FDA Office of Generic Drugs Office of Research & Standards (ORS)
Presentations by External Collaborators and ORS Staff in Fiscal Year 2015

1. Alloway R. American Society of Transplantation Midday Symposium May 2015: Generic Tacrolimus: Good Medicine or Cheap Fix? American Transplant Congress, Philadelphia, PA, May 3, 2015.
2. Alloway R. Generic Tacrolimus: Good Medicine or Cheap Fix?? Results of U01 study comparing tacrolimus brand and the 2 most disparate generics in renal and liver transplant recipients, British Columbia Transplant Patient Support Group, Vancouver, Canada, May 12, 2015.
3. Alloway R. Generic Tacrolimus: Good Medicine or Cheap Fix?? University of Michigan Transplant Grand Rounds, Ann Arbor, MI, Nov 3, 2015.
4. Alloway R. Generics-the good and bad, Minnesota Transplant Immunosuppression 2015: Improving Outcomes, Minneapolis, MN, Oct 8, 2015.
5. Babiskin A, Kim H, Fang L, Lapteva L, Jiang W, Lionberger R. Use of partial AUC to demonstrate bioequivalence of generic methylphenidate extended release products using physiological-based absorption modeling and simulation, American Society for Clinical Pharmacology and Therapeutics Annual Meeting, New Orleans, LA, March, 2015.
6. Boyce H, Smith D, Gurvich V, Byrn S, Hoag SW. Can we standardize household tools? Category 1 Focus Group Meeting, Washington, DC, Nov 4, 2015.
7. Burgess DJ. In Vitro Release Testing and the Development of IVIVC for Long Acting Parenterals, Shanghai Institute of Planned Parenthood Research, Shanghai, China, October, 2015.
8. Burgess DJ. In Vitro Release Testing Methods and the Development of IVIVC for Complex Drug Products, 2nd Annual Bioequivalence Summit, Boston, MA, October, 2015.
9. Burgess DJ. In Vitro Release Testing Methods and the Development of IVIVC for Complex Drug Products, Fudan University, Shanghai, China, October, 2015.
10. Choi S. Bioequivalence Requirements for Ophthalmic Products: CMC and Clinical/Pharmacokinetic Considerations, AAPS 2015, Orlando, FL, October 25-29, 2015.
11. Cohen-Wolkowiez M. Use of Clinical Practice Data and PK/PD Modeling to aid Classification of Narrow Therapeutic Index Drugs, 2015 American Society of Clinical Pharmacokinetics and Therapeutics Annual Meeting, New Orleans, LA, March 3-7, 2015.
12. Cordery SF, Shehab MZ, Bunge AL, Delgado-Charro MB, Guy RH. Sampling The Stratum Corneum To Quantify Drug Uptake From Topical Products, IATDMCT, Rotterdam, The Netherlands, October 11-15, 2015.
13. Doty AC, Hirota K, Olsen K, Ackermann R, Feng R, Qu W, Wang Y, Choi S, Schwendeman A, Schwendeman SP. A Cage Implant System for Assessing In Vivo Controlled Release Performance of Long-Acting Release PLGA Depots, The 9th International Sympsium on Intelligent Drug Delivery Systems at Korea Institute of Science and Technology, Seoul, Korea, 2015.
14. Fang L. Bioequivalence Standards for Narrow Therapeutic Index (NTI) Drugs: Are They Stringent Enough to Ensure Safety and Efficacy? ASCPT, New Orleans, LA, March 15, 2015.
15. Gomeni R, Bressole F, Spencer TJ, Faraone SV. Meta-analytic approach to evaluate alternative models for characterizing the PK profiles of extended release formulations of MPH, American

Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, New Orleans, LA, March 15, 2015.

