharmacokinetic/Pharmacodynamic (PKPD) Effects of SHBG Protein Binding. The 7th Pharmaceutical Sciences World Congres. Virtual. October 4, 2020
- **37. Schmidt S.,** Larkindale J, Kim S, Lingineni K, Morales JF, Corey D, Burton J, Aggarwal V, Romero K. Poster. Development of A Regulatory-Ready Clinical Trial Simulation Tool for Duchenne Muscular Dystrophy. World Muscle Society Virtual Congress. September 28, 2020
- **38. Schmidt S.,** Vandenborne K, Kim S, Willcocks RJ, Morales JF, Lingineni K, Barnard AM, Daniels MJ, Triplett WT, Larkindale J, Walter GA, Rooney WD. Poster. Development of Clinical Trial Simulation Tools for Duchenne Muscular Dystrophy using MR Imaging Biomarkers. World Muscle Society Virtual Congress. September 28, 2020
- **39. Schmidt S.** Symposium. Pharmacokinetics/Pharmacodynamics of Traditional Antimicrobial Drugs: Lessons to Be Learned for Bacteriophages. American College of Clinical Pharmacology. Virtual. Sep 23, 2020.
- **40. Schmidt S.** Symposium. Integration Pharmacometrics and Epidemiological Approaches: Why, What and How. American College of Clinical Pharmacology. Virtual. Sep 22, 2020.
- **41. Schmidt S.,** Lingineni K, Cicali B, Chaturvedula A, Cristofoletti R, Wendl T, Hoechel J, Wiesinger H, Vozmediano V, Zhao P. Poster. 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. Virtual. September 11, 2020.
- **42. Schmidt S. Speech.** Scientific Methods: A Personal Perspective. Innovation Montessori Ocoee. Winter Garden, FL, USA. Sep 4, 2020.
- **43. Schmidt S.,** Larkindale J, Kim S, Lingineni K, Morales JF, Corey D, Burton J, Aggarwal V, Romero K. Poster. The Duchenne Regulatory Science Consortium: Solutions to Bottlenecks That Slow Drug Development. Poster. Parent Project Muscular Dystrophy 2020 Virtual Annual Conference. July 22, 2022.
- **44. Schmidt S.,** Cicali B, Cristofoletti R, Wendl T, Lingineni K, Hoechel J, Wiesinger H, Vozmediano V. Poster. Expansion of a Levonorgestrel Physiologically-Based Pharmacokinetic Model (PBPK) to Evaluate the Pharmacokinetic/Pharmacodynamic (PKPD) Effects of SHBG Protein Binding. 6th Pharmaceutical Sciences World Congress. Montreal, Canada, (Meeting cancelled due to COVID-19 pandemic). May 22, 2020.
- **45. Schmidt S. Seminar.** Mathematical Modeling Experimental Considerations. Global Alliance for TB Drug Development. New York. May 5, 2020.
- **46. Schmidt S.** "A Model-and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution in Breakout Session 4: Data Analysis and Model-Based Bioequivalence during the FY 2020 Generic Drug Regulatory Science Initiatives Public Workshop" presented at an U.S. Food and Drug Administration, Office of Generic Drugs workshop. Webinar presented online due to COVID19. May 04, 2020.

- **47. Schmidt S.** Lecture. The Role of Model-Informed Drug Discovery and Development in Enhancing Public Health: State of the Art, Innovation or Disruption?. U.S. Food and Drug Administration. Silver Spring, MD. Mar 4, 2020.
- **48. Schmidt S.,** Lingineni K, Conrado DJ, Corey D, Hill H, Larkindale L, Romero K, Kim S. Poster. Towards Achieving Regulatory Endorsement of a Disease Progression Model-based Clinical Trial Simulation Tool for Duchenne Muscular Dystrophy—Model of Progression of Forced Vital Capacity. American Society of Clinical Pharmacology & Therapeutics. Canceled due to COVID-19, Houston, TX. March 3, 2020.
- **49. Schmidt S.,** Lingineni K, Turgeon J, Michaud V. Poster. PBPK modeling of Clopidogrel and its active metabolite when administered alone or during concomitant administration with Esomeprazole considering time-dependent inhibition. American Society of Clinical Pharmacology & Therapeutics. Canceled due to COVID-19, Houston, TX. March 3, 2020.
- **50. Schmidt S.,** Kim S, Willcocks RJ, Morales JF, Daniels MJ, Triplett WT, Larkindale J, Walter GA, Rooney WD. Poster. Development of Clinical Trial Simulation Tools for Duchenne Muscular Dystrophy using MR Imaging Biomarkers. 18th International Conference on Duchenne and Becker Muscular Dystrophy held in Rome, Italy. February 28, 2020.
- **51. Schmidt S.**, Lien Y, Lam E, Vozmediano V. Speech. Optimizing ketamine dosing regimen in critically ill patients on ECMO therapy using a population pharmacokinetic approach. 33rd UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 10, 2020.
- **52. Schmidt S.,** Lingineni K, Farhan N, Kim S, Gordon L, Penzak S, Hadigan C, George JM. Poster. Quantitative benefit-risk assessment of P-gp mediated drug-drug interactions of dabigatran co-administered with pharmacokinetic enhancers in patients with renal impairment. 33rd UF College of Pharmacy Annual Research Showcase, Gainesville, FL. February 10, 2020.
- **53. Schmidt S.** "Combining Forces in Drug Development and Regulatory Decision Making: The Time Has Come" presented at ANVISA, Brasilia, Brazil, November 4, 2019.
- **54.** Brown JD, **Schmidt S.** "Combining Real-World Data Analysis and Pharmacometrics to Assess the Value of Generic Drugs: Retrospective and Prospective Examples in Cardiology Therapeutic Areas" presented at the Academy of Managed Care Pharmacy Nexus 2019, National Harbor, MD. October 29, 2019 to November 01, 2019.
- **55. Schmidt S.** "The Big Black Box The Review and Revision Process of your Manuscript Explained and How it Helps you in Writing your Manuscript" presented at the Annual Meeting of the American College of Clinical Pharmacology. Chicago, September 15, 2019.
- **56. Schmidt S.** "Ontogeny and Phase II Metabolism of Drugs" presented at an U.S. Food and Drug Administration workshop. Bethesda. May 16, 2019.
- 57. **Schmidt S.** "Pharmacometrics, PBPK, QSP What's Next?" presented at Rosa Webinar Series, March 14, 2019.
- 58. **Schmidt S**, Cicali B, Kirouac D. Poster. Developing a QSP Model Repository for CPT-PSP: Challenges and Future Opportunities. The American Society for Clinical Pharmacology and Therapeutics. Washington, DC. Mar 14, 2019 Mar 14, 2019.
- **59. Schmidt S,** Badee J, Qiu N, Parrott N, Fowler S. "Optimization of experimental conditions of automated glucuronidation assays in human liver microsomes using a cocktail approach and high-performance liquid chromatography-tandem mass spectrometry" presented at 2019 Hot Topics in the Lab, one-day Drug Metabolism Discussion Group meeting. March 07, 2019. Cambridge, UK.

