Richard C. Zink, PhD

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SUMMARY

Richard C. Zink (*he/him*) is Vice President of Biostatistics and Statistical Programming at Lexitas Pharma Services. He established the Biostatistics and Statistical Programming department in 2020 and leads in the design and analysis of ophthalmology clinical trials on behalf of their clients. Prior to Lexitas, Richard spent 17 years in and around medical product development at a real-world data company where he led data management and statistics in the analysis and reporting of data derived from electronic medical records; a software company where he developed and supported platforms to analyze and visualize safety and data quality outcomes from clinical trials; and pharmaceutical companies where he served as lead statistician for numerous clinical trials and provided statistical consulting and support to other departments.

Richard is currently Associate Editor for the DIA journal *Therapeutic Innovation & Regulatory Science*. He is the author of *Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS*, the co-editor of *Modern Approaches to Clinical Trials Using SAS: Classical, Adaptive, and Bayesian Methods*, and a contributor to seven other books on statistical topics in clinical trials and clinical research. He was the 2019 Chair of the Biopharmaceutical Section of the American Statistical Association, and former host of the Biopharmaceutical Section Statistics Podcast where he recorded 100 episodes over a 10-year period. He holds a Ph.D. in Biostatistics from the University of North Carolina at Chapel Hill, where he serves as Adjunct Professor of Biostatistics.

Richard was awarded the distinction of Fellow of the American Statistical Association in 2020 “for leadership and dedication to the Biopharmaceutical Section, including pioneering novel channels of communication; for exemplary contributions to the ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop; and for commitment to students through the scholarship award.”

PHARMACEUTICAL EXPERIENCE

Clinical & Therapeutic Areas

- Antiviral: Chronic Hepatitis B, Human Immunodeficiency Virus
- Gastroenterology: Inflammatory Bowel Disease
- Hepatology: Nonalcoholic Steatohepatitis, Primary Biliary Cholangitis
- Oncology: Chronic Myeloid Leukemia, Hepatocellular Carcinoma
- Ophthalmology: Age-Related Macular Degeneration, Bacterial Conjunctivitis, Blepharitis/Meibomian Gland Disease, Cataracts, Diabetic Macular Edema, Dry Eye Disease, Geographic Atrophy, Glaucoma, Non-Infectious Anterior Uveitis, Sjögren Syndrome
- 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, SOPs, Protocols, CSRs, CRFs, ISEs, and scientific publications
- SDTM and ADaM standards, WHODRUG and MedDRA coding

Nonclinical 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

Lexitas Pharma Services, Inc

- Vice President, Biostatistics and Statistical Programming — Nov 2022 – Present
- Vice President, Data Management, Biostatistics, and Statistical Programming — Jan 2021 – Nov 2022
- Vice President, Biostatistics — Sep 2020 – Jan 2021
  - Leads the Data Management and the Biostatistics and Statistical Programming departments
  - Serves as the principal interface with industry partners and internal stakeholders for data management, biostatistics, or statistical programming-related endeavors
  - Provides statistical and quantitative guidance to address company and departmental needs
  - Coordinates statistical and data management activities in support of data cleaning, standardization, programming, analysis, and reporting
  - Develops and drives strategic initiatives for process improvement to enhance performance and quality
  - Oversees administration of standard operating procedures, software tools, training, budgets, and staffing requirements
  - Established the Biostatistics and Statistical Programming department

University of North Carolina at Chapel Hill, Department of Biostatistics

- Adjunct Professor of Biostatistics — Oct 2020 – Sep 2023
- Adjunct Assistant Professor of Biostatistics — Oct 2014 – Sep 2020
  - Provides lectures for courses in clinical trials, categorical data analysis, and statistical leadership

- Serves as masters paper advisor or dissertation committee member
- Engages in collaborative research with other faculty
- Mentors students at various department functions

Target RWE / TARGET PharmaSolutions

• Senior Director, Data Management and Statistics — May 2018 – Sep 2020

• Director of Statistical Services — Apr 2018 – May 2018

- Leads the Data Management and Statistics department, a team of more than 45 statisticians, data managers, statistical programmers, and data abstractors. Oversaw the doubling of the department over a two-year period
- Serves as the principal interface with industry, academic, and regulatory partners as well as internal stakeholders for statistics- or data management–related endeavors
- Provides statistical and quantitative guidance to address company and departmental needs
- Coordinates statistical and data management activities in support of data cleaning, standardization, programming, analysis, and reporting
- Develops and drives strategic initiatives for process improvement to enhance performance and quality
- Oversees administration of standard operating procedures, software tools, training, budgets, and staffing requirements