16. Gomeni R, Bressole F, Spencer TJ, Faraone SV. Optimal study design to evaluate the clinical response of extended release formulations of methylphenidate in a pediatric population, American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, March 15, 2015. New Orleans, LA, New Orleans, LA, March 15, 2015.
17. Gomeni R, Bressole F, Spencer TJ, Faraone SV. Use of a clinical response index derived from a PK/PD model to estimate the optimal in vivo release rate of extended release formulations of MPH, American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, March 15, 2015. New Orleans, LA, New Orleans, LA, March 15, 2015.
18. Guy R. Predicting, Measuring And Optimizing Drug Delivery To The Skin, AGAH 6th Dermatological Product Development Workshop, London, UK, June 24, 2015.
19. Hirota K, et al. Characterization release mechanisms of leuprolide-loaded PLGA microparticles for IVIVC development, AAPS Annual Meeting, Orlando, FL, October, 2015.
20. Jayaraman B, Brasseur J, Wang Y. Influence of Non-homogeneous Particle Distributions on Drug Release in a Couette in vitro Dissolution Device, 68th Annual Meeting of the American Physical Society (APS) Division of Fluid Dynamics, Boston, MA, November 22-24, 2015.
21. Jiang W, et al. FDA OGD updates on generic AEDs and NTI designation, American Epilepsy Society annual meeting, Philadelphia, PA, December, 2015.
22. Khokhar B, Park Y, Pradel F, Palumbo F, Kiptanui Z, Dutcher S, Jiang W, Zuckerman I. Patients' Awareness of Bioequivalence Study Methods Supporting Generic Venlafaxine Extended Release (ER) Tablet Approval, 31st International Conference on Pharmacoepidemiology, August 22-26, 2015.
23. Kim H, Fang L, Choi S, Bourne D, Zhao L, Lionberger R. Exploration of Model-Based Bioequivalence Evaluation as an Alternative Approach for the Sparse Pharmacokinetic Sampling Design, 6th American Conference on Pharmacometrics, Crystal City, VA, October, 2015.
24. Lesko L, 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, Annual Meeting of the American College of Clinical Pharmacology, San Francisco, CA, September, 2015.
25. Lesko L, 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, FDA Science Day, Washington, DC, June, 2015.
26. Murthy N. Evaluating Quality (Q3) Attributes And Potential Failure Modes For Topical Semisolid Drug Products, AAPS Annual Meeting Symposium: Bio-Equivalence Standards for Topicals (BEST): Evidence for Integrating Multiple Quality (Q3) and Performance Tests to Evaluate the Best Generic Products, Orlando, FL, October 28, 2015.
27. Murthy N. Topical Semisolid Drug Product Critical Quality Attributes (Q3 Characterization) With Relevance To Topical Bioequivalence, Rutgers Center for Dermal Research Workshop: The Role of Topical Semi-solid Microstructure on Product Performance and Functionality, Piscataway, NJ, July 15, 2015.
28. Patel N. Development and Validation of Dermal PBPK Model Towards Virtual Bioequivalence Assessment, DMDG Symposium: 100 Years of Drug Delivery, GSK, Ware, October 06, 2015.

29. Polli JE. Bioequivalence studies in patients, 2nd MENA Regulatory Conference on Bioequivalence, Biowaivers, Bioanalysis, Dissolution and Biosimilars, Amman, Jordan, September, 2015.
30. Polli JE. Biopharmaceutic Risk Assessment of Brand And Generic Lamotrigine Tablets: In Vitro And In Vivo, Gazi University Regional Meeting, Antalya, Turkey, November, 2015.
31. Polli JE. Generic versus brand-name lamotrigine bioequivalence in generic-sensitive epilepsy patients: a field test of the public bioequivalence standard, American Epilepsy Society annual meeting, Philadelphia, PA, December, 2015.
32. Raney SG. Characterizing Critical Quality Attributes for Topical Semisolid Dosage Forms, USP Workshop on Quality Testing of Drug Products Applied to the Skin, Rockville, MD, September 22, 2015.
33. Raney SG. Considerations Relating To Product Quality Characterization For Topical Semisolid Dosage Forms, Pharmacopeia Workshop on Quality Attributes of Drug Products Applied to the Skin, Rockville, MD, September 22, 2015.
34. Rantou E. Assessing Bioequivalence of Locally-Acting Generic Products; Statistical Controversies and Arising Issues, ASA Biopharmaceutical Section Statistics Workshop, Washington, DC, September, 2015.
35. Sandell D. Varying Particle Size and Excipient Levels For Three MDIs: Effects on In-Vitro Performance,4th Medicon Valley Inhalation Symposium (MVIC), Medicon Village, Lund, Sweden, October, 2015.
36. Shen J. In Vitro Release Testing Of Complex Parenteral Dosage Forms, SOTAX 10th Annual SAP Apparatus 4 seminar, 2015.
37. Sinner F. Evaluating Topical Bioavailability In Vivo by Dermal Open Flow Microperfusion and Equivalence by IVRT, AAPS Annual Meeting Symposium: Bio-Equivalence Standards for Topicals (BEST): Evidence for Integrating Multiple Quality (Q3) and Performance Tests to Evaluate the Best Generic Products, Orlando, FL, October 28, 2015.
38. Sinner F. Tissue Specific PK and PD Enabled by Open Flow Microperfusion: From Bioequivalence to Mechanism of Drug Action POC Studies, AGAH 6th Dermatological Product Development Workshop, London, UK, June 24, 2015.
39. Stinchcomb A. Evaluating Topical Bioavailability In Vivo by Skin Stripping and In Vitro by IVPT, AAPS Annual Meeting Symposium: Bio-Equivalence Standards for Topicals (BEST): Evidence for Integrating Multiple Quality (Q3) and Performance Tests to Evaluate the Best Generic Products, Orlando, FL, October 28, 2015.
40. Stinchcomb AL. Challenges In The Development Of Bioequivalent Topically Applied Drug Products, Bioequivalence Summit, Boston, MA, October, 2015.
41. Stinchcomb AL. Topical Bioequivalence: Performance Evaluation In Vivo And In Vitro By Skin Stripping And IVPT, AAPS 2015, Orlando, FL, October 25-29, 2015.
42. Szaflarski JP, Privitera M, Diaz F, et al. Bioequivalence Testing of Disparate Generic Lamotrigine Products in People with Epilepsy: The EQUIGEN Repeated Single-Dose Study, 31st International Epilepsy Congress, Istanbul, Turkey, September, 2015.
43. Ting TY. Generic versus brand-name lamotrigine bioequivalence in generic-sensitive epilepsy patients: a field test of the public bioequivalence standard, Antiepileptic Drug and Device Trials XIII, Aventura, FL, May, 2015.