- **60. Schmidt S,** Cicali B, Collin AJ, Vega A, Raghunandan S. Poster. Bridging the Gap of Macrolide Resistance Mechanisms and Clinical Application through PK/PD Modeling and Pharmacovigilance Analyses. University of Florida COP. Gainesville, FL. Feb 11, 2019 Feb 11, 2019.
- **61. Schmidt S,** Farhan N, Basu S, Kim S, Lingineni K, Vozmediano V, Ait-Oudhia S, Fang L, Zhao L, Lesko L. Poster. Application of Physiologically-Based Oral Absorption & Pharmacokinetic Modeling to Investigate Formulation Factors Influencing the Pharmacokinetics of Novel Oral Anticoagulants. University of Florida COP. Gainesville, FL. Feb 11, 2019 Feb 11, 2019.
- **62. Schmidt S,** Lien YT, Madrasi K, Samant S, Kim M, Li F, Li L. Poster. Quantification of postmenopausal osteoporosis population: An system pharmacology approach using bisphosphonates. University of Florida COP. Gainesville, FL. Feb 11, 2019 Feb 11, 2019.
- **63. Schmidt S,** Jiang S, Farhan N, Vozmediano V. Poster. Population parent-metabolite pharmacokinetic modeling of acetaminophen protein adducts, a biomarker of acetaminophen induced hepatotoxicity. University of Florida. Gainesville, FL. Feb 11, 2019 Feb 11, 2019.
- 64. **Schmidt S.** "MID3: An Opportunity for Innovation and Collaboration" presented at the Iberoamerican Pharmacometrics Network meeting. Guadalajara. November 7, 2018.
- 65. **Schmidt S**, Jiang S, Farhan N, Vozmediano V. Poster. Updated physiologically based pharmacokinetic (PBPK) model for acetaminophen metabolism with an emphasis on phase I metabolism. American Association of Pharmaceutical Scientists. Washington, DC. Nov 5, 2018 Nov 5, 2018.
- 66. **Schmidt S**, Cicali B, Collin AJ, Vega A, Raghunandan S. Poster. Bridging the Gap of Macrolide Resistance Mechanisms and Clinical Application through PK/PD Modeling and Pharmacovigilance Analyses. American Conference on Pharmacometrics. San Diego, CA. Oct 10, 2018 Oct 10, 2018.
- 67. **Schmidt S,** Farhan N, Basu S, Kim S, Lingineni K, Vozmediano V, Ait-Oudhia S, Fang L, Lesko L. Poster. Application of Physiologically-Based Oral Absorption & Pharmacokinetic Modeling to Investigate Formulation Factors Influencing the Pharmacokinetics of Novel Oral Anticoagulants. American Conference on Pharmacometrics. San Diego, CA. Oct 10, 2018 Oct 10, 2018.
- 68. **Schmidt S,** Jiang S, Jin JY, Deng R. Poster. Practical identifiability analysis and pharmacokinetic sampling optimization for monoclonal antibodies with nonlinear pharmacokinetics in first-in-human studies. American Conference on Pharmacometrics. San Diego, CA. Oct 10, 2018 Oct 10, 2018.
- 69. **Schmidt S**, Hajihosseini A, Maleki F, Lien YT, Vozmediano V. Poster. The Effect of Monoclonal Antibodies Pharmacokinetics on the Tumor Cells Dynamics: A Bifurcation Analysis. American Conference on Pharmacometrics. San Diego, CA. Oct 8, 2018 Oct 8, 2018.
- 70. **Schmidt S**, Lien YT, Madrasi K, Samant S, Kim M, Li F, Li L. Poster. Quantification of postmenopausal osteoporosis population: An system pharmacology approach using bisphosphonates. Globalization of Pharmaceutics Education Network. Singapore, Singapore. Sep 27, 2018 Sep 28, 2018.
- 71. **Schmidt S,** Jiang S, Vozmediano V, James L, Rahman S. Poster. Population parent-metabolite pharmacokinetic modeling of acetaminophen protein adducts, a biomarker of acetaminophen induced hepatotoxicity. American College of Clinical Pharmacology. Bethesda, MD. Sep 23, 2018 Sep 23, 2018.
- 72. **Schmidt S**, Badee J, Qiu N, Collier CA, Takahashi RH, Parrott N, Fowler S. Poster. Characterization of the ontogeny of hepatic UDP-glucuronosyltransferase enzymes

- based on glucuronidation activity measured in human liver microsomes. American College of Clinical Pharmacology. Bethesda, MD. Sep 22, 2018 Sep 25, 2018.
- 73. **Schmidt S**, Badee J, Qiu N, Parrott N, Fowler S. Poster. Optimization of experimental conditions of automated glucuronidation assays in human liver microsomes using a cocktail approach and ultra-high performance liquid chromatography-tandem mass spectrometry. Gordon Research Conference. Holderness, NH. Jul 8, 2018 Jul 13, 2018.
- 74. **Schmidt S.** "A model- and systems-based approach to efficacy and safety questions related to generic substitution" presented at an U.S. Food and Drug Administration workshop. Silver Spring. May 24, 2018,
- 75. **Schmidt S.** "Integrating human-on-a-chip and clinical endpoints: a physiologically-based modeling approach" presented at Takeda. Boston. March 15, 2018.
- 76. **Schmidt S.** "Pharmacometric models of osteoporosis" presented at Keio University, Tokyo. February 17, 2018.
- 77. **Schmidt S.** "Pharmacometrics and Systems Pharmacology What's in it for me?" presented at Sanofi. Bridgewater. November 13, 2017.
- 78. **Schmidt S.** "How informative and drug-drug interactions of gene-drug interactions?" presented as an American Society for Clinical Pharmacology and Therapeutics (ASCPT) webinar. Orlando. November 6, 2017.
- 79. **Schmidt S.** "A model- and systems-based approach to efficacy and safety questions related to generic substitution" presented at an U.S. Food and Drug Administration, Office of Generic Drugs workshop. Silver Spring. October 2, 2017.
- 80. **Schmidt S.** Symposium. Model-based Assessment of Dosing Strategies in Children for Monoclonal Antibodies Exhibiting Target-mediated Drug Disposition. American College of Clinical Pharmacology. San Diego. Sep 17, 2017.
- 81. **Schmidt S.** "Development and qualification of a mechanistic drug-disease modeling platform to characterize clinically relevant endpoints in Type 2 Diabetes trials" presented at an U.S. Food and Drug Administration workshop. Silver Spring. August 17, 2017.
- 82. **Schmidt S.** "Challenges & opportunities of drug-disease models for post-menopausal osteoporosis". FU Berlin, July 6, 2017.
- 83. **Schmidt S.** "Applied Pharmacometrics What's In It For Me?" FU Berlin, July 5, 2017.
- 84. **Schmidt S.** "Exploration of PK/PD in NDA enabling or early proof of concept studies: an academic perspective" presented at the DIA meeting, Chicago, June 19, 2017.
- 85. **Schmidt S.** "What quantitative clinical pharmacology & life taught me about drugs" presented at the 11th Global Gator Symposium, Düsseldorf, June 17, 2017.
- 86. **Schmidt S.** "Quantitative and systems pharmacology what's in it for me?" presented at Roche, Basel, June 14, 2017.
- 87. **Schmidt S**. "How informative are drug-drug interactions of gene-drug interactions?" presented as webinar for the American College of Clinical Pharmacology (ACCP), March 1, 2017.
- 88. **Schmidt S.** "How quantitative and systems pharmacology can bring value to R&D and ultimately to the patient" presented at the University of Central Florida, Orlando. February 13, 2017
- 89. **Schmidt S.** "Application of sensitivity analysis in evaluation of systems pharmacology models", presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Denver, November 17, 2016.

