Richard C. Zink, Ph.D.

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SUMMARY

Richard C. Zink is Principal Research Statistician Developer in the JMP Life Sciences division at SAS Institute. He is currently a developer for JMP Clinical, an innovative software package designed to streamline the review of clinical trial data. Richard joined SAS in 2011 after eight years in the pharmaceutical industry, where he designed and analyzed clinical trials in diverse therapeutic areas including infectious disease, oncology, and ophthalmology, and participated in US and European drug submissions and FDA advisory committee hearings. Richard is the Publications Officer for the Biopharmaceutical Section of the American Statistical Association, and the Statistics Section Editor for the *Therapeutic Innovation & Regulatory Science (formerly Drug Information Journal)*. He holds a Ph.D. in Biostatistics from the University of North Carolina at Chapel Hill, where he serves as an Adjunct Assistant Professor of Biostatistics. His research interests include data visualization, the analysis of pre- and post-market adverse events, subgroup identification for patients with enhanced treatment response, and the assessment of data integrity in clinical trials. He is author of *Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS*, and co-editor of *Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods*.

PHARMACEUTICAL EXPERIENCE

Clinical & Therapeutic Areas

- Antiviral: HBV, HIV
- Oncology: Chronic Myeloid Leukemia
- Ophthalmology: Dry Eye Disease, Glaucoma, Blepharitis
- Pulmonary: Cystic Fibrosis

Clinical Development

- Design and analysis of clinical trials Phase I-IV
- Simulation of power, futility, probability of success and multiple comparison procedures
- Simulation of best subset of secondary endpoints to control for type I error
- Futility analyses utilizing conditional power and blinded sample size reassessment
- Longitudinal modeling and analysis of correlated outcomes
- Crossover and non-inferiority designs and meta-analysis
- Data mining to locate maximum treatment effect among subgroups
- Data mining methods in pharmacovigilance
- Randomization schedules
- Antiviral and oncology NDAs, MAAs, advisory committees and regulatory response
- Outsource & manage: Biostatistics, Data Management, Statistical Programming, DMC members
- Co-author: SAPs, DMC Charters and SOP, Protocols, CSRs, CRFs, ISEs, and scientific publications
- SDTM and ADaM standards, WHODRUG and MedDRA coding

Preclinical Development

- Design and analysis of *In vitro* and *In vivo* experiments
- Sparse-sampling and resampling methods in pharmacokinetics
- Support INDs and patents

Pharmaceutical Sciences

- Drug product and substance stability
- Shelf-life predictions
- Sample-pooling methods

Corporate, Sales and Marketing
- Due-diligence with investors and potential partners
- Support in/out-licensing activities
- Collaborate with sales analytics for optimal sample allocation and sales-calling methods
- Sales forecasting and simulation

PROFESSIONAL POSITIONS

SAS Institute, Inc., JMP Life Sciences
- Principal Research Statistician Developer — Apr 2011 – Present

University of North Carolina at Chapel Hill, Department of Biostatistics
- Adjunct Assistant Professor — Oct 2014 – Present

Inspire Pharmaceuticals
- Principal Statistical Scientist I — May 2009 – Feb 2011
- Senior Statistical Scientist II — Jul 2006 – May 2009

Bristol-Myers Squibb, Pharmaceutical Research Institute
- Senior Research Biostatistician — Apr 2005 – Jul 2006
- Research Biostatistician — Jul 2003 – Apr 2005

University of North Carolina at Chapel Hill, Department of Biostatistics
- Research Assistant / Consultant
  - Correlated Binary Data — Aug 2002 - May 2003
  - Biometric Consulting Laboratory — Aug 2000 – Aug 2002
  - Statistical Genetics — Aug 1998 – Apr 2000
  - Collaborative Studies Coordinating Center — Jul 1997 – Aug 1998

National Institutes of Health, National Institute on Aging
Laboratory of Cardiovascular Science
- Statistics Intern — Aug 1995 – May 1997

EDUCATION

University of North Carolina at Chapel Hill, Department of Biostatistics
- Doctor of Philosophy in Biostatistics — 1999 – 2003
- Master of Science in Biostatistics — 1997 – 1999

University of Maryland Baltimore County
Department of Mathematics and Statistics
- Bachelor of Science in Mathematics — 1992 – 1996

COMPUTER SKILLS

Statistics Packages: SAS/STAT, SAS/IML, SAS Macro, SAS/Graph, JMP Clinical with some proficiency in SAS/ETS, WinBUGS, East, StatXact, SUDAAN, CART, S-Plus, R, GLIM

Programming Languages: JSL, SQL, C

Genetic Packages: CLUSTAL, PHYLIP, PAUP, SeqLab (GCG)

