

**FDA Office of Generic Drugs Office of Research & Standards (ORS)  
Presentations by External Collaborators and ORS Staff in Fiscal Year 2014**

1. Alloway R. Generic Drugs: Good Medicine or Cheap Fix? Transplant Grand Rounds, Washington University, St Louis, MO, March, 2014.
2. Berg MJ, et al. Equivalence among generic AEDs (EQUIGEN) - single-dose study, 68th Annual Meeting of the American Epilepsy Society, Seattle, WA, December 5-9, 2014.
3. Boyce H, Ashour A, Deshpande T, Hoag SW. Quantification of polymer-excipient concentration in commercial pharmaceutical drug products by diffuse reflectance near infrared spectroscopy, International Diffuse Reflectance Conference (IDRC), Chambersburg, PA, Aug 2-8, 2014.
4. Cohen-Wolkowicz, M. Clinical practice data to aid narrow therapeutic index drug classification, Questioning the Bioequivalence Standards for Antiepileptic Drugs conference, Silver Spring, MD, May, 2014.
5. Diaz FJ, et al. Random-effects linear modeling and sample size computations for two special cross-over designs of average bioequivalence studies, Symposium of the Kansas-Western Missouri Chapter of the American Statistical Association, Innovations in Design, Analysis, and Dissemination: Frontiers in Biostatistical Methods, Kansas City, MO, April 24-25, 2014.
6. Diaz FJ, et al. Random-effects linear modeling and sample size computations for two special cross-over designs of average bioequivalence studies, Joint Statistical Meeting of the American Statistical Association, Boston, MA, August 2-7, 2014.
7. Ficker D, et al. Patients reporting problems after generic antiepileptic drug switches are unlikely to participate in a generic bioequivalence trial, 68th Annual Meeting of the American Epilepsy Society, Seattle, WA, December 5-9, 2014.
8. Holt J, Hickey A, Sandell D. From Q2 To QbD: The Influence of Formulation Changes on MDI Performance, Respiratory Drug Delivery (RDD) Asia Conference, Goa, India, November 13, 2014.
9. Jiang W, et al. FDA OGD'S Post-Marketing Studies To Ensure Therapeutic Equivalence Of Generic Anti-Epileptic Drugs In Epilepsy Patients, 2014 American Epilepsy Society Annual Meeting, Seattle, WA, December 4-8, 2014.
10. Jiang W, et al. Lamotrigine, a Narrow Therapeutic Index Drug or Not? 2014 American Academy of Neurology Annual Meeting, Philadelphia, PA, April 26 – May 3, 2014.
11. Jiang W, et al. Pharmaceutical Quality Assessment of Generic Lamotrigine IR Tablets, 2014 American Academy of Neurology Annual Meeting, Philadelphia, PA, April 26 – May 3, 2014.
12. Longest PW. In silico orally inhaled product development, Orlando Inhalation Conference - Approaches in International Regulation, Orlando, FL, March 19-21, 2014.
13. Polli J. Can I trust my generic antiepileptic drug? Methods and limitations of bioequivalence testing, Neurology Grand Rounds, University of Maryland,, Baltimore, MD, January, 2014.
14. Polli JE, Ting TY, Jiang W. Can we trust standard healthy volunteer data to assess generic drug quality: Lamotrigine experience in patients? Abstracts of the Annual Meeting of the American Academy of Neurology, Philadelphia, PA, April 26 – May 3, 2014.
15. Polli JE, Ting TY, Jiang W. What a “drop-out” reveals about the nocebo effect in patients, Abstracts of the Annual Meeting of the American Academy of Neurology, Philadelphia, PA, April 26 – May 3, 2014.

16. Polli JE. Results of Bioequivalence in Epilepsy Patients (BEEP) Study, University of Copenhagen, Copenhagen, Denmark, October, 2014.
17. Privitera M, et al. Testing of disparate generic lamotrigine products using chronic dosing in people with epilepsy: the EQUIGEN study, 68th Annual Meeting of the American Epilepsy Society, Seattle, WA, December 5-9, 2014.
18. Shen J, Qu W, Choi S, Wang Y, Burgess DJ. Development of an In Vitro Release Testing Method for Porous PLGA Microsphere, AAPS 2014, San Diego, CA, November 2-6, 2014.
19. Smith D, et al. Subject-unrecognized medication adherence errors in the equivalence among generic AED (EQUIGEN) chronic dose trial, 68th Annual Meeting of the American Epilepsy Society, Seattle, WA, December 5-9, 2014.
20. Ting TY, Jiang W, Polli JE. Generic versus brand-name lamotrigine bioequivalence in generic-sensitive epilepsy patients: a field test of the public bioequivalence standard, Abstracts of the Annual Meeting of the American Academy of Neurology, Philadelphia, PA, April 26 – May 3, 2014.
21. Wu K, et al. Pharmaceutical Quality Assessment of Generic Lamotrigine IR Tablets, 2014 American Academy of Neurology Annual Meeting, Philadelphia, PA, April 26 – May 3, 2014.