- 90. **Schmidt S.** "Pharmacogenomics: assessment of therapeutic risk vs. benefit", presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Denver, November 15, 2016.
- 91. **Schmidt S**. "How Quantitative and Systems Pharmacology Can Bring Value to R&D", presented at Sanofi-Aventis, Bridgewater, NJ, April 14, 2016.
- 92. **Schmidt S**. "Modeling and Simulation as Applied to drug Development and Regulatory Decision Making", presented at the University of Central Florida Translational Science seminar, Orlando, April 11, 2016.
- 93. **Schmidt S**. "Development of a Drug-Disease Model for Postmenopausal Osteoporosis", presented at the JSCPT/ISOP meeting in Tokyo, Japan, December 9, 2015
- 94. **Schmidt S.** "Drug-Disease Modeling Applied to Drug Development and Regulatory Decision Making in the Type 2 Diabetes Mellitus Arena", presented at the Keio University/PMDA workshop, Tokyo, Japan, December 8, 2015.
- 95. **Schmidt S.** "The Application of Quantitative Clinical Pharmacology Tools in Drug Development and Regulatory Decision Making: a Value Added Proposition", Eli Lilly, Indianapolis, November 11, 2015.
- 96. **Schmidt S.** "Quantitative Systems Pharmacology: How Complex Do We Want/Need to Be?" QSP Special Interest Group Tutorial at ACoP sponsored by ISoP, Crystal City, October 7, 2015.
- 97. **Schmidt S.** "Mechanism-Based Drug-Disease Modeling Applied to Drug Development and Regulatory Decision Making", 10th International Congress of Pharmaceutical Sciences, Ribeirão Preto, Brazil, September 8, 2015.
- 98. Lesko LJ, Biliouris K, Samant T, Combes F, Fang L, **Schmidt S**. Poster. A Modeland Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution. FDA Science Day. Washington D.C. May 27, 2015.
- 99. **Schmidt S.** "How Quantitative Clinical Pharmacology Can Bring Value to the Patient", Translational Science Research Seminar Series at Nemours Children's Hospital, Orlando, March 9, 2015.
- 100. **Schmidt S**. "Physiologically-based modeling in translational research", VI PPGCF UFRGS Meeting, Porto Alegre, November 21, 2014.
- 101. Samant S, Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Zheng S, Trame MN, Lesko LJ, **Schmidt S**. "A semi-physiological population pharmacokinetic/pharmacodynamic model for the development of a bedside-ready dosing algorithm of clopidogrel", ASCPT, Atlanta, March 22, 2014.
- 102. Jiang XL, Zhao P, Barrett JA, Lesko LJ, **Schmidt S**. "Application od physiologically-based pharmacokinetic modeling to predict acetaminophen metabolism & pharmacokinetics in children", ASCPT, Atlanta, March 21, 2014. **ASCPT Encore abstract
- 103. **Schmidt S.** "How systems pharmacology can bring value to the patient" presented at the Universidade Federal do Rio Grande do Sul, Porto Alegre, December 10, 2013.
- 104. Jiang XL, Zhao P, Lesko LJ, **Schmidt S**. "Application of physiologically-based pharmacokinetic (PBPK) model in predicting drug metabolism and pharmacokinetics in pediatric populations a case study of acetaminophen" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Indianapolis, IN, March 5-9, 2013. **ASCPT Presidential Fellow Award presentation
- 105. **Schmidt S**. Seminar. Chances and limitations of model-based drug development. Amgen. Seattle. Nov 2, 2012.

- 106. **Schmidt S.** "Pharmakokinetik beim Intensivpatienten: Brauchen wir individuelle Dosierungen?" presented at the 23. Jahrestagung der Paul-Ehrlich-Gesellschaft für Chemotherapie e.V. (PEG), Dresden, October 12, 2012.
- 107. **Schmidt S.** "Mechanism-based analysis of disease systems: principle and application to post-menopausal oateoporosis" presented at the 1⁰ Congresso da Associação Brasiliera de Ciências Farmacêuticas, Ipojuco, October 7, 2012.
- 108. Jiang XL, Zhao P, Lesko LJ, **Schmidt S.** Poster. Development of a physiologically-based pharmacokinetic (PBPK) model for acetaminophen by integrating clinical pharmacokinetic and in vitro enzyme kinetic data. U.S. Food and Drug Administration. Silver Springs. Sep 7, 2012. Office of Clinical Pharmacology Science Day Poster Award
- 109. **Schmidt S**. Seminar. Mechanism-based analysis of disease systems: principle and application to post-menopausal oateoporosis. Daiichi Sankyo. Parsippany, NJ. Aug 21, 2012.
- 110. **Schmidt S**. Seminar. Mechanism-based analysis of disease systems: principle and application to post-menopausal oateoporosis. Merck. Elkton, VA. Aug 20, 2012.
- 111. **Schmidt S**. Seminar. Pharmacometrics & systems pharmacology: how the center will bring value to patients. National Advisory Board (NAB) of the College of Pharmacy Meeting. Orlando. Apr 13, 2012.
- 112. **Schmidt S.** Seminar. Pharmacometrics & systems pharmacology: how the center will bring value to patients. Nemours Research Strategy Retreat. Delaware. Mar 5, 2012
- 113. **Schmidt S**. Seminar. Mechanism-based analysis of disease systems: principle and application to post-menopausal osteoporosis. U.S. Food and Drug Administration. Silver Springs. Feb 22, 2012.
- 114. **Schmidt S.** "Mechanism-based PKPD modeling: principle and applications" Keynote speaker at the 10th Congress of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Budapest, June 28, 2011.
- 115. **Schmidt S.** "Coping with time scales in disease systems analysis: application to bone remodeling" presented at the 20th meeting of the population approach group in Europe (PAGE), June 10, 2011.
- 116. **Schmidt S.** "Microdialysis: a valuable tool for identifying clinically relevant PK/PD relationships" presented at the 13th International Conference for in vivo Methods: Monitoring Molecules in Neuroscience, Brussels, September 16, 2010.
- 117. **Schmidt S.** "Potency of RWJ-416457 against MRSA compared to Linezolid" presented at the annual meeting of the International Society of Anti-Infective Pharmacology (ISAP), Chicago, IL, September 20, 2007.
- 118. **Schmidt S.** "Linezolid against MRSA A new *in vitro* Model" presented at the Annual Infectious Disease Fellowship Forum, Park City, UT, June 24 27, 2007 & Genentech Podium Presentation, San Francisco, CA, September 9, 2007.
- 119. **Schmidt S.** "PK/PD modeling of Linezolid against MRSA" presented at the 17th annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, March 31 April 3, 2007.
- 120. **Schmidt S.** "PK/PD challenges of *in vitro* time-kill curves a new modeling approach" presented at the annual meeting of the International Society of Anti-Infective Pharmacology (ISAP), San Francisco, CA, September 30, 2006.
- 121. **Schmidt S.** "Experimental pitfalls in protein binding measurements" presented at the Annual Infectious Disease Fellowship Forum, Brainerd, MN, June 8-11, 2006.
- 122. **Schmidt S.** "Effect of protein binding on the efficacy of ceftriaxone" presented at the Annual Infectious Disease Fellowship Forum, Charleston, SC, May 25, 2005.

List of Papers Presented at Scientific Meetings:

- 1. Lingineni K, Farhan N, Kim S, Gordon L, Penzak S, Hadigan C, George JM, **Schmidt** S. Poster Title: "Quantitative benefit-risk assessment of P-gp mediated drug-drug interactions of dabi-gatran co-administered with pharmacokinetic enhancers in patients with renal impairment", University of Florida, 2020.
- 2. Lingineni K, Morales JF, Conrado D, Corey D, Hill M, Vong C, Burton J, Larkindale J, Romero K, Schmidt S, Kim S. Towards Achieving Regulatory Endorsement of a Disease Progression Model-based Clinical Trial Simulation Tool for Duchenne Muscular Dys-trophy— Models of Progression of Timed Motor Function Tests. ACoP Virtual meeting. Nov 10-12, 2020. **Student abstract award.
- 3. Lingineni K, Cicali B, Chaturvedula A, Cristofoletti R, Wendl T, Hoechel J, Wiesinger H, Vozmediano V, Zhao P, **Schmidt S**. Quantitative Evaluation of Levonorgestrel Efficacy inDrug-Drug Interaction (DDI) Scenarios in Healthy and Obese Women: Applications of Inte-grated Physiologically-based Pharmacokinetic (PBPK) Modeling & Model Based Meta Analy-sis (MBMA). ACCP Virtual meeting. Sep 11-14, 2020. ** **Students abstract award & Wayne A. Colburn Memorial Award Winner.**
- 4. Lingineni K, Conrado DJ, Corey D, Hill M, Larkindale J, Romero K, **Schmidt S**, Kim S. Towards Achieving Regulatory Endorsement of a Disease Progression Model-based Clinical Trial Simu-lation Tool for Duchenne Muscular Dystrophy— Model of Progression of Forced Vital Capacity. Houston. Mar 20-23, 2020. ** **Presidential Trainee award & Jason Morrow award.**
- 5. Lingineni K., Conrado D., Corey D., Hill M., Larkindale J., Romero K., **Schmidt S.**, Kim S. *Poster*. "Towards Achieving Regulatory Endorsement of a Disease Progression Model-based Clinical Trial Simulation Tool for Duchenne Muscular Dystrophy "An Exemplar using Clinical Data from the North Star Ambulatory Assessment" presented at Annual Meeting of the American Conference on Pharmacometrics (ACoP), Orlando, FL, October 20-23, 2019.
- 6. Klopp-Schulze L., Mueller-Schoel A., Joerger M., Neven P., Koolen SLW., Mathijssen RHJ., **Schmidt S.**, Kloft C. *Poster*. "At the interface of physiologically-based and nonlinear mixed-effects modelling: Enhancing the quantitative understanding of the complex pharmacokinetics and –genetics of tamoxifen and its major metabolites" presented at Annual Meeting of the American Conference on Pharmacometrics (ACoP), Orlando, FL, October 20-23, 2019.
- 7. Lingineni K., Farhan N., Kim S., Penzak S., Hadigan C., George JM., **Schmidt S.** *Poster*. "Quantitative Benefit-Risk Assessment of P-gp mediated Drug-Drug Interactions (DDIs) of Dabigatran Co-administered with Pharmacokinetic Enhancers in Patients with Renal Impairment" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), Chicago, IL September 15-17, 2019.
- 8. Cicali B., **Schmidt S.**, Brown JD. *Poster*. "Novel Application of Pharmacoepidemiology for the Examination of Possible Pharmacokinetic/Pharmacodynamic Mechanisms of Macrolide Antibiotic Resistance" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), Chicago, IL September 15-17, 2019.
- 9. Lien YT., Lam E., Vozmediano V., Rochani A., Kaushal G., Tanjuako J., Thoma BN., Hirose H., Kraft WK., **Schmidt S.** *Poster*. "Ketamine Population Pharmacokinetics in Critically III Patients on Extracorporeal Membrane Oxygenation Therapy" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), Chicago, IL September 15-17, 2019.
- 10. **Schmidt S**, Cicali B, Kirouac D. *Poster*. "Developing a QSP Model Repository for CPT-PSP: Challenges and Future Opportunities "presented at The American Society for Clinical Pharmacology and Therapeutics, Washington, DC, March 13-14, 2019.