Operating Systems: Windows, UNIX

Word Processing: LaTeX, Word, Excel, PowerPoint, WordPerfect

PROFESSIONAL SOCIETIES

American Statistical Association 1998 – Present
Biopharmaceutical Section

- Publications Officer (elected) 2016 – 2018
- Steering Committee 2014 – Present
- Scientific Working Group on Safety Data Analysis 2014 – Present
- Communication-Publications Committee 2013 – Present
- Mentoring Program 2015 – Present
- Podcasts (http://www.buzzsprout.com/16296/) 2013 – Present
- Regulatory-Industry Statistics Workshop
  - Industry co-chair 2015
  - Steering Committee 2014 – 2017
  - Organizing Committee 2012 – 2015
  - Co-editor for Special Issue for *Statistics in Biopharmaceutical Research* 2015

Drug Information Association 2011 – Present

- Bayesian Scientific Working Group – Safety Team 2013 – Present
- Statistical Section Editor of *Therapeutic Innovation & Regulatory Science* 2012 – Present
- Editorial Board of *Therapeutic Innovation & Regulatory Science* 2011 – Present

Statisticians in the Pharmaceutical Industry 2013 – Present

International Biometric Society, Eastern North American Region 1998 – 2012

PROFESSIONAL DEVELOPMENT

American Statistical Association Biopharmaceutical Section Webinars

- Data Monitoring in Practice: Making Your DMC Effective 2010
- Advances in Non-Parametric Dose-Response Models in Adaptive Designs 2010
- Bayesian Clinical Trials 2009
- Assessment of QTc Prolongation in Clinical Drug Development 2008
- Adaptive Designs in Clinical Trials: Introduction, Term. & Classification 2007
- Generalized Linear Mixed Models 2007
- Multiple Comparisons in Clinical Trials 2007

American Statistical Association Biopharmaceutical Section Statistics Workshop

- Introduction to PK/PD Modeling for Statisticians 2015
- Dose Finding in Drug Development with Focus on MCP-Mod 2015

American Statistical Association Joint Statistical Meetings Short Courses

- Applied Data Mining 2010
- R for SAS, SPSS & Stata Users 2010
- Bayesian Adaptive Methods for Clinical trials 2010

- Modern Practical Bayesian Clinical Trial Design 2008
- Evaluating p(Success) for Decision-Making in Drug Development 2008
- Non-Clinical Statistics for Drug Discovery 2007
- Dose Finding in Drug Development 2007
- Statistical Monitoring of Clinical Trials 2007

International Biometric Society ENAR Spring Meeting Short Courses
- Adaptive Designs in Drug Development 2006
- Power and Sample Size Using SAS/STAT Software 2006
- Statistical Evaluation of Surrogate Endpoints in Clinical Trials 2005
- Up-and-Down Procedures & Other Response Adaptive Designs 2005
- Statistical Analysis with Missing Data 2004
- Introduction to Joint Modeling of Longitudinal & Time-to-Event Data 2004

Leadership Training
- SAS Speaker Boot Camp – Strategic Communication Skills 2014
- Strozzi Institute Leadership Dojo 2009
- Grinnell Leadership Jumpstart® 2009
- Crucial Confrontations 2006

Statistical Software Packages
- Introduction to the JMP Scripting Language 2011
- SAS SQL 1: Essentials 2011
- Design and Interim Monitoring of Flexible Clinical Trials Using East 2006
- SAS Macro Processing: Advanced Topics 2003
- SAS: Longitudinal Data Analysis with Discrete and Continuous Responses 2003

TEACHING EXPERIENCE

University of North Carolina at Chapel Hill, Department of Biostatistics
- Guest Lecturer, Design and Analysis of Clinical Trials Fall 2012, 2014, 2016
- Guest Lecturer, Leadership in Biostatistics Fall 2015
- Guest Lecturer, Field Observations in Biostatistics Fall 2015
- Course Assistant, Principles of Experimental Analysis Fall 2000
- Course Assistant, Probability and Mathematical Statistics I Fall 1998

Campbell University, Department of Clinical Research
- Course Director, Experimental Design and Biostatistics Fall 2007 – 2008
- Guest Lecturer, Experimental Design and Biostatistics Fall 2006

HONORS & AWARDS

SAS Institute, Inc.
- Blogger of the Year for JMP Blog 2013
- Winner of Poster Session, CDISC European Interchange 2012

Inspire Pharmaceuticals
- Richard Evans Team Awards 2010, 2008
- You Inspire Me Awards 2010, 2008, 2007

Bristol Myers Squibb
- Dasatinib Team Award 2006
- PRI Star Awards (x2, x3, x2) 2006, 2005, 2004
- BDOC Triumph Award 2005

- Entecavir Team Award 2005

University of North Carolina at Chapel Hill
- Max Halperin Award for Academic Excellence 2000
- Best Departmental Master's Paper 2000
- Delta Omega, National Honorary Society in Public Health 1999
- National Institute of Environmental Health Sciences Training Grant 1998 – 2003

University of Maryland Baltimore County
- Magna Cum Laude 1996
- Pi Mu Epsilon, National Honorary Mathematics Society 1995
- Scholarship from the American Legion 1992 – 1996
- Semester academic honors 1992 – 1996

MANUSCRIPTS

1. **Zink RC**, Dmitrienko A & Dmitrienko A. (2016). Rethinking the clinically-based thresholds of TransCelerate BioPharma for risk-based monitoring. In preparation for *Therapeutic Innovation & Regulatory Science*.

