

## Stephan Schmidt, Ph.D., F.C.P

July 1, 2017

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### Personal Information:

Place of Birth: Sonneberg, Germany

Date of Birth: January 4, 1978

Nationality: German

Marital Status: Married, 2009

### Positions:

- 2017 - present Associate Professor  
Center for Pharmacometrics & Systems Pharmacology  
Department of Pharmaceutics  
College of Pharmacy  
University of Florida
- 2017 - present Associate Chair  
Department of Pharmaceutics  
College of Pharmacy  
University of Florida
- 2016 - present 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:**

- 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 *in vitro* 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)
  - PHA6125 (Advanced Pharmacokinetics and Pharmacodynamics)
- 2011 Lecturer at the Dutch Top Institute Pharma's (TI Pharma) Drug Discovery & Development Cycle (DDC)
- Interfacing discovery and development
  - PK/PD modeling
- 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
- PHA5127 & PHA5128
  - Pharmaceutical Skill Laboratory

### **Professional Affiliations:**

- 2015 - present International Pharmaceutical Federation (Federation Internationale Pharmaceutique, FIP)
- 2013 - present International Society of Pharmacometrics (ISoP)
- 2013 - present American Society for Clinical Pharmacology and Therapeutics (ASCPT)
- 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 - 2015 American Association of Pharmaceutical Scientists (AAPS)

**Additional Professional Activities:**

- 2017 - present 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 - present Editorial Board Member *CPT Pharmacometrics Syst Pharmacol*
- 2015 - present Vice Chair of the Systems Pharmacology Community for the American Society for Clinical Pharmacology and Therapeutics (ASCPT)
- 2015 - present Chair of the BPS Special Interest Group on PK/PD and Systems Pharmacology
- 2015 - present American College of Clinical Pharmacology (ACCP) 2016 Program Committee Member
- 2015 20<sup>th</sup> 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 - present 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: NIAID, 1P01AI123036-01

Title: “Optimizing Combination Therapy to Accelerate Clinical Cure of Tuberculosis”

Time period: 08/2016 – 07/2021

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 – 09/2017

Amount: \$2,209,415

Role: I (10%, 15%, 20%)

Source: FDA, Center for Drug Evaluation Research – Office of Generic Drugs, U01 RFA-FD-14-011

Title: “A Model- and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution”

Time period: 09/2014 – 09/2017

Amount: \$750,000

Role: co-PI (20%)

**Ongoing Research Support – Industry:**

N/A

**Completed Research Support – Federal:**

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

**Completed Research Support – Industry:**

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: 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 – 12/2015

Post-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%)

Role: PI

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%)

Agency: 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: 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: 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

Role: PI

**Completed Research Support – Other:**

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 *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™ 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. Deng J, Vozmediano V, Rodriguez M, Cavallari LH, **Schmidt S**. Genotype-guided dosing of warfarin through modeling and simulation. *Eur J Pharm Sci*. 2017 In Press.
2. Lesko LJ, Fang L, **Schmidt S**, Trame MN. Introduction: An Integrated Bioinformatics and Quantitative Modeling Approach to Investigate Potential Claims of Oral Generic Drug Product Bioequivalence. Accepted for publication in *J Clin Pharmacol*.
3. Samant T, Lukacova V, **Schmidt S**. Development and qualification of physiologically based pharmacokinetic models for drugs with atypical distribution behavior: a desipramine case study. *CPT Pharmacometrics Syst Pharmacol*. 2017; **6**:315-321
4. Arwood MJ, Deng J, Drodza K, Pugach O, Nutescu EA, **Schmidt S**, Duarte JD, Cavallari LH. Anticoagulation endpoints with clinical implementation of warfarin pharmacogenetics dosing in a real-world setting: A proposal for a new pharmacogenetics dosing approach. *Clin Pharmacol Ther* 2017; **101**:675-683.
5. Hamadeh IS, Klinker KP, Borgert SJ, Richards AI, Li W, Mangal N, Hiemenz JW, **Schmidt S**, Langae TY, Peloquin CA, Johnson JA, Cavallari LH. Impact of the CYP2C19 genotype on voriconazole exposure in adults with invasive fungal infections. *Pharmacogenet Genomics*. 2017; **27**:190-196.
6. Samant S, Jiang XL, Peletier LA, Shuldiner AR, Horenstein RB, Lewis JP, Lesko LJ, **Schmidt S**. Identifying clinically-relevant sources of variability: the clopidogrel challenge. *Clin Pharmacol Ther* 2017; **101**:264-273.
7. Jiang XL, Shen HW, Mager DE, **Schmidt S**, Yu AM. Development of a mechanism-based pharmacokinetic/pharmacodynamic model to characterize the thermoregulatory effects of serotonergic drugs in mice. *Acta Pharmaceutica Sinica B*. 2016; **6**:492-503.

