

JIE CHEN, MD, PhD

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SUMMARY

- More than 23 years of experience in biopharmaceutical research, development, regulation and life-cycle management of drugs and biologics in a broad range of therapeutic areas (CVM, oncology, immuno-oncology, diabetes, obesity, respiratory, infection diseases, immunology, dermatology)
- Technical knowledge and insights in biopharmaceutical statistics with focuses on innovative trial design and data analysis, safety evaluation, IND/NDA/BLA and ICH practice
- Problem-solving skills in statistical innovation and its applications to biopharmaceutical product development
- Professional leadership with respect to visionary and strategic thinking, planning, and execution
- Good communication and inter-personal skills with clear mind-set and extraordinary passion

EDUCATION

- *Temple University*, Philadelphia, Pennsylvania
Ph.D., Statistics, December 2003; **M.S.**, Statistics, May 2000
- *University of Oklahoma Health Sciences Center*, Oklahoma City, Oklahoma,
M.P.H., Biostatistics and Epidemiology, December 1994
- *Shanghai First College of Medicine School of Public Health* (Now *Fudan University School of Public Health*), Shanghai, China
M.S., Biostatistics, July 1989; **M.D.**, July 1984

PROFESSIONAL EXPERIENCES

- *Distinguished Scientist*, February 2017 – Present, Methodology Research, Biostatistics and Research Decision Science, Merck Research Laboratories, Upper Gwynedd, Pennsylvania
- *Sr. Global Group Head, Biostatistical Science & Pharmacometrics*, April 2015 – January 2017, Novartis Pharmaceuticals Co., One Health Plaza, East Hanover, NJ (int'l assignment to Shanghai)
- *Senior Director*, Head of Biometrics & Information Sciences, February 2014 – April 2015, AstraZeneca Global Medicines Development (GMD) China (Shanghai)
- *Director & Senior Director*, Head of Biostatistics and Statistical Programming, July 2010 – February 2014, Merck Serono (Beijing) Pharmaceutical R&D Co., Ltd.
- *Director*, statistics, May 2009 – July 2010, Global Medical Services, Abbott Laboratories, Abbott Park, IL
- *Senior Biometrician & Associate Director*, December 2004 – May 2009, Investigational Research, Merck Research Laboratories, Upper Gwynedd, PA
- *Biometrician, Senior Biometrician*, June 1997 – December 2004, Vaccine Biometrics Research, Merck Research Laboratories, West Point, PA

- *Senior Project Scientist*, May 1995 – May 1997, Vaccine Quality Operations, Merck Manufacturing Division, West Point, PA
- *Biostatistician*, December 1994 – May 1995, Trilogy Consulting Corporation, Waukegan, IL
- *Graduate Research Assistant*, September 1992 – December 1994, Center for Epidemiologic Research, University of Oklahoma Health Science Center, Oklahoma City, OK
- *Director*, July 1989 – June 1991, Information Research Office, Shanghai Population Information & Research Center, Shanghai, China
- *Public Health Officer*, July 1984 – June 1986, Shanghai Municipal Bureau of Health, Shanghai, China

PROFESSIONAL SERVICES

- *Adjunct faculty*, Temple University, Dec. 2017 – present
- *President*, *The International Society for Biopharmaceutical Statistics (ISBS)*, www.IsBioStat.org, 2010-present
- *Guest Lecturer*, Shanghai Center of Mathematics, Fudan University, 2016
- *Scientific Program Committee*, *CEN-ISBS Joint Symposium*, Medical University of Vienna, 2017 (www.CENISBS2017.org)
- *Organizing Committee*, *UMBC-Stanford Workshop on Clinical Trials and regulatory Science*, University of Maryland Baltimore County campus, 2015 & 2016
- *Executive Committee*, *The Fourth International Symposium on Biopharmaceutical Statistics* to be held in Beijing, China, June 29 - July 1, 2015
- *Co-Guest Editor*, a Special Issue of the *Journal of Biopharmaceutical Statistics* on medical product safety, 2013
- *Co-Chair, Executive Committee*, *The Second International Symposium on Biopharmaceutical Statistics*, jointly organized by EMA, ISBS and IBS-German Region, Berlin, Germany, February 28 - March 3, 2011 (www.IsBioStat.org)
- *Member of Steering Committee and Round-Table Co-Chair*, *2010 FDA/Industry Statistics Workshop*, Washington DC, September 20-23, 2010
- *Co-Guest Editor*, *Statistics in Biopharmaceutical Research*, 2009
- *Current Index to Statistics Management Committee*, American Statistical Association, 2008 - 2010
- *Co-Chair, Executive Committee*, *the First International Symposium on Biopharmaceutical Statistics*, June 30 - July 2, 2008, Shanghai, China (www.IsBioStat.org)
- *Organizing Committee*, *the 5th International Conference on Multiple Comparison Procedures*, July 9 - 11, 2007, Vienna, Austria (www.mcp-conference.org)
- *Co-Guest Editor* (with Jason Hsu and Frank Bretz), *Biometrical Journal*, 2007
- *Co-Organizer*, *the 4th International Conference on Multiple Comparison Procedures*, Shanghai, China, 2005
- Serving as a referee for
 - *Biometrical Journal* (2006, 2010, 2012, 2015)