2. Marchenko O, Jiang Q, Chuang-Stein C, Mehta C, Levenson M, Russek-Cohen E, Liu L, Sanchez-Kam M, **Zink RC**, Ke C, Ma H, Maca J & Park S. (2016). Statistical considerations for cardiovascular outcome trials in patients with type 2 diabetes mellitus. Responded to reviewers comments for *Statistics in Biopharmaceutical Research*.

3. **Zink RC** & Zhang W,eds. (2016, Aug). Special Issue: Papers from the 2015 ASA Biopharmaceutical Section Statistics Workshop. *Statistics in Biopharmaceutical Research*.

4. **Zink RC** & Zhang W. (2016). Guest editors' note. *Statistics in Biopharmaceutical Research*. *In press*.

5. **Zink RC** & Jiang X. (2016). Using contour plots to assess the sensitivity of clinical trial design assumptions. *Therapeutic Innovation & Regulatory Science* 50: 496-509.

6. Marchenko O, Jiang Q, Chakravarty A, Ke C, Ma H, Maca J, Russek-Cohen E, Sanchez-Kam M, **Zink RC** & Chuang-Stein C. (2015). Evaluation and review of strategies to assess cardiovascular risk in clinical trials in patients with type 2 diabetes mellitus. *Statistics in Biopharmaceutical Research 7: 253-266*.

7. **Zink RC** & Antonijevic Z. (2015). Reduce the cost of success: Adaptive and Bayesian designs to the rescue. *DIA Global Forum* 7(2): 40-45.

8. **Zink RC**. (2014). Exploring the challenges, impacts and implications of risk-based monitoring. *Clinical Investigation* 4: 785-789.

9. By K, Qaqish BF, Preisser JS, Perin J & **Zink RC**. (2014). ORTH: R and SAS software for regression models of correlated binary data based on orthogonalized residuals and alternating logistic regressions. *Computer Methods and Programs in Biomedicine* 113: 557-568.

10. **Zink RC**, Wolfinger RD & Mann G. (2013). Summarizing the incidence of adverse events using volcano plots and time windows. *Clinical Trials* 10: 398-406.

11. **Zink RC**, Huang Q, Zhang L & Bao W. (2013). Statistical and graphical approaches for disproportionality analysis of spontaneously-reported adverse events in pharmacovigilance. *Chinese Journal of Natural Medicines* 11: 314−20.

12. **Zink RC** & Koch GG. (2012). NParCov3: A SAS/IML macro for non-parametric analysis of covariance. *Journal of Statistical Software* 50:3, 1-17. http://www.jstatsoft.org/v50/i03/**.**

13. Qaqish BF, **Zink RC** & Preisser JS. (2012). Orthogonalized residuals for estimation of marginally specified association parameters in multivariate binary data. *Scandinavian Journal of Statistics* 39, 515-27.

14. **Zink RC** & Mann G. (2012). On the importance of a single data standard. *Drug Information Journal* 46, 362-7.

15. Nichols JJ, Bickle KM, **Zink RC**, Schiewe MD, Haque RM & Nichols KK. (2012). Safety and efficacy of topical azithromycin ophthalmic solution 1.0% in the treatment of contact lens-related dry eye. *Eye & Contact Lens* 38, 73-9.

16. By K, Qaqish BF, Preisser JS, Perin J & **Zink RC**. (2011). ORTH: R and SAS software for regression models of correlated binary data based on orthogonalized residuals and alternating logistic regressions. *The University of North Carolina at Chapel Hill Department of Biostatistics Technical Report Series.* Working Paper 22. http://biostats.bepress.com/uncbiostat/papers/art22

17. Haque RM, Torkildsen GL, Shapiro A, Brubaker K, **Zink RC**, Kowalski R, Mah F & Pflugfelder S. (2010). Multi-center, open-label study evaluating the efficacy of azithromycin ophthalmic solution 1% on the signs and symptoms of patients with blepharitis. *Cornea* 29, 871-7.

18. Stewart WC, Crean CS, **Zink RC**, Brubaker K, Haque R & Hwang DG. (2010). Pharmacokinetics of azithromycin and moxifloxacin in human conjunctiva and aqueous humor during and after the approved dosing regimens. *American Journal of Ophthalmology* 150, 744-51.