SAS Institute, Inc., JMP Life Sciences

• Principal Research Statistician Developer — Apr 2011 – Mar 2018

- Served as lead developer for JMP Clinical prototyping, developing, and contributing to numerous safety and data integrity analysis platforms for pharmaceutical and regulatory customers
- Led research efforts and software development into new methodologies to help expand customer base
- Published research to illustrate novel methodologies in the scientific literature
- Shared CDISC expertise among development team

Inspire Pharmaceuticals

• Principal Statistical Scientist I — May 2009 – Feb 2011

• Senior Statistical Scientist II — Jul 2006 – May 2009

- Served as lead statistician for multiple ophthalmology programs in Phase II-IV trials
- Identified, outsourced, and managed statistical and data management vendors and oversaw implementation of CDISC standards
- Utilized numerous methodologies to enhance decision making across ophthalmology and pulmonary programs such as simulations drug dispensation of a rare drug supply to minimize the likelihood of on-site shortages, Bayesian analyses to understand the probability of success to determine appropriate trial size and duration, data mining methods to identify treatment-sensitive subgroups, and unblinded sample size re-estimation and interim futility analyses

- Implemented ongoing meetings with nonclinical development, contributing to the design and analysis of assay, animal, and pharmacokinetic studies

Bristol-Myers Squibb, Pharmaceutical Research Institute

- Senior Research Biostatistician — Apr 2005 – Jul 2006
- Research Biostatistician — Jul 2003 – Apr 2005
  - Served as clinical trial statistician for dasatinib program in chronic myeloid leukemia. Had primary responsibility across six phase II studies for algorithm development for determining efficacious response. Led clinical validation efforts of this algorithm. Key contributor to FDA ODAC meeting
  - Served as clinical trial statistician for entecavir program in chronic HBV. Had primary responsibility across the phase III program for analyses of sustained response. Key contributor to FDA AVDAC meeting and EMA response

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 (since 1995), SAS/IML, SAS Macro, SAS/Graph, JMP / JMP Pro, JMP Clinical with some proficiency in SAS/ETS, WinBUGS, East, StatXact, SUDAAN, CART, S-Plus, R, GLIM

Programming Languages: JSL, SQL, C

Operating Systems: Windows, UNIX

Word Processing: LaTeX, Microsoft Office

PROFESSIONAL SOCIETIES

Association for Research in Vision and Ophthalmology (ARVO) — 2023 – Present

American Statistical Association (ASA) 1998 – Present

- ASA Fellow 2020
- Lester R. Curtin Award Committee 2020
- ASA Speaker's Bureau 2018 – Present

Biopharmaceutical Section (BIOP)

- Proposed successful commitment of annual BIOP funding for Meeting Within a Meeting (MWM) Statistics Workshop and Beyond AP Statistics Workshop for math, science, and AP statistics teachers 2020
- 40th Anniversary Committee 2020 – 2021
- Chair (elected) 2018 – 2020
- Scientific Working Group on Real World Data/Evidence 2018 – 2020
- Outreach Committee, Proposal Author 2017
- Section Scholarship Award, Proposal Author 2017
- Publications Officer (elected) 2016 – 2017
- Webinar Archive (2008-2020), Curator 2016 – 2021
- Mentoring Program 2015 – Present
- Steering Committee 2014 – 2021
- Scientific Working Group on Safety Data Analysis 2014 – 2021
- Communication-Publications Committee 2013 – 2021
- Podcasts, Organizer and Interviewer 2012 – 2022
- Regulatory-Industry Statistics Workshop
  - Chair of Task Force 2017 – 2018
  - Industry co-chair 2015
  - Steering Committee 2014 – 2018
  - Co-editor for Special Issue for *Statistics in Biopharmaceutical Research* 2015 – 2016
  - Organizing Committee 2012 – 2018

North Carolina Chapter 2018 – Present

Drug Information Association (DIA) 2011 – Present

- Associate Editor of *Therapeutic Innovation & Regulatory Science* 2017 – Present
- Statistical Section Editor of *Therapeutic Innovation & Regulatory Science* 2012 – 2017
- Editorial Board of *Therapeutic Innovation & Regulatory Science* 2011 – Present

National Institute of Statistical Sciences 2019 - 2020

- Member, Communication and Marketing Committee

Statisticians in the Pharmaceutical Industry (PSI) 2013 – 2017

International Biometric Society, Eastern North American Region 1998 – 2012

PROFESSIONAL DEVELOPMENT

American Statistical Association Biopharmaceutical Section Webinars

- Estimands: The New Bedrock of Drug Development 2022
- Estimands in Practice 2020
- Generating and Harnessing RWE, HIT and AI in the Era of Big Data 2019
- Data Monitoring in Practice: Making Your DMC Effective 2010
- 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