- *Biometrics* (2007, 2008, 2012)
- *Communications in Statistics - Theory and Methods* (2004, 2005)
- *Journal of Biopharmaceutical Statistics* (2003, 2006, 2007, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017)
- *Journal of Statistical Planning and Inference* (2003)
- *Journal of Infection and Public Health* (2015, 2016, 2017)
- *Statistics in Biopharmaceutical Research* (2008, 2010, 2012, 2015)
- *Statistics in Medicine* (2009, 2011, 2016)
- *Statistical Methods in Medical Research* (2010, 2013)
- *The American Statistician* (2012)

PUBLICATIONS

Book (Available in April 2018)

1. **Chen, J.**, Heyse, J. and Lai, T. L. (2018) *Medical Product Safety Evaluation: Biological Models and Statistical Methods*. Chapman & Hall, New York.

Articles in peer reviewed journals or book

1. **Chen, J.**, Zhao, N. Q. (2017) and He, R. Y. Recent Advances in Drug Development and Regulatory Science in China (to appear in *ICSA Bulletin*).
2. **Chen, J.**, Lin, R., Zhao, Z. (2017) Some Design Considerations for Simultaneous Global Drug Development (*under revision*).
3. **Chen, J.**, Lai, T. L., and Heyse, J. F. (2017) Sequential Generalized Likelihood Ratio Tests for Proportional Changes of Two Poisson Processes (*in preparation*).
4. **Chen, J.**, Chen, W. F., Zhao, N. Q., and Qin, G. Y. (2017) A Unified Approach to Simultaneous Testing of Superiority and Non-inferiority on Multiple Endpoints in Clinical Trials (*Submitted*).
5. Miao, J., Lai, T. L., **Chen, J.** and Heyse, J. F. (2017) Sensitivity versus specificity in the evaluation of adverse event data from clinical trials. *Medical Safety and Global Health*, **6**:133. (doi: 10.4172/2574-0407/1000133)
6. **Chen, J.** (2015) Sequential Testing for Safety Evaluation. *Statistical Methods for Evaluating Safety in Medical Product Development*, Ed. by A. L. Gould. Wiley, New York, NY.
7. Chen, W. F., Zhao, N. Q. and **Chen, J.** (2013) A Bayesian Approach to Sequential Monitoring of Medical Product Safety. *Journal of Biopharmaceutical Statistics*, **23**:213-230.
8. **Chen, J.**, Luo, J. F., Liu, K. and Merhotra, D. V. (2011) On Power and Sample Size Computation for Multiple Testing Procedures. *Computational Statistics and Data Analysis*, **55**: 110 - 122. (doi:10.1016/j.csda.2010.05.024)
9. **Chen, J.**, Zhong, J. L. and Nie, L. (2010) Bayesian Approach to Stability Analysis. *Encyclopedia of Biopharmaceutical Statistics* 3rd Ed., S.C. Chow (ed), 111-115.
10. Shih, M. C., Lai, T., Heyse, J. F., **Chen, J.** (2010) Sequential Generalized Likelihood Ratio Tests for Vaccine Safety Evaluation. *Statistics in Medicine*, **29**:2698-2708.
11. **Chen, J.** and Zhao, X. (2010) A Bayesian Measurement Error Approach to QT Interval Correction and Prolongation. *Journal of Biopharmaceutical Statistics*, **20**: 523 - 542.