19. **Zink RC** & Qaqish BF. (2009). Correlated binary regression using orthogonalized residuals. *Collection of Biostatistics Research Archive (COBRA) Reprint Series*. Article 51. http://biostats.bepress.com/cobra/ps/art51

20. Lai CL, Shouval D, Lok AS, Chang TT, Cheinquer H, Goodman Z, DeHertogh D, Wilber R, **Zink RC**, Cross A, Colonno R & Fernandes L. (2006). Entecavir versus lamivudine for patients with HBeAg-negative chronic hepatitis B. *New England Journal of Medicine* 354 (10), 1011-1020.

21. Sloane PD, Hoeffer B, Mitchell CM, McKenzie DA, Barrick AL, Rader J, Stewart BJ, Talerico KA, Rasin J, **Zink RC** & Koch GG. (2004). Effect of person-centered showering and the towel bath on bathing-associated aggression, agitation and discomfort in nursing home residents with dementia: a randomized, controlled trial. *Journal of the American Geriatrics Society* 52, 1795-1804.

22. **Zink RC**. (2003). Correlated binary regression using orthogonalized residuals. Doctoral Dissertation, Department of Biostatistics, University of North Carolina at Chapel Hill, USA.

23. **Zink RC**. (1999). Can amino-acid sequences of HIV-1 isolates predict neutralization? Master's Paper, Department of Biostatistics, University of North Carolina at Chapel Hill, USA.

24. Rywik TM, Blackman MR, Yataco AR, Vaitkevicius PV, **Zink RC**, Cottrell EH, Wright JG, Katzel LI & Fleg JL. (1999). Enhanced endothelial vasoreactivity in endurance-trained older men. *Journal of Applied Physiology* 87, 2136–2142.

BOOKS AND CHAPTERS

1. **Zink RC**. (2017). Uncovering fraud, misconduct and other data quality issues in clinical trials. In: Peace KE, Chen DGD & Menon SM, eds. *ICSA Biostatistics Book Series of the Biopharmaceutical Applied Statistics Symposium (BASS). Volume 3: Pharmaceutical Applications*. Springer. In preparation.

2. **Zink RC**. (2017). Detecting safety signals among adverse events in clinical trials. In: Peace KE, Chen DGD & Menon SM, eds. *ICSA Biostatistics Book Series of the Biopharmaceutical Applied Statistics Symposium (BASS). Volume 2: Biostatistical Analysis of Clinical Trials*. Springer. In preparation.

3. Ivanova A, Marchenko O, Jiang Q & **Zink RC**. (2017). Safety analysis in oncology trials. In: Roychoudhury S

& Lahiri S, eds. *Statistical Challenges in Oncology Clinical Development*. Under review.

4. **Zink RC,** Koch GG & Chung Y. (2017). Non-parametric randomization-based analysis of covariance. In: Dmitrienko A & Koch GG, eds. *Analysis of Clinical Trials Using SAS: A Practical Guide, Second Edition*. Cary, NC: SAS Institute Inc. Under Review.

5. Menon S & **Zink RC**, eds. (2015). *Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods*. Cary, NC: SAS Institute Inc.

6. Wu J, Menon S, **Zink RC** & Perevozskaya I. (2015). Designing and monitoring group sequential clinical trials. In: Menon S & Zink RC, eds. *Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods*. Cary, NC: SAS Institute Inc.

7. **Zink RC**, Shen L, Wolfinger RD & Showalter HDH. (2015). Assessment of methods to identify patient subgroups with enhanced treatment response in randomized clinical trials. In: Chen Z, Liu A, Qu Y, Tang L, Ting N & Tsong Y, eds. *Applied Statistics in Biomedicine and Clinical Trials Design: Selected Papers from 2013 ICSA/ISBS Joint Statistical Meetings*. Cham, Switzerland: Springer.

8. **Zink RC**. (2014). *Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP® and SAS®*. Cary, NC: SAS Institute Inc.

9. **Zink RC**. (2012). Sampling methodology: implications for drawing conclusions from clinical research findings. In: Supino PG & Borer JS, eds. *Principles of Research Methodology: A Guide for Clinical Professionals*. New York: Springer.

OTHER PUBLICATIONS

1. **Zink RC** & Jiang X. (2017). Using data visualization to assess the sensitivity of clinical trial design assumptions. *Biopharm Report* 24 (forthcoming).

2. **Zink RC** (2016). Session 221: Envision the future: How big data impact our regulatory environment. *DIA Global Forum* 8(4): 18.

3. **Zink RC**. (2015). Using the relationships among study procedures to assess data quality. *JMPer Cable* 30: 13-15. Available at: http://www.jmp.com/about/newsletters/jmpercable/.