Holly Speaks
- Cultural Awareness 2022

Collaborative Institutional Training Initiative
- Biomedical Researcher Basic Course 2021
- GCP for Clinical Trials with Investigational Drugs and Medical Devices Refresher course 2021
- Good Clinical Practice Course 2020
- Health Information Privacy and Security (HIPS) for Clinical Investigators 2020

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

International Council for Harmonisation
- Draft (Step 2) guideline ICH E9(R1): Estimands and Sensitivity Analysis in Clinical Trials 2020

Leadership and Communication Training
- ASA Section Leadership Workshop: Storytelling for Impact 2020
- Mettlesome Workshop on Better Communication 2019
- The Effective Statistician Leadership Program 2019
- Effective Statistician - How to be More Innovative and Drive Change 2019
- Introduction to Improv 2018
- Fundamentals of Improv Comedy for Scientists 2017
- 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 w/ Discrete and Continuous Responses 2003

TEACHING EXPERIENCE

University of North Carolina at Chapel Hill, Department of Biostatistics
- Guest Lecturer, Clinical Trials Epidemiology Spring 2017, 2018
- Guest Lecturer, Design and Analysis of Clinical Trials Fall 2012, 2014, 2016, 2018, 2021
- Guest Lecturer, Leadership in Biostatistics Fall 2015, 2018
- Guest Lecturer, Models and Methodology in Categorical Data Fall 2018
- Guest Lecturer, Field Observations in Biostatistics Fall 2015-2017
- 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

American Statistical Association
- ASA Fellow 2020

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. Sall K, Foulks GN, Pucker AD, Ice KL, **RC Zink** & Magrath G. (2023). Validation of a modified National Eye Institute grading scale for corneal fluorescein staining. *Clinical Ophthalmology* 17: 757–767.

2. Levenson M, He W, Chen J, Fang Y, Faries D, Goldstein BA, Ho M, Lee K, Mishra-Kalyani P, Rockhold F, Wang H & **Zink RC**. (2023). Biostatistical considerations when using RWD and RWE in clinical studies for regulatory purposes: A landscape assessment. *Statistics in Biopharmaceutical Research* 15: 3-13.

3. Tauber J, Remington C, Gazis D & **Zink RC**. (2022). Predictability of clinical efficacy following LipiFlow thermal pulsation treatment in patients with meibomian gland dysfunction: a pilot study. Submitted to *Clinical Ophthalmology*.

4. Shing T, Preisser J & **Zink RC**. (2021). GEECORR: A SAS macro for regression models of binary correlated responses and within-cluster correlation using generalized estimating equations. *Computer Methods and Programs in Biomedicine* 208: https://doi.org/10.1016/j.cmpb.2021.106276.

5. Cabrera R, Singal AG, Colombo M, Kelley RK, Lee H, Mospan AR, Meyer T, Newell P, Parikh ND, Sangro B, Reddy KR, Watkins S, Zink RC, & Di Bisceglie AM. (2021). A real-world observational cohort of patients with hepatocellular carcinoma (HCC): Design and rationale for TARGET-HCC. *Hepatology Communications* 5: 538-547.

6. Fried MW, Crawford JM, Mospan AR, Watkins SE, Hernandez BM, **Zink RC**, Elliott S, Burleson K, Landis C, Reddy KR & Brown RS. (2021). Patient characteristics and outcomes of 11,721 patients with COVID-19 hospitalized across the United States. *Clinical Infectious Diseases* 72: e558-e565.

7. Weinberg E, Trinh HN, Firpi RJ, Bhamidimarri KR, Klein S, Durlam J, Watkins S, Reddy KR, Weiss M, **Zink RC** & Lok A. (2021). Lean Americans with nonalcoholic fatty liver disease have lower rates of cirrhosis and comorbid diseases. *Clinical Gastroenterology and Hepatology* 19: 996-1008.

8. Silverman R, Fine J, **Zink RC** & Ivanova A. (2019). Permutation and bootstrap testing for the sequential parallel comparison design. *Statistics in Biopharmaceutical Research* 11: 44-51.

9. **Zink RC**, Castro-Schilo L & Ding J. (2018). Understanding the influence of individual variables contributing to multivariate outliers in assessments of data quality. *Pharmaceutical Statistics* 17: 846-853.

10. **Zink RC**, Dmitrienko A & Dmitrienko A. (2018). Rethinking the clinically-based thresholds of TransCelerate BioPharma for risk-based monitoring. *Therapeutic Innovation & Regulatory Science* 52: 560-571.