8. Peletier LA, Jiang XL, Samant S, and **Schmidt S**. Analysis of a complex physiology-directed model for inhibition of platelet aggregation by clopidogrel. *Discrete Continuous Dyn Syst Ser A*. 2017; **37**:945-61.
9. Pigatto MC, de Araujo BV, Torres BG, **Schmidt S**, Magni P, Dalla Costa T. Population Pharmacokinetic Modeling of Etoposide Free Concentrations in Solid Tumor. *Pharm Res*. 2016; **33**: 1657-70.
10. Lagishetty CV, Deng J, Lesko LJ, Rogers H, Pacanowski M, **Schmidt S**. How informative are drug-drug interactions of gene-drug interactions? *J Clin Pharmacol*. 2016; **56**: 1221-31.
11. Gaitonde P, Garhyan P, Link C, Chien JY, Trame MN, **Schmidt S**. A comprehensive review of novel drug-disease models in diabetes drug development. *Clin Pharmacokinet*. 2016; **55**:769-88.
12. Jiang XL, Samant S, Horenstein RB, Shuldiner AR, Yerges-Armstrong LM, Peletier LA, Lesko LJ, **Schmidt S**. Development of a physiology-directed population pharmacokinetic and pharmacodynamic model for characterizing the impact of genetic and demographic factors on clopidogrel response in healthy adults. *Eur J Pharm Sci*. 2016; **82**: 64-78.
13. 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 and term neonates for Biopharmaceutics Classification System (BCS) class I and II compounds. *Br J Clin Pharmacol*. 2016; **81**: 137-47.
14. Zimmermann ES, Laureano JV, dos Santos CN, **Schmidt S**, Lagishetty CV, de Castro WV, Dalla Costa T. A simultaneous semi-mechanistic population analysis of levofloxacin in plasma, lung and prostate to describe the influence of efflux transporters on drug distribution following intravenous and intratracheal administration. *Antimicrob Agents Chemother*. 2015; **60**: 946-54
15. Samant TS, Mangal N, Lukacova V, **Schmidt S**. Quantitative clinical pharmacology for size and age scaling in pediatric drug development: a systematic review. *J Clin Pharmacol*. 2015; **55**: 1207-17. **\*\*Editor's choice of the month**
16. Jiang XL, Samant S, Lesko LJ, **Schmidt S**. Clinical pharmacokinetics and pharmacodynamics of clopidogrel. *Clin Pharmacokinet*. 2015; **54**: 147-166.
17. Zhang XY, Trame MN, Lesko LJ, **Schmidt S**. Sobol sensitivity analysis: a tool to guide the development and evaluation of systems pharmacology models. *CPT Pharmacometrics Syst Pharmacol*. 2015 Feb 25; 4:e6. doi: 10.1002/psp4.6.
18. Zheng S, Matzneller P, Zeitlinger M, **Schmidt S**. Development of a population pharmacokinetic model characterizing the tissue distribution of azithromycin in healthy subjects. *Antimicrob Agents Chemother*. 2014; **58**: 6675-84.
19. Zheng S, Gaitonde P, Andrew MA, Gibbs MA, Lesko LJ, **Schmidt S**. Model-based assessment of dosing strategies in children for monoclonal antibodies exhibiting target-mediated drug disposition. *CPT Pharmacometrics Syst Pharmacol*. 2014 Oct 1;3:e138. doi: 10.1038/psp.2014.38.
20. Lesko LJ and **Schmidt S**. Clinical implementation of genetic testing in medicine: a US regulatory science perspective. *Br J Clin Pharmacol*. 2014; **77**: 606-11.