4. **Zink RC**. (2014). Gain career insights from biopharmaceutical section podcasts. *AmStat News*, American Statistical Association.

5. **Zink RC**. (2014). Identifying quality issues and misconduct using analyses of digit preference. *JMPer Cable* 29: 3-4. Available at: http://www.jmp.com/about/newsletters/jmpercable/.

6. Izem R & **Zink RC**. (2013). Podcasts from the biopharmaceutical section, will you tune in? *AmStat News*, American Statistical Association.

7. **Zink RC.** (2012). Review of *Clinical Trial Design: Bayesian and Frequentist Adaptive Methods*. *Drug Information Journal,* 46: 746-47.

8. **Zink RC.** (2009). *Data Monitoring Committees*. Standard Operating Procedure 6301, Inspire Pharmaceuticals.

SOFTWARE

1. **Zink RC**. (2013). WinBUGS to JMP add-in, JMP Life Sciences, SAS Institute, Inc.

2. **Zink RC** & Koch GG. (2012). NParCov3: A SAS/IML macro for non-parametric analysis of covariance. *Journal of Statistical Software* 50:3, 1-17. http://www.jstatsoft.org/v50/i03/**.**

3. **Zink RC**. (2012). JMP MCMC diagnostics add-in with probability calculators, JMP Life Sciences, SAS Institute, Inc.

4. **Zink RC**. (2012). JMP forest plot add-in for confidence or credible intervals, JMP Life Sciences, SAS Institute, Inc.

5. **Zink RC** & Preisser JS. (2003). SAS macro GEECORR, analysis of correlated binary data using method of prentice (1988). Department of Biostatistics, University of North Carolina at Chapel Hill, USA. http://www.bios.unc.edu/~jpreisse/software.htm

6. **Zink RC** & Qaqish BF. (2003). SAS macro ORTHRES, analysis of correlated binary data using orthogonalized residuals. Department of Biostatistics, University of North Carolina at Chapel Hill, USA. http://www.bios.unc.edu/~qaqish/software.htm

7. **Zink RC** & Koch GG. (2002). SAS macro NParCov, version 2, non-parametric analysis of covariance. Biometric Consulting Laboratory, Department of Biostatistics, University of North Carolina at Chapel Hill, USA. [bcl@bios.unc.edu]

INVITED PRESENTATIONS AT SCIENTIFIC MEETINGS

1. **Zink RC**. (2017). Tentative title: Randomization-based nonparametric analysis methods for randomized clinical trials. Conference on Nonparametrics in Modern Biomedical and Clinical Sciences.

2. **Zink RC**. (2016). Uncovering fraud, misconduct and other data quality issues in clinical trials. Biopharmaceutical Applied Statistics Symposium (BASS).

3. **Zink RC** & Jiang X. (2016). Using power contours to assess the sensitivity of clinical trial design assumptions**.** International Indian Statistical Association Conference.

4. **Zink RC**. (2016). Uncovering fraud, misconduct and other data quality issues in clinical trials. SAS User Group Japan Annual Meeting. Plenary presentation.

5. **Zink RC** & Foglia D. (2016). Efficient safety assessment in clinical trials using the computer-generated AE narratives of JMP Clinical. PharmaSUG.

6. **Zink RC**. (2015). Analytical considerations for risk-based monitoring. Statisticians in the Pharmaceutical Industry Annual Meeting.

7. **Zink RC**. (2015). Subgroup analyses for personalized medicine. Statisticians in the Pharmaceutical Industry Annual Meeting.

8. **Zink RC**. (2014). Risk-based monitoring of clinical trials using JMP Clinical. SAS Global Forum and PharmaSUG (the latter presented by Kelci Miclaus).

9. **Zink RC**. (2014). Graphical approaches for disproportionality analysis of spontaneously-reported adverse events in pharmacovigilance. International Biometric Society, Eastern North American Region Annual Meeting.

10. **Zink RC**, Wolfinger RD & Mann G. (2013). Summarizing the incidence of adverse events using volcano plots. ASA Biopharmaceutical Section FDA-Industry Workshop.

11. **Zink, RC**. (2013). Rigorous and consistent assessment of methods to identify subgroups with enhanced treatment response. ICSA 2013 Applied Statistics Symposium/ISBS International Symposium on

Biopharmaceutical Statistics Joint Meeting.

12. **Zink RC**. (2013). Ensuring data quality and identifying potential fraud in clinical trials. Statisticians in the Pharmaceutical Industry Annual Meeting.

13. **Zink RC**. (2013). Ensuring data quality and identifying potential fraud in clinical trials. Quality and Productivity Research Conference.

14. **Zink RC**. (2013). Assessing drug safety with Bayesian hierarchical modeling using PROC MCMC and JMP. SAS Global Forum and PharmaSUG (presented by Doug Robinson).