11. **Zink RC**, Marchenko O, Sanchez-Kam M, Ma H & Jiang Q. (2018). Sources of safety data and statistical strategies for design and analysis: Clinical trials. *Therapeutic Innovation & Regulatory Science* 52: 141-158.

12. Izem R, Sanchez-Kam M, Ma H, **Zink RC** & Zhao Y. (2018). Sources of safety data and statistical strategies for design and analysis: Postmarket surveillance. *Therapeutic Innovation & Regulatory Science* 52: 159-169.

13. Marchenko O, Russek-Cohen E, Levenson M, **Zink RC**, Krukas-Hampel M & Jiang Q. (2018). Sources of safety data and statistical strategies for design and analysis: Real world insights. *Therapeutic Innovation & Regulatory Science* 52: 170-186.

14. 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. (2017). Statistical considerations for cardiovascular outcome trials in patients with type 2 diabetes mellitus. *Statistics in Biopharmaceutical Research* 9: 347-360.

15. **Zink RC** & Zhang W, eds. (2016, Aug). Special Issue: Papers from the 2015 ASA Biopharmaceutical Section Statistics Workshop. *Statistics in Biopharmaceutical Research* 8.

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

17. 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.

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

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

20. 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.

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

22. **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.

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

24. 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.

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

26. 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.

27. 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.

28. 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.

29. 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.

30. **Zink RC** & Qaqish BF. (2009). Correlated binary regression using orthogonalized residuals. *Collection of Biostatistics Research Archive (COBRA) Reprint Series*. Article 51.

31. 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: 1011-1020.

32. 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.

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

34. **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.

35. 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**, Munsaka M, Emir B, Ma Y, Li J, Wang W & Bennett D. (2022). Analysis considerations for real-world evidence and clinical trials related to safety. In Wang W, Buchanan J, Li J & Munsaka M, eds. *Quantitative Drug Safety and Benefit Risk Evaluation: Practical and Cross-Disciplinary Approaches*. Boca Raton, Florida: Chapman & Hall/CRC Press.

2. Ivanova A, Marchenko O, Jiang Q & **Zink RC**. (2018). Safety monitoring and analysis in oncology trials. In: Roychoudhury S & Lahiri S, eds. *Statistical Approaches in Oncology Clinical Development*. Boca Raton, Florida: Chapman & Hall/CRC Press.

3. **Zink RC**. (2018). 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*. Singapore: Springer Nature.

4. **Zink RC**. (2018). 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*. Singapore: Springer Nature.

5. **Zink RC,** Koch GG, Chung Y & Wiener LE. (2017). Advanced randomization-based methods in clinical trials. In: Dmitrienko A & Koch GG, eds. *Analysis of Clinical Trials Using SAS: A Practical Guide, Second Edition*. Cary, NC: SAS Institute Inc.

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

7. 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.

8. **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.

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

10. **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**. (2022). A reflection on 100 podcast episodes. The Biopharmaceutical Report.

2. **Zink RC**. (2021). My ASA story: Richard Zink, biostatistician and podcaster. AmStat News.

3. Fu H, Lee L, Liu M, Tang J, Wang Y, Zheng T, Zink RC, Zou KH. (2021). ICSA symposium panelists offer leadership advice. AmStat News.

4. **Zink RC** & Wu M. (2021). Celebrating the 40th Anniversary of the Biopharmaceutical Section: The Early Years (1966-1990). The Biopharmaceutical Report.

5. **Zink RC** & Wu M. (2021). Celebrating the 40th Anniversary of the Biopharmaceutical Section: The Early Years (1966-1990). AmStat News.

6. **Zink RC**. (2020). Biopharmaceutical section cracks code on cross-sector collaborations. *Amstat News*.

7. **Zink RC**. (2018). Introduction to the special section for sources of safety data and statistical strategies for design and analysis. *Therapeutic Innovation & Regulatory Science* 52: 140.

8. **Zink RC**. (2017, Nov). My thoughts on certifications. *AmStat News*, American Statistical Association.

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

10. **Zink RC** & Zhang W. (2016). Guest editors' note. *Statistics in Biopharmaceutical Research* 8: 229.

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

12. **Zink RC**. (2015). Using the relationships among study procedures to assess data quality. *JMPer Cable* 30: 13-15.

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

14. **Zink RC**. (2014). Identifying quality issues and misconduct using analyses of digit preference. *JMPer Cable* 29: 3-4.

15. Izem R & **Zink RC**. (2013, Aug). Tune into podcasts from the Biopharmaceutical Section. *AmStat News*, American Statistical Association.

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

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**.**

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.

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.