12. **Chen, J.**, Heyse, J., Heaton, P. and Kuter, B. (2010) On Age Dependence of Intussusception Risk of Tetravalent Rhesus-Human Reassortant Rotavirus Vaccine: Is It Beyond Doubt? *American Journal of Epidemiology* **171**: 1046 - 1054.
13. Nie, L., Chu, H., Cheng, Y., Spurney, C., Nagaraju, K., **Chen, J.** (2009) Marginal and conditional approaches to multivariate variables subject to limit of detection. *Journal of Biopharmaceutical Statistics*, **19**: 1151-1161.
14. Zhao, N.Q., Yao, C. and **Chen, J.** (2008) On the Amendments of China's Provisions for Drug Registration. *Drug Information Journal* **42**: 467 - 475.
15. **Chen, J.**, Zhong, J. L. and Nie, L. (2008) Bayesian Hierarchical Modeling of Drug Stability Data. *Statistics in Medicine* **27**: 2361-2380.
16. Bretz, F., and **Chen, J.**, and Hsu, J. (2007) Preface. *Biometrical Journal* **49**: 5 - 6.
17. Chen, F., **Chen, J.** and Hsu, J. (2007) Current Status of Statistical Requirements for Clinical Trials in China. *Drug Information Journal* **42**: 321-330.
18. Lehman, H., **Chen, J.**, Gould, L., Kassekert, R., Beninger, P., Carney, R., Goldberg, M., Goss, M., Kidos, K., Sharrar, R., Shields, K., Sweet, A., Wiholm, B., Honig, P. (2007). An Evaluation of Computer-Aided Disproportionality Analysis for Post-Marketing Signal Detection. *Clinical Pharmacology and Therapeutics* **82**: 173-180 .
19. **Chen, J.** and Sarkar, S. K. (2006) A Bayesian Determination of Threshold for Identifying Differentially Expressed Genes in Microarray Experiments. *Statistics in Medicines* **25**: 3174-3189. (doi: 10.1002/sim.2422)
20. Gao, X., Alvo, M., **Chen, J.**, and Li, G (2006) Nonparametric Multiple Comparison Procedures for Unbalanced One-Way Factorial Designs. *Journal of Statistical Planning and Inference* **138**: 2574-2591.
21. Ranheim, T., Mathis, P., Joelsson, D., Smith, M. E., Campbell, K. M., Lucas, G., Barmat, S., Melissen, E., Benz, R., Lewis, J. A., **Chen, J.**, Schofield, T., Sitrin, R. D., Hennessey, J. P. (2006) Development and Application of a Quantitative RT-PCR Potency Assay for a Pentavalent Rotavirus Vaccine (RotaTeq®). *Journal of Virological Methods* **131**: 193-201.
22. **Chen, J.** and Sarkar, S. K. (2004). Multiple Testing of Response Rates with A Control: A Bayesian Stepwise Approach. *Journal of Statistical Planning and Inference* **125**: 3-16.
23. **Chen, J.** (2003). Bayesian Approaches to Simultaneous Testing of Multiple Hypotheses. *Ph.D. dissertation, Temple University.*
24. **Chen, J.** (1991). Family Planning Programs and Their Impact on Fertility: The Case of Shanghai. *China Population Research Leads* **6**: 1-19.
25. **Chen, J.** (1991). The Impact of Birth Control Methods on Chinese Women's Fertility. *Population Dynamics* **2**, 37-42.
26. Ning, H. and **Chen, J.** (1990) *A Bird's Eye-View of Population and Family Planning in Shanghai.* Shanghai Population Information Center.
27. **Chen, J.** and Yan, Y. (1989) Sociomedical Aspects of Pregnancy Among Adolescents. *Population Studies and Reports* **4**: 34-40.
28. **Chen, J.** and Zheng, H. (1989) An Application of Prevalence Model: The Case of Shanghai. *Population Dynamics* **3**: 37-44.

29. Gao, E. and **Chen, J.** (1989) An Analysis of Infant Birth Weight and Its Determinants. *Collection of the China In-Depth Fertility Survey (Phase-I)*. Shanghai Bureau of Statistics.
30. Gao, E. and **Chen, J.** (1987). Fertility Rates and Contraceptive Prevalence in Shanghai County. *Acta Academia Medicinea Shanghai Suppl.* **2**, 113-118.
31. He, C., **Chen, J.**, and Zhang B. L. (1987) Health Status of the Elderly Population in Shanghai County. *Shanghai Sciences and Technologies* **2**, 34-37.