- 11. **Schmidt S**, Badee J, Qiu N, Parrott N, Fowler S. *Poster*. "Optimization of experimental conditions of automated glucuronidation assays in human liver microsomes using a cocktail approach and high-performance liquid chromatography-tandem mass spectrometry" presented at 2019 Hot Topics in the Lab, one-day Drug Metabolism Discussion Group meeting, UK, March 7, 2019.
- 12. **Schmidt S,** Cicali B, Collin AJ, Vega A, Raghunandan S. *Poster*. "Bridging the Gap of Macrolide Resistance Mechanisms and Clinical Application through PK/PD Modeling and Pharmacovigilance Analyses "*presented* at the University of Florida COP, Gainesville, FL, February 11, 2019.
- 13. **Schmidt S**, Farhan N, Basu S, Kim S, Lingineni K, Vozmediano V, Ait-Oudhia S, Fang L, Zhao L, Lesko L. *Poster*. "Application of Physiologically-Based Oral Absorption & Pharmacokinetic Modeling to Investigate Formulation Factors Influencing the Pharmacokinetics of Novel Oral Anticoagulants" presented at the University of Florida COP, Gainesville, FL, February 11, 2019.
- 14. **Schmidt S,** Lien YT, Madrasi K, Samant S, Kim M, Li F, Li L. *Poster*. "Quantification of postmenopausal osteoporosis population: An system pharmacology approach using bisphosphonates" presented at the University of Florida COP, Gainesville, FL, February 11, 2019.
- 15. **Schmidt S,** Jiang S, Farhan N, Vozmediano V. *Poster*. "Population parent-metabolite pharmacokinetic modeling of acetaminophen protein adducts, a biomarker of acetaminophen induced hepatotoxicity" presented at the University of Florida. Gainesville, FL, February 11, 2019
- 16. **Schmidt S,** Jiang S, Farhan N, Vozmediano V. *Poster*. "Updated physiologically based pharmacokinetic (PBPK) model for acetaminophen metabolism with an emphasis on phase I metabolism" presented at the American Association of Pharmaceutical Scientists, Washington, DC. November 5, 2018.
- 17. **Schmidt S**, Cicali B, Collin AJ, Vega A, Raghunandan S. *Poster*. "Bridging the Gap of Macrolide Resistance Mechanisms and Clinical Application through PK/PD Modeling and Pharmacovigilance Analyses" presented at the American Conference on Pharmacometrics, San Diego, CA. October 10, 2018.
- 18. **Schmidt S,** Farhan N, Basu S, Kim S, Lingineni K, Vozmediano V, Ait-Oudhia S, Fang L, Lesko L. *Poster*. "Application of Physiologically-Based Oral Absorption & Pharmacokinetic Modeling to Investigate Formulation Factors Influencing the Pharmacokinetics of Novel Oral Anticoagulants "presented at the American Conference on Pharmacometrics, San Diego, CA. October 10, 2018.
- 19. **Schmidt S,** Jiang S, Jin JY, Deng R. *Poster*. "Practical identifiability analysis and pharmacokinetic sampling optimization for monoclonal antibodies with nonlinear pharmacokinetics in first-in-human studies" presented at the American Conference on Pharmacometrics, San Diego, CA. October 10, 2018.
- 20. **Schmidt S,** Hajihosseini A, Maleki F, Lien YT, Vozmediano V. *Poster*. "The Effect of Monoclonal Antibodies Pharmacokinetics on the Tumor Cells Dynamics: A Bifurcation Analysis "presented at the American Conference on Pharmacometrics, San Diego, CA. October 8, 2018.
- 21. **Schmidt S,** Lien YT, Madrasi K, Samant S, Kim M, Li F, Li L. *Poster*. "Quantification of postmenopausal osteoporosis population: An system pharmacology approach using bisphosphonates" presented at the Globalization of Pharmaceutics Education Network, Singapore, September 27-28, 2018
- 22. Badee J, Qiu N, Collier AC, Takahashi RH, Forrest W, Schmidt S, Parrott N, Fowler S. Poster and Presentation. "Characterization of the Ontogeny of Hepatic UGT Enzymes Based on Glucuronidation Activity Measured in Human Liver Microsomes" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP),

- Bethesda, September 23-25, 2018. **ACCP Student and Trainee Award and Colburn Memorial Award.
- 23. **Schmidt S,** Jiang S, Vozmediano V, James L, Rahman S. *Poster*. "Population parent-metabolite pharmacokinetic modeling of acetaminophen protein adducts, a biomarker of acetaminophen induced hepatotoxicity" presented at the American College of Clinical Pharmacology, Bethesda, MD, September 23, 2018.
- 24. **Schmidt S**, Badee J, Qiu N, Parrott N, Fowler S. *Poster*. "Optimization of experimental conditions of automated glucuronidation assays in human liver microsomes using a cocktail approach and ultra-high performance liquid chromatography-tandem mass spectrometry" presented at the Gordon Research Conference, Holderness, July 8-13, 2018.
- 25. De Miranda Silva C, Mangal N, Michaud V, Turgeon J, Lesko LJ, **Schmidt S**. *Poster*. "Predicting the impact of CYP2D6/UGT2B7 Gene-drug and CYP mediated Drug-drug interactions on oxycodone and oxymorphone pharmacokinetics" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Orlando, March 21, 2018.
- 26. Berkovitz SD, Fox KA, **Schmidt S**, Weitz JI, Garmann D, Kubitza D, Mueck W, Peters G, Reinecke I, Solms A, Spiro TE, Yan X, Zhang L, Willmann S. *Poster*. "The effects of rivaroxaban exposure and clinical risk factors on efficacy and safety outcomes in the prevention of venous thromboembolism after elective hip or knee replacement surgery" presented at the Annual Meeting of the American Society of Hematology (ASH), Atlanta, December 11, 2017.
- 27. Berkovitz SD, Weitz JI, **Schmidt S**, Fox KA, Garmann D, Kubitza D, Mueck W, Peters G, Reinecke I, Solms A, Spiro TE, Yan X, Zhang L, Willmann S. *Poster*. "The effects of rivaroxaban exposure and clinical risk factors on efficacy and safety outcomes in patients treated for venous thromboembolism" presented at the Annual Meeting of the American Society of Hematology (ASH), Atlanta, December 9, 2017.
- 28. Yan X, Peters G, Sharma A, Nandy P, Nessel C, Garmann D, Willmann S, Hermanowski-Vosatka A, Solms, A, Berkowitz SD, Spiro TE, Fox KE, Weitz JI, **Schmidt S**, Piccini, JP, Patel M, Becker RC, Zhang L. *Poster*. "The effect of rivaroxaban exposure and clinical risk factors on efficacy and safety outcomes in patients with nonvalvular atrial fibrillation" presented at the Annual Meeting of the American Society of Hematology (ASH), Atlanta, December 9, 2017.
- 29. Kim S, Lingineni K, Meng A, Sharma VD, Miller R, Trame MN, Brown JD. Fang L, Lesko LJ, **Schmidt S**. *Poster*. "A model and systems based approach to safety and efficacy questions related to generic substitution a novel oral anticoagulants case study" presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), San Diego, November 13, 2017.
- 30. Mehta H, Bernstein G, He J, Oldenhof J, Mills C, Milova D, Setnik, B, **Schmidt S**, Nasrat H, Dick C. *Poster*. "Insights from structural model deliniate PK associated with abuse potential following intranasal administration in recreational drug users" presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), San Diego, November 15, 2017 & at the American Conference on Pharmacometrics (ACoP), Fort Lauderdale, October 17, 2017.
- 31. Lien YT, Madrasi K, Samant S, Kim MJ, Li F, **Schmidt S**. *Poster and Presentation*. "Quantification of postmenopausal osteoporosis population: a systems pharmacology approach using bisphosphonates" presented at the Annual Meeting of the American Conference on Pharmacometrics (ACoP), Fort Lauderdale, October 17, 2017. **Ouality Trainee Abstract Award
- 32. De Miranda Silva C, Vozmediano Esteban V, Nakatani Y, Mangal N, Basu S, Samant T, Yang H, Michaud V, Turgeon J, Lesko LJ, **Schmidt S**. *Poster*. "Development of a