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. Ball G, Corrigan-Curay J, **Zink RC**. (2021). Closing keynote panel: IND safety reporting – FDA and industry alignment. Panelist. World Drug Safety Congress Americas.

2. Bekele N, Koprowicz K, Munsaka M, Nelson E & **Zink RC**. (2021). Data visualization game: Who is winning: Sponsors, third parties or someone else? Panelist. Joint Statistical Meetings.

3. Fu H, Lee L, Liu M, Tang J, Wang Y, Zheng T & **Zink RC**. (2020). Leadership in statistics and data science. Panelist. International Chinese Statistical Association Annual Conference.

4. Florance A, Levine R, Léger C, Monti K, Swift D, Wijayawardana SR, **Zink RC**. (2020). Everyone Counts in ASA – An informational walk through the organization, activities and opportunities. Panelist. Joint Statistical Meetings.

5. **Zink RC**. (2020). Using statistics and data visualization to improve data quality. PhUSE Single Day Event, New Jersey.

6. **Zink RC**. (2019). From real-world data to real-world evidence: A case study of direct-acting antivirals for the treatment of hepatitis C infection. SAMSI Conference on Advances in Precision and Personalized Medicine.

7. **Zink RC**. (2018). Understanding the individual contributions to multivariate outliers in assessments of data quality. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

8. **Zink RC**. (2017). Randomization-based nonparametric methods for clinical trials. Nonparametrics in Modern Biomedical and Clinical Sciences Conference.

9. **Zink RC**. (2017). Using contour plots to assess the sensitivity of clinical trial design assumptions. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

10. **Zink RC**. (2017). Sources of safety data and statistical strategies for design and analysis in clinical trials. Joint Statistical Meetings.

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

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

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

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

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

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

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

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

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

20. **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.

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

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

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

24. **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.

SHORT COURSE INSTRUCTOR AT SCIENTIFIC MEETINGS

1. **Zink RC** & Miclaus KJ. (2021). Data visualization in the life sciences. DIA Annual Meeting.

2. Ma Y, **Zink RC**, Buchanan J & Wang W. (2021). Designing, integrating, and analyzing RCT/RWE in safety decision making. DIA/FDA Biostatistics Industry and Regulator Forum.

3. **Zink RC** & Miclaus KJ. (2020). Data visualization in the life sciences. DIA Annual Meeting.

4. Ma Y, Emir B & **Zink RC**. (2019). Designing and integrating the RCT/RWE in safety decision making. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

5. **Zink RC** & Miclaus KJ. (2019). Data visualization in the life sciences. DIA Annual Meeting.

6. Izem R, **Zink RC** & Wang W. (2018). Designing and integrating the RCT/RWE in safety decision making. The 74th Deming Conference on Applied Statistics.

7. **Zink RC** & Miclaus KJ. (2018). Data visualization in the life sciences. DIA Annual Meeting.

8. **Zink RC** & Miclaus KJ. (2017). Data visualization in the life sciences. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

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

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

11. **Zink RC**. (2012). Advanced visual analytic approaches to safety analysis in clinical trials. Biopharmaceutical Applied Statistics Symposium.

CONTRIBUTED PRESENTATIONS AT SCIENTIFIC MEETINGS

1. **Zink RC**. (2019). From real world data to real world evidence: A case study of direct-acting antivirals for the treatment of hepatitis C infection. DIA Annual Meeting.

2. **Zink RC**. (2018). The power of podcast: Promoting statistics and data science in the age of social media. Topic contributed panel session at Joint Statistical Meetings.

3. **Zink RC**. (2018). Understanding the individual contributions to multivariate outliers in assessments of data quality. DIA Annual Meeting.

4. **Zink RC**. (2018). Identifying the professional patient in clinical trials. 21st DIA Annual Workshop in Japan for Clinical Data Management.

5. **Zink RC**. (2017). Sources of safety data and statistical strategies for design and analysis in clinical trials. DIA Annual Meeting.

6. **Zink RC**. (2017). Removing an ICH bottleneck: Efficient safety assessment using computer-generated adverse event narratives. DIA Annual Meeting.

7. **Zink RC**. (2017). Beyond the trees: The majesty of the forest plot. JMP Discovery Summit Europe.

8. **Zink RC**. (2017). Rethinking the clinically-based thresholds of TransCelerate BioPharma for risk-based monitoring. 20th DIA Annual Workshop in Japan for Clinical Data Management.

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

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

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

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

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

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

15. **Zink RC**. (2014). Signal detection of potentially fraudulent activity in clinical trials. Topic contributed session at Joint Statistical Meetings.