15. **Zink RC**, Wolfinger RD, Tan PY, Neville P & Lam ML. (2012). Considerations for subgroup identification of patients with enhanced treatment response in clinical trials. Statistical Learning and Data Mining Annual Conference.

CONTRIBUTED PRESENTATIONS AT SCIENTIFIC MEETINGS

1. Jiang X & **Zink RC**. (2016). Predictive modeling for patient recruitment in multicenter trials. JMP Discovery Summit.

2. **Zink RC** & Jiang X. (2016). Using power contours to assess the sensitivity of clinical trial design assumptions**.** Joint Statistical Meetings.

3. **Zink RC**. (2016). Risk-based monitoring and fraud detection in clinical trials. JMP Discovery Summit Europe.

4. **Zink RC**. (2016). Risk-based approaches to assess data integrity in medical product development. 19th DIA Annual Workshop in Japan for Clinical Data Management.

5. **Zink RC**. (2015). Using correlation patterns of study findings to assess data quality in clinical trials. Joint Statistical Meetings.

6. **Zink RC**. (2015). Screening to assess data quality in clinical trials. DIA Annual Meeting.

7. **Zink RC**. (2014). Signal detection of potentially fraudulent activity in clinical trials. Topic Contributed Session at Joint Statistical Meetings.

8. **Zink RC**. (2014). Risk-based monitoring and fraud detection in clinical trials. Drug Information Association Annual Meeting.

9. **Zink RC**. (2014). Using volcano plots for signal detection analyses in clinical trials. Statisticians in the Pharmaceutical Industry Annual Meeting.

10. **Zink RC** & Wolfinger RD. (2012). Developing a complete picture of patient safety in clinical trials. SouthEast SAS Users Group Conference.

11. **Zink RC**. (2012). Visual analytic approaches for the analysis of spontaneously-reported adverse events in post-market surveillance. JMP Discovery Summit.

12. Wolfinger RD, **Zink RC** & Boyle W. (2012). Dynamic comparison of simulated adaptive trials. Joint Statistical Meetings.

13. Bao W, Mann G, **Zink RC** & Wolfinger R. (2012). JMP Clinical: standardized visual analytics for clinical trials research. PharmaSUG China Conference.

14. Scott A & **Zink RC**. (2012). CDISC data standards can facilitate composition of adverse event narratives.

Society of Clinical Trials Annual Meeting.

15. **Zink RC**, Wolfinger RD & Mann G. (2012). Summarizing the incidence of adverse events using volcano plots and time windows. Society of Clinical Trials Annual Meeting.

16. Bickle KM, Nichols KK, Haque R, **Zink RC**, Schiewe M & Nichols JJ. (2012). Efficacy of topical azithromycin ophthalmic solution 1.0% in the treatment of contact lens-related dry eye. Association for Research in Vision and Ophthalmology Annual Meeting.

17. **Zink RC**. (2010). The status of ADaM: putting ADaM into practice. 4th Annual FDA/DIA Statistics Forum (filling in for SJ Kenny).

18. Ritch R, Schiewe M, **Zink RC**, Lemp M, Kaufman PL, Haque R, Brazzell RK & Vittitow JL. (2010). Latrunculin B (INS115644) reduces intraocular pressure in ocular hypertension and primary open angle glaucoma. Association for Research in Vision and Ophthalmology Annual Meeting.

19. Trattler WB, Kuhn KL, Haque R, **Zink RC** & Luchs JI. (2009). Topical azithromycin improves blepharitis signs and symptoms. American Society of Cataract and Refractive Surgery Annual Meeting.

20. Touhey D, Shapiro A, Torkildsen G, Haque R, **Zink RC**, Kowalski RP, Mah FS & Pflugfelder SC. (2009). Efficacy of topical azithromycin ophthalmic solution 1.0% in the treatment of chronic blepharitis patients. Association for Research in Vision and Ophthalmology Annual Meeting.

21. Stewart WC, Crean CS, **Zink RC**, Haque R & Hwang DG. (2009). Pharmacokinetics of azithromycin and moxifloxacin in human conjunctiva and aqueous humor during and after the approved dosing regimens. Association for Research in Vision and Ophthalmology Annual Meeting.

22. Bodnar W, Vittitow JL, Godin S, Verhoeven R, Powell K, Amar T, **Zink RC** & Crean CS. (2008). Ocular pharmacokinetics and tissue distribution of azithromycin following topical administration of Azasite™. Association for Research in Vision and Ophthalmology Annual Meeting.

23. Crean CS, Vittitow J, **Zink RC**, Richards L, Verhoeven RS, Powell KD & Brazzell RK. (2008). Comparison of Azasite and azithromycin 1% for bacterial conjunctivitis. American Society of Cataract and Refractive Surgery Annual Meeting.