- physiologically based pharmacokinetic model for oxycodone" presented at the Annual Meeting of the American Conference on Pharmacometrics (ACoP), Fort Lauderdale, October 17, 2017.
- 33. Schmulenson E, Schlender JF, Frechen S, **Schmidt S**, Jaehde U. *Poster*. "Systemic pharmacotherapy support during chronic kidney disease using a novel conceptual framework" presented at the Annual Meeting of the American Conference on Pharmacometrics (ACoP), Fort Lauderdale, October 17, 2017.
- 34. Yan X, Peters G, Garmann D, Willmann S, Hermanowski-Vosatka A, Nandy P, Solms A, Berkowitz SD, Spiro T, Fox KA, Weitz JI, **Schmidt S**, Zhang L. *Poster*. "The effect of rivaroxaban exposure and clinical risk factors on efficacy and safety outcomes in patients with acute coronary syndromes" presented at the Annual Meeting of the American Conference on Pharmacometrics (ACoP), Fort Lauderdale, October 17, 2017.
- 35. Lien Y, Sharma V, Basu S, Yang H, Wang W, Zhou H, Bihorel S, **Schmidt S**. Poster. "A novel interactive quantitative clinical pharmacology approach applied to biomarker identification in oncology" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Diego, September 17, 2017.
- 36. Basu S, Samant T, Trescot A, Palmer M, Cavallari L, Lesko LJ, **Schmidt S**. *Poster*. "Development and application of a PBPK model for prediction of the drug-drug interaction (DDI) and gene-drug interaction (GDI) of oxycodone and CYP perpetrators" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Washington, March 16, 2017.
- 37. Lien Y, Sharma V, Basu S, Yang H, Wang W, Zhou H, Ait-Oudhia S, **Schmidt S**. *Poster*. "The quest for biomarkers in oncology: an opportunity for quantitative clinical pharmacology approaches" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Washington, March 16, 2017.
- 38. Basu, S, Yang H, Fang L, Sales MG, Zhao, L, Trame MN, Lesko LJ, **Schmidt S**. *Poster*. "Physiologically based absorption modeling as a tool to evaluate the bioequivalence of metoprolol ER products" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Washington, March 16, 2017.
- 39. Arwood MJ, Deng J, Drozda, Pugach O, Nutescu EA, **Schmidt S**, Duarte JD, Cavallari LH. *Poster*. "Clinical implementation of warfarin pharmacogenetics in a real-world setting: a proposal for a new pharmacogenetic dosing approach for diverse patient populations" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Washington, March 15, 2017. **ASCPT Presidential Fellow Award
- 40. Sharma VD, Trame MN, **Schmidt S**, Fang L, Lesko LJ. *Poster*. "Development of a pharmacokinetic (PK)/pharmacodynamic (PD) model to evaluate the impact of variation in bioavailability on PD for extended release metoprolol formulations" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Washington, March 15, 2017. **ASCPT Presidential Fellow Award
- 41. De Miranda Silva C, Rocha A, Tozatto E, da Silva LM, Donadi EA, Lanchote VL, **Schmidt S**, Bulitta JB. *Poster*. "Modeling acute pain decrease based on in vitro COX-2 inhibition via an enantioselective systems pharmacology approach for etodolac" presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), Denver, November 14, 2016.
- 42. Hurtado FK, Garhyan P, Chien JY, **Schmidt S**. *Poster*. "Predicting end-of-tril fasting glucose and HbA_{1c} via mechanistic PK/PD modeling based on longitudinal Type 2 Diabetes trial data" presented at Annual Meeting of the American Conference on Pharmacometrics (ACoP), Arlington, October 24, 2016.

- 43. Zheng S, Krasniqi S, Matzneller P, Zeitlinger M, Bulitta JB, **Schmidt S**. *Poster*. "Development of an integrated population pharmacokinetic model characterizing the tissue distribution of azithromycin and erythromycin in healthy subjects" presented at Annual Meeting of the American Conference on Pharmacometrics (ACoP), Arlington, October 24, 2016.
- 44. Deng J, Arwood MA, Duarte J, Cavallari L, **Schmidt S**. Poster. "Development of a universal pharmacogenetics-guided warfarin dosing nomogram" presented at Annual Meeting of the American Conference on Pharmacometrics (ACoP), Arlington, October 24, 2016.
- 45. Basu S, Niederalt C, Yang H, Lien YT, Eissing T, **Schmidt S**. *Poster*. "Development and qualification of a pediatric PBPK model for biologics in PK-Sim[®]" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 25, 2016. ***ACCP Student and Trainee Award*
- 46. Mangal N, Hamadeh I, Samant T, Langaee T, Cavallari L, Johnson J, Bulitta JB, Schmidt S. *Poster*. "Development of a CYP2C19 genotype-directed dosing algorithm for voriconazole" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 25, 2016. **ACCP Student and Trainee Award
- 47. Madrasi K, Samant S, Kim MJ, Li F, Voss S, Kehoe T, **Schmidt S**, Li L. *Presentation*. "Development of a mechanism-based drug-disease model to quantify postmenopausal osteoporosis" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), San Diego, March 12, 2016.
- 48. Samant TS, **Schmidt S**, Trescot A, Norton S, Palmer M, Lesko LJ. *Poster*. "Pharmacogenetics guided physiologically-based pharmacokinetic (PBPK) modeling of oxycodone and its metabolites for chronic pain management (CPM)" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), San Diego, March 10, 2016.
- 49. Hurtado FK, Gaitonde P, Garrhyan P, Chien JY, **Schmidt S**. *Poster*. "Development of a mechanism-based drug-disease modeling platform for Type 2 Diabetes Mellitus". presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), San Diego, March 10, 2016.
- 50. **Schmidt S**. Lecture. Development of a drug-disease model for postmenopausal osteoporosis. JSCPT/ISoP. Tokyo, Japan. Dec 9, 2015.
- 51. **Schmidt S**. Workshop. Drug-disease modeling applied to drug development and regulatory decision making in the Type 2 Diabetes Mellitus arena. Keio University/PMDA. Tokyo, Japan. Dec 8, 2015.
- 52. Schlender JF, Samant TS, Meyer M, Thelen K, Willmann S, Eissing T, **Schmidt S**, Jaehde U. *Poster*. "Impact of aging on bioavailability and multiple enzymatic elimination pathways using a lifespan physiologically-based pharmacokinetic (PBPK) approach" presented at the Annual Meeting of the American Association of Pharmaceutical Scientists (AAPS), October 28, 2015.
- 53. Lagishetty CV, Samant TS, Ge L, Trame MN, Natarajan K, Yuan J, Torrente JM, Lesko LJ, **Schmidt S**." Pharmacokinetic and pharmacodynamic drug interaction between flibanserin and fluconazole" presented at the 20th North American Meeting of the International Society for the Study Xenobiotics (ISSX), October 21, 2015.
- 54. Mangal N, Shroads A, Langaee T, Stacpoole P, **Schmidt S**. "Model guided dose optimization of dichloracetate for the treatment of congenital lactic acidosis" presented at the 20th North American Meeting of the International Society for the Study Xenobiotics (ISSX), October 21, 2015.