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

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

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

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

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

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

22. Scott A & **Zink RC**. (2012). CDISC data standards can facilitate composition of adverse event narratives. Society of Clinical Trials Annual Meeting.

23. **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.

24. 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.

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

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. **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.

39. 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. Pucker AD, **Zink RC**, Sall K, Foulks GN, Ice KL, Brubaker K & Magrath G. (2023). Evaluating the intra- and inter-examiner repeatability of the Lexitas modified NEI grading scale. Association for Research in Vision and Ophthalmology Annual Meeting.

2. Kim HP; Idowu MO, **Zink RC**, Mospan AR, Roden M, Newsome P, Lok A, Thuluvath P, Taunk J, Fried MW, Sanyal AJ & Barritt AS. (2020). Heterogeneous documentation and poor concordance of NASH pathology may limit its clinical utility in real-world practice. American Association for the Study of Liver Diseases Annual Meeting.

3. Mayo MJ, Mospan A, Smith H, McLaughlin M, Thompson A, Sandefur R, **Zink RC**, Bowlus C & Levy C. (2020). Pruritus in primary biliary cholangitis is under-treated in clinical practice: results from TARGET-PBC. American Association for the Study of Liver Diseases Annual Meeting.

4. Carey E, Smith H, McLaughlin M, Thompson A, Mospan A, Sandefur R, Zink RC, Kim WR & Levy C. (2020). The pervasive impact of pruritus on quality of life in patients with primary biliary cholangitis (PBC): real world experience in TARGET-PBC. American Association for the Study of Liver Diseases Annual Meeting.

5. Mesenbrink P, Barritt AS, Loomba R, Newsome PN, Sanyal AJ & **Zink RC**. (2020). Predicting advanced fibrosis using non-invasive clinical tests and modern machine learning methods in TARGET-NASH. EASL International Liver Congress.

6. Weinberg E, Trinh HN, Firpi RJ, Bhamidimarri KR, Klein S, Malahias L, **Zink RC** & Anna Lok. (2019). Lean NAFLD patients have lower prevalence of cardiovascular, metabolic and severe liver disease compared to overweight or obese patients with NAFLD. EASL International Liver Congress.

7. Cabrera R, Singal A, Colombo M, El-Khoueiry A, Kelley RK, Lee H, Malahias L, Meyer T, Newell P, Parikh N, Sangro B, Reddy KR, **Zink RC** & Di Bisceglie A. (2019). Management of hepatocellular carcinoma (HCC) in a real life multinational, longitudinal, observational study (TARGET-HCC). EASL International Liver Congress.

8. Parikh ND, Malahias L, Brown RS, Cabrera R, Jones PD, Landis C, Lee H, Mantry P, Mena E, Poddar N, Reddy KR, Shrestha R, Thuluvath P, **Zink RC**, Singal AG. (2019). Regional, racial/ethnic, and socioeconomic disparities and treatment outcomes in patients with hepatocellular carcinoma (HCC) in the US. Gastrointestinal Cancers Symposium.

9. Carey EJ, Levy C, Mayo MJ, Bowlus CL, Deane K, Sandefur RA, Laliberte PH, **Zink RC** & Kim WR. (2018). Patient-reported indicators of health and symptoms in US patients with primary biliary cholangitis. American Association for the Study of Liver Diseases Annual Meeting.

10. Zhao B & **Zink RC**. (2017). E_{max} modeling for assessing dose-response relationships using JMP. JMP Discovery Summit.

11. **Zink RC** & Jiang X. (2017). Using contour plots to assess the sensitivity of clinical trial design assumptions. JMP Discovery Summit.

12. Zhao B & **Zink RC**. (2017). E_{max} modeling for assessing dose-response relationships using JMP. Joint Statistical Meetings.

13. Dmitrienko A, Miclaus K & **Zink RC**. (2017). Analysis of adverse event relationships in clinical trials using JMP. Joint Statistical Meetings.

14. **Zink RC**, Dmitrienko A & Dmitrienko A. (2017). Rethinking the clinically-based thresholds of TransCelerate BioPharma for risk-based monitoring. Statisticians in the Pharmaceutical Industry Annual Meeting.

15. **Zink RC**. (2017). Using power contours to assess the sensitivity of clinical trial design assumptions. Statisticians in the Pharmaceutical Industry Annual Meeting.

16. **Zink RC** & Foglia D. (2017). Efficient safety assessment in clinical trials using the computer-generated AE narratives of JMP Clinical. JMP Discovery Summit Europe.

17. 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.

18. 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.

19. 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.

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

21. **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.