21. Brill M, Houwink A, **Schmidt S**, van Dongen E, Hazebroek E, van Ramshorst B, Deneer V, Mouton J, Knibbe C. Reduced subcutaneous tissue distribution of cefazolin in morbidly obese versus non-obese patients determined using clinical microdialysis. *J Antimicrob Chemother.* 2014; **69**: 715-23.
22. Barbour A, **Schmidt S**, Zhuang L, Rand KH, Derendorf H. Application of pharmacokinetic/pharmacodynamic modeling and simulation for the prediction of target attainment of ceftobiprole against methicillin-resistant *Staphylococcus aureus* using MIC and time-kill curve based approaches. *Int J Antimicrob Agents.* 2014; **43**: 60-7
23. Jiang XL, Zhao P, Barrett JS, Lesko LJ, **Schmidt S**. Application of physiologically-based pharmacokinetic modeling to predict acetaminophen metabolism & pharmacokinetics in children. *CPT Pharmacometrics Syst Pharmacol.* 2013 Oct 16;2:e80. doi: 10.1038/psp.2013.55.
24. Boroujerdi MA, **Schmidt S**. A negative feedback model for a mechanism based description of longitudinal observations: application for bone turnover markers. *Methods Inf Med.* 2013; **52**: 484-93
25. Heuberger J, **Schmidt S**, Derendorf H. When is protein binding important? *J Pharm Sci.* 2013; **102**: 3458-67
26. Lesko LJ, Zheng S, **Schmidt S**. Systems approach in risk assessment. *Clin Pharmacol Ther.* 2013; **93**: 413-424.
27. Gonzales D, **Schmidt S**, Derendorf H. Importance of relating efficacy measures to unbound drug concentrations for anti-infective agents. *Clin Microbiol Rev.* 2013; **26**: 274-88.
28. Post TM, **Schmidt S**, Peletier LA, de Greef R, Kerbusch T, Danhof M. Application of a mechanism-based disease systems model for osteoporosis to clinical data. *J Pharmacokinetic Pharmacodyn.* 2013; **40**: 143-56
29. Lesko LJ and **Schmidt S**. Individualization: history, present state and opportunities for the future. *Clin Pharmacol Ther.* 2012; **92**: 458-66
30. **Schmidt S**, Post TM, Peletier LA, Boroujerdi MA, Danhof M. Coping with time scales in disease systems analysis: application to bone remodeling. *J Pharmacokinetic Pharmacodyn.* 2011; **38**: 873-900.
31. Liem-Moolenaar M, de Boer P, Timmers M, Schoemaker RC, van Hasselt JGC, **Schmidt S**, van Gerven JMA Pharmacokinetic-pharmacodynamic relationships of central nervous system effects of scopolamine in healthy subjects. *Br J Clin Pharmacol.* 2011; **71**: 886-98
32. Burkhardt O, Kumar V, **Schmidt S**, Kielstein JT, Welte T, Derendorf H. Underdosing of ertapenem in critically ill patients with pneumonia confirmed by Monte Carlo simulations. *Int J Antimicrob Agents.* 2010; **35**: 96-7.
33. **Schmidt S**, Gonzalez D, Derendorf H. Significance of protein binding in pharmacokinetics and pharmacodynamics. *J Pharm Sci.* 2010; **99**: 1107-22.
34. **Schmidt S**, Sabarinath SN, Barbour A, Abbanat D, Manitpisitkul P, Sha S, Derendorf H. pharmacokinetic-pharmacodynamic modeling of the in vitro activity of oxazolidinone antimicrobial agents against methicillin-resistant *Staphylococcus aureus*. *Antimicrob Agents Chemother.* 2009; **53**: 5039-45.