- 55. **Schmidt S**. Symposium. Quantitative systems pharmacology: how complex do we want/need to be? QSP Special Interest Group Tutorial at ACoP sponsored by ISoP. Crystal City. Oct 7, 2015.
- 56. Samant S, Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Peletier LA, Lesko LJ, **Schmidt S**. "A Physiologically-Based Pharmacokinetic/Pharmacodynamic Model for Evaluating Clinically Important Drug-Drug Interactions and Genetic Polymorphisms: A Clopidogrel Case Study" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 27-29, 2015. **ACCP Student and Trainee Award
- 57. Deng J, Lagishetty C, Lesko LJ, Rogers H, Pacanowski M, **Schmidt S**. "Can Drug-Drug Interactions Be Used to Inform Gene-Drug Interactions and *Vice Versa*?" presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 27-29, 2015. **ACCP Student and Trainee Award
- 58. Biliouris K, Trame MN, **Schmidt S**, Fang L, Lesko LJ. "Integrated Data Mining and Systems Pharmacology to Explore the Comparative Safety of Brand-Name and Generic Drugs." presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 28, 2015.
- 59. Lesko LJ, Biliouris K, Samant T, Combes F, Fang L, **Schmidt S**, Trame MN. "A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution." presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 28, 2015.
- 60. Samant TS, **Schmidt S**, Fang L, Trame MN, Lesko LJ. "Use of Physiologically Based Pharmacokinetic Modeling as a Computational and Mathematical Tool to Evaluate Switchability of Generic and Brand Name Products." presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 28, 2015.
- 61. **Schmidt S**. Lecture. Mechanism-based drug-disease modeling applied to drug development and regulatory decision making. 10th International Congress of Pharmaceutical Sciences. Ribeirão Preto, Brazil. Sep 8, 2015.
- 62. Biliouris K, Trame MN, **Schmidt S**, Fang L, Lesko LJ. "Integrated Data Mining and Systems Pharmacology to Explore the Comparative Safety of Brand-Name and Generic Drugs." presented at the Annual meeting of the population approach group in Europe (PAGE), Abstract 3430, June 2015, Hersonissos, Crete
- 63. Lesko LJ, Biliouris K, Samant T, Combes F, Fang L, **Schmidt S**, Trame MN. "A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution." presented at the FDA Science Day, Washington DC, March 2015.
- 64. Lagishetty C, Deng J, Lesko LJ, Rogers H, **Schmidt S**. "How informative are drugdrug interactions of gene-drug interactions and vice versa?" presented at the presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), New Orleans, March 6, 2015. **Late Breaker Abstract
- 65. Samant TS, Lukacova V, Lesko LJ, **Schmidt S**. "Characterizing the changes in drug clearance from neonates to adults by physiologically based pharmacokinetic modeling using GastroPlus" presented at the presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), New Orleans, March 5, 2015
- 66. Gaitonde P, Garhyan P, Chien JY, **Schmidt S**. "Drug-systems disease model to predict treatment outcome in Type 2 Diabetes Mellitus" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), New Orleans, March 5, 2015.

- 67. Samant S, Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Peletier LA, Zhang X, Trame MN, Lesko LJ, **Schmidt S.** "Using Innovative Computational Tools to Identify Clinically Important Drivers of Variability in Clopidogrel Antiplatelet Therapy" presented at the presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), New Orleans, March 5, 2015.
- 68. **Schmidt S**. Lecture. Physiologically-based modeling in translational research. VI PPGCF UFRGS. Porto Alegre, Brazil. Nov 21, 2014 Nov 21, 2014.
- 69. Zheng S, Gaitonde P, Andrew MA, Gibbs MA, Lesko LJ, **Schmidt S**. Poster. Model-based comparison of monoclonal antibody dosing strategies for application in children. Institute for Child Health Policy (ICHP). Gainesville. Nov 4, 2014. **Encore abstract at ASCPT 2015**
- 70. Samant T, Lukacova V, Lesko LJ, **Schmidt S**. "Enzyme focused PBPK modelling in adults for candidate drugs using GastroPlus" presented at the 5th American Conference on Pharmacometrics, Las Vegas, October 15, 2014.
- 71. Gaitonde P, Biliouris K, Norris D, Nestorov I, **Schmidt S**, Rogge M, Lesko LJ, Trame MN. "Development of a non-human primate, semi-mechanistic pharmacokinetic model for pediatric phase I predictions for the treatment of spinal muscular atrophy" presented at the 5th American Conference on Pharmacometrics, Las Vegas, October 15, 2014.
- 72. Mangal N, Samant T, Hamadeh I, Johnson J, Langaee T, **Schmidt S**. "Development of a CYP2C19 genotype guided dosing algorithm for voriconazole" presented at the 5th American Conference on Pharmacometrics, Las Vegas, October 14, 2014.
- 73. Zheng S, Gaitonde P, Andrew MA, Gibbs MA, Lesko LJ, **Schmidt S**. "Model-based comparison of monoclonal antibody dosing strategies for application in children" presented at the 5th American Conference on Pharmacometrics, Las Vegas, October 13, 2014. ***Encore abstract at ASCPT 2015*
- 74. Samant S, Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Peletier LA, Zhang X, Trame MN, Lesko LJ, **Schmidt S.** "Using innovative tools for personalizing antiplatelet therapy" presented at the 5th American Conference on Pharmacometrics, Las Vegas, October 13, 2014.
- 75. Gaitonde P, Trame MN, Garhyan P, Chien JY, **Schmidt S**. "Development of a Drug-Systems-Disease Model for Type 2 Diabtes Mellitus" presented at the 43nd Annual Meeting of the American College of Clinical Pharmacology (ACCP), Atlanta, September 16, 2014. **ACCP Student and Trainee Award
- 76. Somani AA, Thelen K, Zheng S, Trame MN, Coboeken K, Meyer M, Schnizler K, Ince I, Willmann S, **Schmidt S**. "Evaluation of changes in oral drug absorption in preterm neonates" presented at the 43nd Annual Meeting of the American College of Clinical Pharmacology (ACCP), Atlanta, September 14, 2014. **ACCP Student and Trainee Award
- 77. Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Peletier LA, Trame MN, Lesko LJ, "**Schmidt S**. Development of a Bedside-Ready Dosing Algorithm for Clopidogrel", Atlanta, September 14, 2014.
- 78. Somani AA, Thelen K, Zheng S, Trame MN, Coboeken K, Meyer M, Schnizler K, Ince I, Willmann S, Schmidt S. "Evaluation of changes in oral drug absorption in preterm neonates for Biopharmaceutics Classification System (BCS) class I and II compounds" presented at the 23rd meeting of the population approach group in Europe (PAGE), Alicante, June 12, 2014.
- 79. Zheng S, Matzneller P, Zeitlinger M, Lesko LJ, **Schmidt S**. "Development of a population pharmacokinetic model characterizing the tissue distribution of azithromycin in healthy subjects" presented at the 24th annual meeting of the