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

23. **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**. (2020). Analysis considerations for real-world data alone and in conjunction with data from randomized controlled trials with applications to safety. DIA-ASA Interdisciplinary Safety Evaluation (DAISE) Fan Club Webinar Series.

2. **Zink RC**. (2018). Using statistics and data visualization to improve data quality. PhUSE Data Visualizations Working Group.

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

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

5. **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.

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

OTHER PRESENTATIONS

1. **Zink RC**. (2023). Statistics careers in the medical product industry. Duke Department of Statistical Science, Statistical Science Proseminar.

2. Bailer J, Colopy GW, Peng R & **Zink RC**. (2021). Episode 7: Turning the Tables on Glen, Richard, Roger, and John. Practical Significance Podcast.

3. **Zink RC**. (2021). Biostatistics, COVID-19, and some potentially useful advice for future bio(statisticians) and data scientists. California Polytechnic State University Statistics Club Seminar.

4. Lisa LaVange & **Zink RC**. (2021). Master protocol efficiencies speeding COVID-19 treatments. Interviewer. DIA Podcast.

5. **Zink RC**. (2021). It is never too early to think about statistical leadership. UNC-Chapel Hill Department of Biostatistics Seminar.

6. Kilaru R, Lisic J, & **Zink RC**. (2020). Overview of opportunities for statisticians at TARGET PharmaSolutions. National Institute of Statistical Sciences 4th Virtual Industry Career Fair.

7. **Zink RC**. (2019). Current trends in the pharmaceutical industry and how they will affect you as a statistician. The Effective Statistician Podcast.

8. **Zink RC**. (2019). Careers for statisticians in the medical product industry. ASA Student Chapter & Statistics Club Meeting, Minnesota State University, Mankato.

9. **Zink RC**. (2018). Promoting statistics through the ASA Biopharmaceutical Section podcast. NC ASA Mentoring and Early Career Development Workshop. Invited Keynote.

10. Howard AG, Schwartz T, Wang X, **Zink RC**. (2018). UNC BIOS alumni career panel for doctoral students. Department of Biostatistics, UNC-Chapel Hill.

11. Jiang Q, Marchenko O, **Zink RC**. (2018). Statistical strategies for using sources of safety data. DIA Podcast.

12. **Zink RC**. (2018). An introduction to biostatistics. Research Triangle High School, A.P. Statistics Class.

13. **Zink RC**. (2017). An introduction to biostatistics. Research Triangle High School, A.P. Statistics Class.

14. **Zink RC**. (2017). Rethinking the clinically-based thresholds of TransCelerate BioPharma for risk-based monitoring. RBM Working Group Seminar, University of Tokyo, Tokyo, Japan.

15. **Zink RC**. (2017). An overview of methods to assess data integrity in clinical trials. Seminar at the National Cerebral and Cardiovascular Center (NCVC), Osaka, Japan.

16. **Zink RC**. (2017). Beyond the trees: The majesty of the forest plot. Kyoto University Department of Biostatistics Seminar, Kyoto, Japan.

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

18. **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.

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

20. **Zink RC**. (2015). Risk-based approaches to assess data integrity in medical product development. Novo Nordisk Biostatistics International Meeting, Helsingör, Denmark. Plenary Presentation.

21. Helms R, Pan W, Weaver M, **Zink RC**. (2013). UNC BIOS alumni career panel for doctoral students. Department of Biostatistics, UNC-Chapel Hill.

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

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

24. **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.

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

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

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

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

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

MANUSCRIPTS & BOOKS REVIEWED

1. Various Authors. (2022). Article, *SoftwareX*.
2. Various Authors. (2022). Article, *Scientific Reports*.
3. Various Authors. (2020). Article, *Health Services and Outcomes Research Methodology*.
4. Various Authors. (2020). Article, *Contemporary Clinical Trials Communications*.
5. Various Authors. (2020). Article, *Clinical Trials*.
6. Horstman J & Smith C. (2020). *Clinical Trial Reporting Using SAS*. Cary, NC: SAS Institute Inc. In Technical Review.
7. Various Authors. (2019). Article, *Pharmaceutical Statistics*.
8. Various Authors. (2018). Article, *Journal of the American Medical Informatics Association*.
9. Various Authors. (2018). Article, *Clinical Trials*.
10. Various Authors. (2017). Article, *Journal of the American Medical Informatics Association*.
11. Lievense R. (2017). *A Straightforward Guide to Solving Pharmaceutical Manufacturing and Development Problems with JMP®*. Cary, NC: SAS Institute Inc.
12. Figard S. (2017). *Biostatistics with JMP®: An Introductory Course.* Cary, NC: SAS Institute Inc.
13. Various Authors. (2017). Article, *Statistics in Medicine*.
14. Various Authors. (2017). Article, *American Medical Informatics Association*.
15. Bihl T. (2017). *Biostatistics Using JMP®: A Practical Guide.* Cary, NC: SAS Institute Inc.
16. Carver R. (2017). *Preparing Data for Analysis with JMP®*. Cary, NC: SAS Institute Inc.
17. Nandakumar S & Dmitrienko A. (2017). Dose-finding methods. In: Dmitrienko A & Koch GG, eds. *Analysis of Clinical Trials Using SAS: A Practical Guide, Second Edition*. Cary, NC: SAS Institute Inc.
18. Various Authors. (2016). Article, *Journal of the American Medical Association.*
19. Various Authors. (2016). Article, *Journal of Biopharmaceutical Statistics*.
20. Various Authors. (2016). Article, *Statistics in Medicine*.
21. Various Authors. (2015). Article, *Clinical Trials*.
22. Various Authors. (2015). Article, *Statistics in Biopharmaceutical Research*.
23. Stone CA & Zhu X. (2015). Bayesian Estimation and Item Response Theory Using SAS. Cary, NC: SAS Institute Inc.