24. Cortes J, Kim DW, Rosti G, Rousselot P, Bleickardt E, **Zink R** & Sawyers C. (2006). Dasatinib in patients with chronic myeloid leukemia (CML) in myeloid blast crisis who are resistant or intolerant to imatinib: updated results of the CA180006 START-B study. American Society of Clinical Oncology Annual Meeting.

25. Shouval D, Akarca US, Hatzis G, Kitis G, Lai CL, Cheinquer H, Chang TT, **Zink R**, Zhu J & Brett-Smith H. (2006). Continued virologic and biochemical improvement through 96 weeks of entecavir treatment in HBeAg(-) chronic hepatitis B patients (study ETV-027). Association for the Study of the Liver European Meeting.

26. Talpaz M, Rousselot P, Kim DW, Guilhot F, Corm S, Bleickardt E, **Zink R**, Rosti G, Coutre S & Sawyers C. (2005). A phase II study of dasatinib in patients with chronic myeloid leukemia (CML) in myeloid blast crisis who are resistant or intolerant to imatinib: first results of the CA180006 START-B study. American Society of Hematology Annual Meeting.

27. Schiff E, Lee WM, Chao YC, Sette H, Schalm SC, Brett-Smith H & **Zink RC.** (2005). Efficacy and safety of entecavir and lamivudine in compensated, cirrhotic patients with chronic hepatitis B. American Association for the Study of Liver Diseases Annual Meeting.

28. Lai CL, Chang TT, Chao YC, Tanwandee T, Thongsawat S, Lee SD, Angus P, Batur Y, Akarca US, Fernandes L, **Zink RC**, Cross A & Wilber R. (2005). Sustained response off-treatment to entecavir and lamivudine in nucleoside-naive, HBeAg-negative patients: 24-week follow-up results of phase 3 study -027. Association

for the Study of the Liver Asian Pacific Meeting.

29. Shouval D, Lai CL, Cheinquer H, Lok A, DeHertogh D, Wilbur R, Cross A, **Zink R** & Fernandes L. (2004). Entecavir demonstrates superior histologic and virologic efficacy over lamivudine in nucleoside-naive HBeAg(−) chronic hepatitis B: Results of Phase III trial ETV-027. American Association for the Study of Liver Diseases Annual Meeting.

30. **Zink RC** & Qaqish BF. (2003). Orthogonalized residuals for estimation of marginally specified association parameters in multivariate binary data. International Biometric Society, Eastern North American Region Annual Meeting.

31. Seillier-Moiseiwitsch F, **Zink RC**, Lawrence D & Budrevich R. (1999). Can amino-acid sequences predict neutralization patterns for HIV-1 isolates? International Biometric Society, Eastern North American Region Annual Meeting.

POSTERS PRESENTED AT SCIENTIFIC MEETINGS

1. Dmitrienko A & **Zink RC**. (2016). Using funnel plots to develop risk-based monitoring rules for binomial and Poisson outcomes in clinical trials. JMP Discovery Summit.

2. Dmitrienko A & **Zink RC**. (2016). Risk-based monitoring rules for binomial and Poisson outcomes in clinical trials with software implementation in JMP. Joint Statistical Meetings.

3. Dmitrienko A & **Zink RC**. (2016). Exposure adjustment in risk-based monitoring in clinical trials with software implementation in JMP. Annual Symposium of the Kansas-Western Missouri Chapter of the American Statistical Association.

4. Jiang X & **Zink RC**. (2016). Predictive modeling for patient recruitment in multicenter trials. JMP Discovery Summit Europe.

5. **Zink RC**. (2015). Assessing the cardiovascular risk of anti-diabetic therapies in patients with type 2 diabetes mellitus. Statisticians in the Pharmaceutical Industry Annual Meeting.

6. **Zink RC**. (2013). Truly efficient reviews for clinical trials. JMP Discovery Summit.

7. **Zink RC**. (2012). CDISC standards can benefit medical writers in authoring adverse event narratives. CDISC European Interchange. Winner of Poster Session.

WEBINARS

1. **Zink RC**. (2016). Using contour plots to assess the sensitivity of clinical trial design assumptions. DIA Virtual Journal Club.

2. **Zink RC**. (2015). Analytical considerations for risk-based monitoring. Statisticians in the Pharmaceutical Industry Scientific Committee Webinar: Risk-Based Monitoring.

3. **Zink RC**. (2015). Evaluating the probability of a successful clinical trial to guide decision making in medical product development. Statisticians in the Pharmaceutical Industry Scientific Committee Webinar: Communicating Complex Statistical Concepts.

4. **Zink RC**. (2013). Detecting safety signals among adverse events in clinical trials. ASA Biopharmaceutical Section Web-based Training Series.