- European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Barcelona, May 12, 2014.
- 80. Samant S, Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Zheng S, Trame MN, **Schmidt S**. Paper. A semi-physiological population pharmacokinetic/pharmacodynamic model for the development of a bedside-ready dosing algorithm of clopidogrel. American Society for Clinical Pharmacology and Therapeutics. Atlanta. Mar 22, 2014.
- 81. **Schmidt S**. Symposium. Challenges and opportunities for physiologically-based pharmacokinetic (PBPK) modeling in pediatric drug development. American Society for Clinical Pharmacology and Therapeutics (ASCPT). Atlanta. Mar 21, 2014.
- 82. Jiang XL, Zhao P, Barrett JA, Lesko LJ, **Schmidt S**. Paper. Application of physiologicallyy-based pharmacokinetic modeling to predict acetaminophen metabolism & pharmacokinetics in children. American Society for Clinical Pharmacology and Therapeutics (ASCPT). Atlanta. Mar 21, 2014. ASCPT Encore Abstract
- 83. Gaitonde P, Trame MN, Syvanen S, Lesko LJ, **Schmidt S**. "Mechanism-based evaluation of codeine toxicity in children" presented at the presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Atlanta, March 20, 2014.
- 84. **Schmidt S**. Lecture. How systems pharmacology can bring value to the patient. Universidade Federal do Rio Grande do Sul. Porto Alegre, Brazil. Dec 10, 2013
- 85. Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Samant S, Lesko LJ, Schmidt S. "Development of a minimal physiologically-based pharmacokinetic and pharmacodynamics model for characterizing the impact of genetic and demographic factors on clopidogrel treatment response in healthy adults" presented at the 42nd Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 23, 2013. **ACCP Student and Trainee Award, New Member Abstract Award
- 86. Zheng S, Matzneller P, Zeitlinger M, Lesko LJ, **Schmidt S**. "Development of a tissue distribution population pharmacokinetic model for azithromycin" presented at the 42nd Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 23, 2013. **ACCP Student and Trainee Award
- 87. Jiang XL, Zhao P, Lesko LJ, **Schmidt S**. "Mechanistic prediction of acetaminophen metabolism and pharmacokinetics in children using a physiologically-based pharmacokinetic (PBPK) modeling approach" presented at the 22nd meeting of the population approach group in Europe (PAGE), Glasgow, June 12, 2013.
- 88. Jiang XL, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Samant S, Lesko LJ, Schmidt S. "A CYP2C19 genotype-directed population pharmacokinetic and pharmacodynamic analysis of clopidogrel in healthy adults" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Indianapolis, March 8, 2013. **Encore abstract at ASCPT 2014
- 89. Jiang XL, Zhao P, Lesko LJ, **Schmidt S**. "Application of physiologically-based pharmacokinetic (PBPK) model in predicting drug metabolism and pharmacokinetics in pediatric populations a case study of acetaminophen" presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), Indianapolis, March 5-9, 2013. **ASCPT Presidential Fellow Award
- 90. **Schmidt S**. Lecture. Pharmakokinetik beim Intensivpatienten: Brauchen wir individuelle Dosierungen? 23. Jahrestagung der Paul-Ehrlich-Gesellschaft für Chemotherapie e.V. (PEG). Dresden, Germany. Oct 12, 2012.
- 91. **Schmidt S**. Lecture. Mechanism-based analysis of disease systems: principle and application to post-menopausal oateoporosis. 10 Congresso da Associação Brasiliera de Ciências Farmacêuticas. Ipojuco, Brazil. Oct 7, 2012.

- 92. Jiang XL, Zhao P, Lesko LJ, **Schmidt S**. "Development of a physiologically-based pharmacokinetic (PBPK) model of acetaminophen by integrating clinical pharmacokinetic and in vitro enzyme kinetic data" presented at the U.S. Food and Drug Administration's Science Day, Silver Springs, September 7, 2012. **FDA Office of Clinical Pharmacology Science Day Poster Award
- 93. **Schmidt S**, Post TM, Peletier LA, Boroujerdi MA, Danhof M. "Mathematical model reduction: an innovative tool for analyzing complex dynamic systems" presented at the 40th Annual Meeting of the American College of Clinical Pharmacology (ACCP), Chicago, September 12, 2011. **ACCP Student and Trainee Award
- 94. **Schmidt S**. Keynote. Mechanism-based PKPD modeling: principle and applications. 10th Congress of the European Association for Clinical Pharmacology and Therapeutics (EACPT). Budapest, Hungary. Jun 28, 2011.
- 95. Boroujerdi MA, **Schmidt S**, Della Pasqua OE, Danhof M. "A negative feedback model for a mechanism-based description of longitudinal data: application for bone turnover markers" presented at the 20th meeting of the population approach group in Europe (PAGE), Athens, June 8, 2011.
- 96. Singh RP, Viera M, Barbour A, **Schmidt S**, Rout WR, Ben-David K, Burkhardt O, Derendorf H. "Physiological based pharmacokinetic modeling of cefuroxime clinical microdialysis data in morbidly obese females undergoing surgery" presented at the 2010 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition, New Orleans, November 16, 2010.
- 97. **Schmidt S**, Burkhardt O, Derendorf H. "Einfluss der Plasmaproteinbindung auf die Pharmakokinetik und Pharmakodynamic von Beta-Laktamen" presented at the 22. Jahrestagung der Paul-Ehrlich-Gesellschaft (PEG) für Chemotherapie e.V., Bonn, October 8, 2010. **Paul-Ehrlich Society for Chemotherapy Thesis Award
- 98. **Schmidt S**. Lecture. Microdialysis: a valuable tool for identifying clinically relevant PK/PD relationships. 13th International Conference for in vivo Methods: Monitoring Molecules in Neuroscience. Brussels, Belgium. Sep 16, 2010.
- 99. Sahre M, **Schmidt S**, Barbour A, Sabarinath S, Naik R, Seubert CN, Grant MB, Derendorf H. Poster. Microdialysis as a tool for assessment of tissue concentrations of antibiotics in humans. Globalization of Pharmaceutics Education Network (GPEN). Leuven. Sep 11, 2010.
- 100. **Schmidt S**, Post TM, Boroujerdi MA, Peletier LA, Danhof M, Della Pasqua OE. "Implication of differences in model parameterization in osteoporosis" presented at the 19th meeting of the population approach group in Europe (PAGE), June 10, 2010.
- 101. **Schmidt** S, Post TM, Peletier LA, Danhof M, Della Pasqua OE. "Disease progression analysis in osteoporosis: relating bone mineral density to osteoblast and osteoclast activity" presented at the 6th International Symposium on Measurement & Kinetics of In Vivo Drug Effects, Noordwijkerhout, April 22, 2010.
- 102. Gonzalez D, Schmidt S, Derendorf H. "Effect of protein binding on half-life of elimination" presented at the 38th Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Antonio, September 14, 2009. **ACCP Student and Trainee Award
- 103. **Schmidt S**, Burkhardt O, Derendorf H. "Protein binding pitfalls *in vitro* and *in vivo*" presented at the 2008 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition, Atlanta, November 19, 2008.
- 104. Barbour A, Schmidt S, Derendorf H. "Microdialysis-based pharmacokinetic modeling of beta-lactam tissue concentrations" presented at the 2008 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition, Atlanta, November 17, 2008.