35. Barbour A, **Schmidt S**, Ma B, Schiefelbein L, Rand KH, Burkhardt O, Derendorf H. Clinical pharmacokinetics and pharmacodynamics of tigecycline. *Clin Pharmacokinet.* 2009; **48**: 575-84.
36. Barbour A, **Schmidt S**, Rout WR, Ben-David K, Burkhardt O, Derendorf H. Soft tissue penetration of cefuroxime determined by clinical microdialysis in morbidly obese patients undergoing abdominal surgery. *Int J Antimicrob Agents.* 2009; **34**: 231-5.
37. Barbour A, **Schmidt S**, Sabarinath SN, Grant M, Seubert C, Skee D, Murthy B, Derendorf H. Soft-tissue penetration of ceftobiprole in healthy volunteers determined by in vivo microdialysis. *Antimicrob Agents Chemother.* 2009; **53**: 2773-6.
38. Li Y, Nguyen MH, **Schmidt S**, Zhong L, Derendorf H, Clancy CJ. Pharmacokinetic/pharmacodynamic modelling and in vitro simulation of dynamic voriconazole-Candida interactions. *Int J Antimicrob Agents.* 2009; **34**: 240-5.
39. Barbour A, **Schmidt S**, Rand KH, Derendorf H. Ceftobiprole: a novel cephalosporin with activity against Gram-positive and Gram-negative pathogens, including methicillin-resistant *Staphylococcus aureus* (MRSA). *Int J Antimicrob Agents.* 2009; **34**: 1-7.
40. **Schmidt S**, Rock K, Sahre M, Burkhardt O, Brunner M, Lobmeyer MT, Derendorf H. Effect of protein binding on the pharmacological activity of highly bound antibiotics. *Antimicrob Agents Chemother.* 2008; **52**: 3994-4000.
41. **Schmidt S**, Barbour A, Sahre M, Rand KH, Derendorf H. PK/PD: new insights for antibacterial and antiviral applications. *Curr Opin Pharmacol.* 2008; **8**: 549-56.
42. **Schmidt S**, Banks R, Kumar V, Rand KH, Derendorf H. Clinical microdialysis in skin and soft tissues: an update. *J Clin Pharmacol.* 2008; **48**: 351-64.
43. Li Y, Nguyen MH, Cheng S, **Schmidt S**, Zhong L, Derendorf H, Clancy CJ. A pharmacokinetic/pharmacodynamic mathematical model accurately describes the activity of voriconazole against *Candida* spp. in vitro. *Int J Antimicrob Agents.* 2008; **31**: 369-74.
44. Treyaprasert W, **Schmidt S**, Rand KH, Suvanakoot U, Derendorf H. Pharmacokinetic/pharmacodynamic modeling of in vitro activity of azithromycin against four different bacterial strains. *Int J Antimicrob Agents.* 2007; **29**: 263-70.
45. **Schmidt S**, Schuck E, Kumar V, Burkhardt O, Derendorf H. Integration of pharmacokinetic/pharmacodynamic modeling and simulation in the development of new anti-infective agents - minimum inhibitory concentration versus time-kill curves. *Expert Opin Drug Discov* 2007; **2**: 849-60.
46. Burkhardt O, Brunner M, **Schmidt S**, Grant M, Tang Y, Derendorf H. Penetration of ertapenem into skeletal muscle and subcutaneous adipose tissue in healthy volunteers measured by in vivo microdialysis. *J Antimicrob Chemother.* 2006; **58**: 632-6.

**Books:**

**Schmidt S** and Derendorf H (ed.) *Applied pharmacometrics*. Springer, New York, NY, 2014.

### **Book Chapters:**

1. 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.
2. 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.
3. 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.
4. **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 Presentation:**

1. **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.
2. **Schmidt S**. “What quantitative clinical pharmacology & life taught me about drugs” presented at the 11<sup>th</sup> Global Gator Symposium, Düsseldorf, June 17, 2017.
3. **Schmidt S**. “Quantitative and systems pharmacology – what’s in it for me?” presented at Roche, Basel, June 14, 2017.
4. **Schmidt S**. “How informative are drug-drug interactions of gene-drug interactions?” present as webinar for the American College of Clinical Pharmacology (ACCP), March 1, 2017.
5. **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.
6. **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.
7. **Schmidt S**. “How Quantitative and Systems Pharmacology Can Bring Value to R&D”, presented at Sanofi-Aventis, Bridgewater, NJ, April 14, 2016.
8. **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.
9. **Schmidt S**. “Development of a Drug-Disease Model for Postmenopausal Osteoporosis”, presented at the JSCPT/ISOP meeting in Tokyo, Japan, December 9, 2015.
10. **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.
11. **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.