OTHER PRESENTATIONS

1. **Zink RC**. (2016). Detecting safety signals in clinical trials. North Carolina Translational and Clinical Sciences Institute (NC TRACS) Biostatistics Seminar Series.

2. **Zink RC**. (2015). Assessing the cardiovascular risk of anti-diabetic therapies in patients with type 2 diabetes mellitus. UNC-Chapel Hill Department of Biostatistics Seminar.

3. **Zink RC**. (2015). Risk-based approaches to assess data integrity in medical product development. Seminar, Tokyo, Japan.

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5. **Zink RC**. (2012). Visual analytic approaches to safety analysis in clinical trials and post-market surveillance. Seminar, Tokyo, Japan.

6. **Zink RC**. (2010). Dr. Strangelove or: How I learned to stop worrying and love biostatistics. Inspire Pharmaceuticals Seminar.

7. **Zink RC**. (2009). The effect of endpoint time, sample size and pulmozyme status on the probability of success: case study of 08-110. Inspire Pharmaceuticals Denufosol Core Team Seminar.

8. **Zink RC**. (2008). Power and the probability of success: case study of 03-113. Inspire Pharmaceuticals Research & Development Leadership Team Seminar.

9. **Zink RC**. (2008). An introduction to interim statistical analyses using INS37217 nasal spray as an example. Inspire Pharmaceuticals Seminar.

10. **Zink RC**. (2006). An introduction to biostatistics. E.O. Smith High School, A.P. Statistics Class.

11. **Zink RC**. (2005). An illustrated field guide to randomization tests. Bristol-Myers Squibb, 4th Annual A.P. Statistics Colloquium.

12. **Zink RC**. (2004). Nonparametric analysis of covariance. Bristol-Myers Squibb, Biostatistics Forum.

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1. Various Authors. (2016). Article, *Journal of the American Medical Association.*

2. Various Authors. (2016). Article, *Journal of Biopharmaceutical Statistics*.

3. Various Authors. (2016). Article, *Statistics in Medicine*.

4. Various Authors. (2015). Article, *Clinical Trials*.

5. Various Authors. (2015). Article, *Statistics in Biopharmaceutical Research*.

6. Stone CA & Zhu X. (2015). Bayesian Estimation and Item Response Theory Using SAS. Cary, NC: SAS Institute Inc.

7. Hinrichs C & Boiler C. (2014). *JMP Essentials: An Illustrated Guide for New Users, Second Edition*. Cary, NC: SAS Institute Inc.

8. Various Authors. (2013). Article. For *Statistics in Biopharmaceutical Research*.

9. Various Authors. (2010). Stratified multivariate Mann-Whitney estimators for the comparison of two treatments with randomization based covariance adjustment. For *Statistics in Biopharmaceutical*

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10. Various Authors. (2009). Article, *Statistics in Medicine*.

11. Various Authors. (2007). Article, *Statistics in Medicine*.

12. Durham T & Turner R. (2007). *Introduction to Statistics in Pharmaceutical Clinical Trials*. Pharmaceutical Press.

13. Various Authors. (2005). Article, *Statistics in Medicine*.

14. Editors of JPD. (2001). Guidelines for reporting statistical results. *Journal of Prosthetic Dentistry* 85, 5-6.

CONFERENCE & WORKSHOP SESSIONS

1. Menon S & **Zink RC**. (2016). Dose-response design and analysis in drug development. Short Course. The 72nd Deming Conference on Applied Statistics.

2. **Zink RC**, Buyse M & Schuette P. (2016). An overview of methods to assess data integrity in clinical trials. Short Course. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

3. **Zink RC**. (2015). Industry Co-Chair for ASA Biopharmaceutical Section FDA-Industry Statistics Workshop.

4. **Zink RC**. (2015). Session chair for Large trials for major adverse cardiovascular events. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop.

5. **Zink RC**. (2015). Contributed session chair at Joint Statistical Meetings.

6. **Zink RC**. (2014). The role of statisticians in risk-based monitoring and fraud detection in clinical trials. Topic-contributed session organizer and speaker. Joint Statistical Meetings.

7. **Zink RC**. (2013). Ensuring data quality and identifying potential fraud in clinical trials. Organizer and chair. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop.

8. **Zink RC**. (2013). Subgroup identification for patients with enhanced treatment response. Topic-contributed session organizer and chair. Joint Statistical Meetings.

9. Wolfinger RD & **Zink RC**. (2012). Advanced visual analytic approaches to safety analysis in clinical trials. Short Course. Biopharmaceutical Applied Statistics Symposium.

10. **Zink RC**. (2012). Statistical considerations in subgroup identification and analysis in randomized clinical trials. Plenary session co-organizer. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop.

11. Wolfinger RD & **Zink RC**. (2012). Predictive modeling in the life sciences. Computer Technology Workshop. Joint Statistical Meetings.