- 105. Li Y, Nguyen M, Schmidt S, Zhong L, Derendorf H, Clancy C. "Simulating voriconazole-candida interactions using a mathematical model derived from a dynamic *in vitro* time-kill method" presented at 48th Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting, Washington DC, October 27, 2008.
- 106. Sahre M, **Schmidt** S, Barbour A, Rand KH, Derendorf H. "*In vitro* pharmacodynamics of TR-700, the active moiety of prodrug TR-701, a novel oxazolidinone, in a kill-curve model" presented at 48th Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting, Washington DC, October 27, 2008.
- 107. Barbour A, Childs A, Murthy B, **Schmidt S**, Sabarinath S, Tian H, Desai-Krieger D, Balis D, Grant M, Seubert C, Derendorf H. "Soft tissue penetration of ceftobiprole following single dose administration in healthy adults" presented at 48th Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting, Washington DC, October 27, 2008.
- 108. Schmidt S, Roeck K, Sahre M, Derendorf H. "In vitro protein binding needs to be measured in the respective medium and not estimated from reported serum binding" presented at 48th Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46th Annual Meeting, Washington DC, October 27, 2008.
- 109. Sahre M, **Schmidt S**, Barbour A, Sabarinath S, Naik R, Seubert CN, Grant MB, Derendorf H. "Microdialysis as a tool for assessment of tissue concentrations of antibiotics in humans" presented at Globalization of Pharmaceutics Education Network (GPEN), Leuven, September 2008
- 110. Barbour A, **Schmidt S**, Derendorf H. "Combination of clinical microdialysis and *in vitro* pharmacodynamics for dose optimization of beta-lactam antibiotics" presented at the 37th Annual Meeting of the American College of Clinical Pharmacology (ACCP), Philadelphia, September 15, 2008. **ACCP Student and Trainee Award
- 111. **Schmidt S**, Barbour A, Burkhardt O, Rout WR, Ben-David K, Derendorf H. "Soft tissue penetration of cefuroxime determined by clinical microdialysis in six obese patients undergoing abdominal surgery" presented at the 37th Annual Meeting of the American College of Clinical Pharmacology (ACCP), Philadelphia, September 15, 2008.
- 112. Schmidt S, Roeck K, Sahre M, Derendorf H. "Protein binding a source for many pitfalls" presented at the 21st Annual Research Showcase of the College of Pharmacy at the University of Florida, Gainesville, February 21, 2008. **Annual Research Showcase Competition Winner of the College of Pharmacy at the University of Florida
- 113. **Schmidt S**, Barbour A, Ghobrial O, Abbanat D, Manitpisitkul P, Blake J, Sha S, Derendorf H. "Potency of RWJ-416457 against MRSA compared to Linezolid" presented at the 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Chicago, September 17 20, 2007, 1st Emerging Pathogen Institute (EPI) meeting, Gainesville, December 13, 2007.
- 114. **Schmidt S**, Abbanat D, Manitpisitkul P, Blake J, Sha S, Derendorf H. "Linezolid against MRSA a new modeling approach" presented at the 36th Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 9 11, 2007. **ACCP Student and Trainee Award, Genentech Podium Award
- 115. **Schmidt S.** Paper. PK/PD modeling of Linezolid against MRSA. 17th annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID). Munich, Germany. Apr 1, 2007.

- 116. **Schmidt S**, Derendorf H, "Linezolid vs. MRSA a new PK/PD model" presented at 20th Annual Research Showcase of the College of Pharmacy at the University of Florida, Gainesville, February 19, 2007. **Annual Research Showcase Competition Winner of the College of Pharmacy at the University of Florida
- 117. **Schmidt S**. Paper. PK/PD challenges of in vitro time-kill curves a new modeling approach. International Society of Anti-Infective Pharmacology (ISAP). San Francisco, CA. Sep 30, 2006.
- 118. **Schmidt S**, Burkhardt O, Sahre M, Derendorf H. "Experimental pitfalls in protein binding measurements" presented at the 16th annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, April 1 4, 2006, South East Regional Interdisciplinary Symposium (SERIS), Gainesville, May 19 21, 2006, Globalization of Pharmaceutics Education Network (GPEN), Lawrence, October 25 27, 2006. ** South East Regional Interdisciplinary Symposium (SERIS) Poster Competition Winner
- 119. **Schmidt S**, Burkhardt O, Treyaprasert W. Derendorf H. "PK/PD challenges of *in vitro* time-kill curves a new modeling approach" presented at the 16th annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, April 1 4, 2006.
- 120. **Schmidt S**, Burkhardt O, Schubert S, Dalhoff A, Derendorf H. "Carbapenems differences in their antimicrobial activity due to their protein binding" presented at the 16th annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, April 1-4, 2006.
- 121. **Schmidt S**, Treyaprasert W, Derendorf H. "Effect of protein binding on the efficacy of ceftriaxone" presented at the 19th Annual Research Showcase of the College of Pharmacy at the University of Florida, Gainesville, February 23, 2006.

Research Group:

Research Assistant Professors:

Sarah Kim; January 2019 – May 2021 Rodrigo Cristofoletti; July 2019 – 2020 Brian Cicali; July 2022- TBD

Postdoctoral Fellows:

Dr. Xi-Ling Jiang (FDA); March 2012 – December 2013

Dr. Songmao Zheng (Adagene); September 2012 – December 2013

Dr. Mirjam Trame (AVROBIO); May 2013 - April 2014

Dr. Puneet Gaitonde (Pfizer); March 2013 - October 2014

Dr. Amit Somani (FDA); September 2013 – January 2014

Dr. Tanay Samant (Novartis); January 2014 – October 2015

Dr. Chakradhar Lagishetty (GSK); February 2014 – February 2016

Dr. Kumpal Madrasi (EMD Serono); July 2014 – August 2016

Dr. Felipe Hurtado (Novartis); September 2014 – August 2016

Dr. Sumit Basu (Merck); August 2015 - February 2017

Dr. Haitao Yang; (FDA) August 2015 - February 2018

Dr. Harik Chandasana (co-supervised with Dr. Derendorf, GSK); September 2015 – July 2018

Dr. Vishnu Sharma (shared post-doc with Dr. Trame); January 2016 - August 2017

Dr. Carolina de Miranda Silva (Merck); August 2016 - August 2018

Dr. Justine Badee (Novartis); February 2017 – May 2019

Dr. Farzaneh Maleki (Pfizer); July 2017 - November 2019

Dr. Amirhossein Hajihosseini (Biogen); July 2017 - November 2018

- Dr. Mohammed Akbar; July 2017 April 2019
- Dr. Sarah Kim (Assistant Professor at UF); July 2017 December 2018
- Dr. Nashid Farhan (Amgen); August 2017 August 2020
- Dr. Valvanera Vozmediano (Assistant Professor at UF); November 2017 March 2018
- Dr. Vijay Kumar Siripuram (shared post-doc with Dr. Vozmediano); August 2019 TBD
- Dr. Tao Long (Takeda); August 2019 March 2021
- Dr. Estevan Zimmermann (Eisai); October 2019 November 2021
- Dr. Francisco Morales (co-supervised with Dr. Kim); September 2019 TBD
- Dr. Meenakshi Srinivasan (GSK); July 2020 October 2021
- Dr. Soyoung Kim (National Institute of Mathematical Science in South Korea); September 2020 June 2022
- Dr. Michelle Pressly (FDA); October 2020 July 2021
- Dr. Leyanis Rodriguez Vera (shared post-doc with Dr. Vozmediano); July 2021 TBD
- Dr. Ahmed Abulfathi; February 2022 TBD
- Dr. Venkata Krishna Kowthavarapu; November 2022 TBD
- Dr. Carol Conchon Costa; December 2022 TBD
- Dr. Tatiana Iakovleva; February 2022 TBD

Ph.D. Students:

Primary Supervisor:

Jenna A Rhoades (left program for personal reasons); May 2012 – December 2012

Snehal Samant (FDA); August 2012 - August 2016

Jiexin Deng; January (Pfizer); 2013 – December 2016

Naveen Mangal (Biogen); January 2014 - Fall 2017

Sibo Jiang (Pfizer); August 2014 – August 2019

Yi-Ting Lien (Genentech); August 2015 – April 2020

Karthik Lingineni (Novartis); August 2017 – April 2021

Brian Cicali (Research Assistant Professor at UF); January 2018 - May 2022

Mohammed Almoslem; August 2019 - TBD

Huili Chen; August 2020 – TBD

Mai Abdelmageed; August 2021 – TBD

Anthony Gebhart; January 2022 – TBD

Xuefen Yin; January 2022 – TBD

Cameron Humerickhouse; August 2022 – TBD Clemence Boivin-Champeaux; August 2022 - TBD

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Luning Zhuang (committee member)

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Esther Luhmann

Roman Götz

Estevan Zimmermann

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Ramona Gebhard

Martin Ulbricht

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Jennifer Graeff

Yannik Hoffert

Marian Klose

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Yessica Imbriago

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Valvanera Vozmediano Esteban (Dynakin SL)

Yosuke Nakatani (Eisai)

Lena Klopp-Schulze (FU Berlin)