12. **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.
13. **Schmidt S.** “Mechanism-Based Drug-Disease Modeling Applied to Drug Development and Regulatory Decision Making”, 10<sup>th</sup> International Congress of Pharmaceutical Sciences, Ribeirão Preto, Brazil, September 8, 2015.
14. **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.
15. **Schmidt S.** “Physiologically-based modeling in translational research”, VI PPGCF UFRGS Meeting, Porto Alegre, November 21, 2014.
16. 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.
17. Jiang XL, Zhao P, Barrett JA, Lesko LJ, **Schmidt S.** „Application of physiologically-based pharmacokinetic modeling to predict acetaminophen metabolism & pharmacokinetics in children“, ASCPT, Atlanta, March 21, 2014. **\*\*ASCPT Encore abstract**
18. **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.
19. 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**
20. **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.
21. **Schmidt S.** “Mechanism-based analysis of disease systems: principle and application to post-menopausal osteoporosis” presented at the 1<sup>o</sup> Congresso da Associação Brasileira de Ciências Farmacêuticas, Ipojuca, October 7, 2012.
22. **Schmidt S.** “Mechanism-based PKPD modeling: principle and applications” Keynote speaker at the 10<sup>th</sup> Congress of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Budapest, June 28, 2011.
23. **Schmidt S.** “Coping with time scales in disease systems analysis: application to bone remodeling” presented at the 20<sup>th</sup> meeting of the population approach group in Europe (PAGE), June 10, 2011.
24. **Schmidt S.** “Microdialysis: a valuable tool for identifying clinically relevant PK/PD relationships” presented at the 13<sup>th</sup> International Conference for in vivo Methods: Monitoring Molecules in Neuroscience, Brussels, September 16, 2010.
25. **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.

26. **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.
27. **Schmidt S.** “PK/PD modeling of Linezolid against MRSA” presented at the 17<sup>th</sup> annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, March 31 – April 3, 2007.
28. **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.
29. **Schmidt S.** “Experimental pitfalls in protein binding measurements” presented at the Annual Infectious Disease Fellowship Forum, Brainerd, MN, June 8-11, 2006.
30. **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. 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.
2. 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.
3. 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.
4. 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**
5. 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**
6. 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.
7. Hurtado FK, Garhyan P, Chien JY, **Schmidt S.** *Poster.* “Predicting end-of-trial fasting glucose and HbA<sub>1c</sub> 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.

8. 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.
9. 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.
10. 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<sup>®</sup>” presented at the Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 25, 2016. **\*\*ACCP Student and Trainee Award**
11. 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**
12. Madras 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.
13. 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.
14. 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.
15. 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.
16. 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 20<sup>th</sup> North American Meeting of the International Society for the Study Xenobiotics (ISSX), October 21, 2015.
17. 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 20<sup>th</sup> North American Meeting of the International Society for the Study Xenobiotics (ISSX), October 21, 2015.
18. 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**



19. 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**
20. 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.
21. 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.
22. 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.
23. 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
24. 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, M 2015.
25. Lagishetty C, Deng J, Lesko LJ, Rogers H, **Schmidt S**. “How informative are drug-drug 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**
26. 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.
27. Gaitonde P, Garhyan P, Chien JY, **Schmidt S**. “Drug-systems disease model to predict treatment outcome in Type 2 Diabetes Mellitus” presented at the presented at the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (ASCPT), New Orleans, March 5, 2015.
28. 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.
29. Samant T, Lukacova V, Lesko LJ, **Schmidt S**. “Enzyme focused PBPK modelling in adults for candidate drugs using GastroPlus” presented at the 5<sup>th</sup> American Conference on Pharmacometrics, Las Vegas, October 15, 2014.