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

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

26. Various Authors. (2010). Stratified multivariate Mann-Whitney estimators for the comparison of two treatments with randomization based covariance adjustment. For *Statistics in Biopharmaceutical Research*, Special Festschrift issue to honor Professor Gary Koch.

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

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

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

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

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

CONFERENCE & WORKSHOP SESSIONS

1. **Zink RC** & Bubb V. (2021). 40 Years of the Biopharmaceutical Section: Celebrating our Past, Planning for our Future. Town Hall Session Organizer. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

2. **Zink RC** & Bubb V. (2021). 40 Years of the Biopharmaceutical Section: Celebrating our Past, Planning for our Future. Topic Contributed Panel Discussion Organizer. Joint Statistical Meetings.

3. **Zink RC**. (2020). Creating a Statistical Community with the Biopharmaceutical Section. Roundtable. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

4. **Zink RC**. (2019). Real-world data to real world evidence. Roundtable. DIA Annual Meeting.

5. **Zink RC**. (2019). Real-world data to real world evidence. Chair. DIA Annual Meeting.

6. **Zink RC**. (2018). The power of podcast: Promoting statistics and data science in the age of social media. Topic contributed panel organizer. Joint Statistical Meetings.

7. **Zink RC**. (2018). Innovative visualization approaches. Chair. DIA Annual Meeting.

8. **Zink RC** & Miclaus KJ. (2017). Case studies in data visualization for analysis. Tutorial instructor. JMP Discovery Summit.

9. **Zink RC**. (2017). Chat with the publications officer of the biopharmaceutical section. Roundtable luncheon organizer. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

10. Duke S, Forshee R, Soukup M & **Zink R**. (2017). Seeing is believing: effective use of statistical graphics across drug development. Parallel session organizer. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

11. **Zink RC**. (2017, Aug). ASA Ask-Me-Anything Young Professionals Discussion Group.

12. Miclaus KJ & **Zink RC**. (2017). Data visualization for life sciences with JMP. Computer Technology Workshop. Joint Statistical Meetings.

13. **Zink RC**. (2016). Statistical innovation: Better decisions through better methods. Chair. ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop.

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

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

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

17. **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.

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

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

20. **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.

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

MASTER & DOCTORAL STUDENT RESEARCH

1. Ivvone Zhou. (2024). Simulation study to assess the effects of missing data and measurement frequency for the analysis of mean rate of growth in clinical trials of geographic atrophy. Honors Research Thesis Advisor, Bachelor of Science in Public Health.

2. Maya Krishnamoorthy. (2023). Simulation study for non-inferiority trials in subjects with glaucoma or ocular hypertension. Honors Research Thesis Advisor, Bachelor of Science in Public Health.

3. Zhimeng Liu. (2023). Simulation study of the sequential testing of sign and symptom endpoints for superiority trials in dry eye disease. Honors Research Thesis Advisor, Bachelor of Science in Public Health.

4. Laura Elizabeth Wiener. (2019). Extensions of methods for clinical trials: (1) randomization-based ANCOVA for longitudinal clinical trials with missing data, particularly the sequential parallel comparison design, and (2) methods for clarifying criteria for study continuation at interim analysis. Dissertation Committee Member, Doctor of Public Health.

5. Rachel Kloss Silverman. (2017). Methods for the sequential parallel comparison design (SPCD). Dissertation Committee Member, Doctor of Philosophy.

6. Beibo Zhao. (2017). Emax modeling for assessing dose-response relationships. Master Paper Advisor, Master of Science.