30. 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 5<sup>th</sup> American Conference on Pharmacometrics, Las Vegas, October 15, 2014.
31. 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 5<sup>th</sup> American Conference on Pharmacometrics, Las Vegas, October 14, 2014.
32. 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 the Institute for Child Health Policy (IHP) Annual Research Day, Gainesville, November 4, 2014, 5<sup>th</sup> American Conference on Pharmacometrics, Las Vegas, October 13, 2014. **\*\*Encore abstract at ASCPT 2015**
33. 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 5<sup>th</sup> American Conference on Pharmacometrics, Las Vegas, October 13, 2014.
34. Gaitonde P, Trame MN, Garhyan P, Chien JY, **Schmidt S**. “Development of a Drug-Systems-Disease Model for Type 2 Diabetes Mellitus” presented at the 43<sup>rd</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Atlanta, September 16, 2013. **\*\*ACCP Student and Trainee Award**
35. 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 43<sup>rd</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Atlanta, September 14, 2013. **\*\*ACCP Student and Trainee Award**
36. 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.
37. 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 23<sup>rd</sup> meeting of the population approach group in Europe (PAGE), Alicante, June 12, 2014.
38. 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 24<sup>th</sup> annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Barcelona, May 12, 2014.
39. 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.

40. 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 42<sup>nd</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 23, 2013. **\*\*ACCP Student and Trainee Award, New Member Abstract Award**
41. Zheng S, Matzneller P, Zeitlinger M, Lesko LJ, **Schmidt S**. “Development of a tissue distribution population pharmacokinetic model for azithromycin” presented at the 42<sup>nd</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Bethesda, September 23, 2013. **\*\*ACCP Student and Trainee Award**
42. 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 22<sup>nd</sup> meeting of the population approach group in Europe (PAGE), Glasgow, June 12, 2013.
43. 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**
44. 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**
45. 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**
46. **Schmidt S**, Post TM, Peletier LA, Boroujerdi MA, Danhof M. “Mathematical model reduction: an innovative tool for analyzing complex dynamic systems” presented at the 40<sup>th</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Chicago, September 12, 2011. **\*\*ACCP Student and Trainee Award**
47. 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 20<sup>th</sup> meeting of the population approach group in Europe (PAGE), Athens, June 8, 2011.
48. 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.
49. **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**

50. **Schmidt S**, Post TM, Boroujerdi MA, Peletier LA, Danhof M, Della Pasqua OE. “Implication of differences in model parameterization in osteoporosis” presented at the 19<sup>th</sup> meeting of the population approach group in Europe (PAGE), June 10, 2010.
51. **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 6<sup>th</sup> International Symposium on Measurement & Kinetics of In Vivo Drug Effects, Noordwijkerhout, April 22, 2010.
52. Gonzalez D, **Schmidt S**, Derendorf H. “Effect of protein binding on half-life of elimination” presented at at the 38<sup>th</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Antonio, September 14, 2009. **\*\*ACCP Student and Trainee Award**
53. **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.
54. 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.
55. 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 48<sup>th</sup> Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46<sup>th</sup> Annual Meeting, Washington DC, October 27, 2008.
56. 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 48<sup>th</sup> Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46<sup>th</sup> Annual Meeting, Washington DC, October 27, 2008.
57. 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 48<sup>th</sup> Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46<sup>th</sup> Annual Meeting, Washington DC, October 27, 2008.
58. **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 48<sup>th</sup> Annual Interscience on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA) 46<sup>th</sup> Annual Meeting, Washington DC, October 27, 2008.
59. 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

60. Barbour A, **Schmidt S**, Derendorf H. “Combination of clinical microdialysis and *in vitro* pharmacodynamics for dose optimization of beta-lactam antibiotics” presented at the 37<sup>th</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Philadelphia, September 15, 2008. **\*\*ACCP Student and Trainee Award**
61. **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 37<sup>th</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), Philadelphia, September 15, 2008.
62. **Schmidt S**, Roeck K, Sahre M, Derendorf H. “Protein binding – a source for many pitfalls” presented at the 21<sup>st</sup> 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**
63. **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 47<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Chicago, September 17 – 20, 2007, 1<sup>st</sup> Emerging Pathogen Institute (EPI) meeting, Gainesville, December 13, 2007.
64. **Schmidt S**, Abbanat D, Manitpisitkul P, Blake J, Sha S, Derendorf H. “Linezolid against MRSA – a new modeling approach” presented at the 36<sup>th</sup> Annual Meeting of the American College of Clinical Pharmacology (ACCP), San Francisco, September 9 – 11, 2007. **\*\*ACCP Student and Trainee Award, Genentech Podium Award**
65. **Schmidt S**, Derendorf H, “Linezolid vs. MRSA – a new PK/PD model” presented at 20<sup>th</sup> 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**
66. **Schmidt S**, Burkhardt O, Sahre M, Derendorf H. “Experimental pitfalls in protein binding measurements” presented at the 16<sup>th</sup> 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**
67. **Schmidt S**, Burkhardt O, Treyaprasert W, Derendorf H. “PK/PD challenges of *in vitro* time-kill curves – a new modeling approach” presented at the 16<sup>th</sup> annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, April 1 – 4, 2006.
68. **Schmidt S**, Burkhardt O, Schubert S, Dalhoff A, Derendorf H. “Carbapenems – differences in their antimicrobial activity due to their protein binding” presented at the 16<sup>th</sup> annual meeting of the European Society of Clinical Microbiology and Infectious Diseases (ECCMID), Munich, April 1-4, 2006.
69. **Schmidt S**, Treyaprasert W, Derendorf H. “Effect of protein binding on the efficacy of ceftriaxone” presented at the 19<sup>th</sup> Annual Research Showcase of the College of Pharmacy at the University of Florida, Gainesville, February 23, 2006.

## **Research Group:**

### ***Postdoctoral Fellows:***

Xi-Ling Jiang (Janssen Pharmaceuticals, Inc.); March 2012 – December 2013  
Songmao Zheng (Janssen Pharmaceuticals, Inc.); September 2012 – December 2013  
Mirjam Trame (Assistant Professor at UF); May 2013 – April 2014  
Puneet Gaitonde (Pfizer); March 2013 – October 2014  
Amit Somani (Alkermes); September 2013 – January 2014  
Tanay Samant (Novartis); January 2014 – October 2015  
Chakradhar Lagishetty (GSK); February 2014 – February 2016  
Kumpal Madrasi; (Applied Biomath) July 2014 – August 2016  
Felipe Hurtado; (Novartis) September 2014 – August 2016  
Sumit Basu; June 2015 - TBD  
Haitao Yang; August 2015 - TBD  
Vishnu Dutt Sharma (shared post-doc with Dr. Trame); January 2016 – TBD  
Carolina de Miranda Silva; August 2016 – TBD  
Amirhossein Hajihosseini; July 2017 – TBD  
Farzaneh Maleki; July 2017 – TBD  
Sarah Kim; July 2017 - TBD

### ***Ph.D. Students:***

#### Primary Supervisor:

Jenna A Rhoades (left program for personal reasons); May 2012 – December 2012  
Snehal Samant; August 2012 – August 2016  
Jiexin Deng; January 2013 – December 2016  
Naveen Mangal; January 2014 – Anticipated Summer 2017  
Sibo Jiang; August 2014 – Anticipated Fall 2018  
Yi-Ting Lien; August 2015 – Anticipated Fall 2019

#### Committee Member:

Xuyang Song (committee member)  
Luning Zhuang (committee member)  
Andressa Braga (committee member)

### ***Masters Students:***

Jules Heuberger

### ***International Exchange Students:***

Catharina Link  
Teresa Wermter  
Lucia Auctor  
Michaela Breitsamer  
Esther Luhmann  
Roman Götz  
Estevan Zimmermann  
Miriam Sturm  
Johanna Schäfer  
Carolina de Miranda Silva  
Markus Meyer  
Maximilian Siebert

***Visiting Scientists:***

Valvanera Vozmediano Esteban (Dynakin SL)

Yosuke Nakatani (Eisai)

Lena Klopp-Schulze (FU Berlin)