CONFERENCE AND INVITED PRESENTATIONS

1. **Chen, J.** (2015) Sequential Generalized Likelihood Ratio tests. *2015 ICSA China Statistical Conference*, July 4-5, 2015
2. **Chen, J. and Lai, T. L.** (2014) Change-Point Methods for Medical Product Safety Evaluation. *2014 Workshop on Change-Point and Related Topics*, Shanghai Jiaotong University, Shanghai, China, May 9-10, 2014
3. **Chen, J.** (2013) Sequential Generalized Likelihood Ratio Tests for Safety Evaluation. *DIA China*, May 15, 2013
4. **Chen, J.** (2013) Strategies for Statistical Evaluation of Safety Data in Clinical Trials. *The 6th Annual Drug Safety & Public Policy Summit*, Shanghai, China, July 24-25, 2013
5. **Chen, J.** (2012) Multi-Regional Clinical Trail Designs by Incorporating Within and Between Region Variations. *Invited presentation at ICH Workshop organized by the Beijing Biometric Forum*, Beijing, China, October 20, 2012
6. **Chen, J.** (2012) Statistical Analysis of Safety Data in Clinical Trials. *Invited presentation at the Biostatistics Summer Workshop*, Osaka, Japan, August 17 - 19, 2012
7. **Chen, J.** and Tsong Y.(2011) Statistical Methods for Biopharmaceutical Product Safety Surveillance. *Short Course given at The Second International Symposium on Biopharmaceutical Statistics*, Berlin, Germany, February 27 - March 3, 2011
8. **Chen, J.** and Tsong, Y. (2010) Quantitative Pharmacovigilance: Statistical Approaches to Medical Product Safety Evaluation. *Short Course given at the FDA/Industry Statistics Workshop*, Washington DC, September 20 - 21, 2010
9. **Chen, J.** (2010) Power and Sample Size Determination for Superiority-Noninferiority Trials with Multiple Endpoints and a Mixture of Monitoring Schemes. *Invited presentation, Multiple Comparisons in Clinical Trials: Evaluating Practice and Regulations*, Washington DC, January 25-27, 2010
10. **Chen, J.** (2010) Statistical Challenges Evaluating the Safety of Vaccines: A Case Study of Rotavirus Vaccines. *Invited presentation at the HSPH - Merck Workshop on Vaccines and the Control of Disease*, Harvard School of Public Health, May 20-21, 2010
11. **Chen, J.** (2009) Quantitative Pharmacovigilance: Statistical Approaches to Medical Product Safety Surveillance. Short course given at *Fudan University, Taiwan's National Health Research Institute, Taiwan's Center for Drug Evaluation, National Taipei University and Foundation of Medical Professionals Alliance in Taiwan*, December 9-19, 2009
12. **Chen, J.** (2009) Sequential Approaches for Safety Evaluation. *Invited presentation, Center for Biological Evaluation (EBER), US Food and Drug Administration*, May 20, 2009
13. **Chen, J.** (2008) Sequential Probability Ratio Tests with Application to Drug Research and Development. *Invited presentation, Department of Statistics, Stanford University*, October 20, 2008

14. **Chen, J.**, Luo, J. F., Liu, K. and Mehrotra, D. (2008) Power and Sample Size for Stepwise Procedures. *The First International Symposium on Biopharmaceutical Statistics*, June 30 - July 2, 2008, Shanghai, China
15. **Chen, J.** (2007) Multiple Testing in Change-Point Problem. *The 5th International Conference on Multiple Comparison Procedures*, July 9-11, 2007, Vienna, Austria
16. **Chen, J.** (2006) A Bayesian Approach to Controlling the False Classification Rate. *Invited presentation, the American Statistical Association Connecticut Chapter*, Connecticut, March 10, 2006
17. **Chen, J.** and Sarkar, S. K. (2004) Bayesian Average FDR and FNR in Single-Step Procedure with Application to Microarray Experiments *The American Statistical Association Joint Statistical Meeting*, Toronto, Canada, August 8-12, 2004
18. **Chen, J.** (2004) The Role of Statistics in Biopharmaceutical Research: From Early Discovery to Post-Marketing Monitoring. *Invited presentation, Bridging Chinese and Global Healthcare Markets - International Symposium on FDA Regulatory Guidelines*, sponsored by Blue Bell Consulting and Fudan University. Shanghai, China, July 6- 7, 2004
19. **Chen, J.** (2004) Bayesian Consideration of Misclassification Rates with Application in Microarray Experiments (*invited Departmental Seminar talk*), Department of Mathematics and Statistics, University of Maryland, MD
20. **Chen, J.** (2004) A Bayes Decision-Theoretic Approach to the FDR and FNR in Single-Step Procedures (*invited Departmental Seminar talk*), Department of Mathematics and Statistics, York University, Toronto, Canada
21. **Chen, J.** (2004) A Bayesian Perspective on the False Discovery and False Non-discovery Rates. *2004 ENAR Spring Meeting*, Pittsburgh, PA, USA.
22. **Chen, J.** (1994) Risk Factors Associated with Cardiovascular Disease in American Indians. *The Fifth Annual Conference of Oklahoma Public Health Association*, Oklahoma City, Oklahoma, July 28-30, 1994.
23. **Chen, J.** (1991) Family Planing Programs and Their Impact on Fertility. Invited Paper, *The 22nd International Summer Seminar on Population*, Honolulu, Hawaii, June 2-21, 1991.
24. **Chen, J.** (1990) Evaluation of Family Planning Programs: Methodological Issues. *International Population Forum*, Guangzhou, China, April 10-17, 1990.
25. **Chen, J.** (1990) Population Information and Policy. *Invited presentation, the 2nd International Conference on Population Information*, Beijing, China, January 10-13, 1990.

PROFESSIONAL MEMBERSHIPS

- American Statistical Association
- International Biometric Society (ENAR)
- International Chinese Statistical Association (ICSA)
- International Society for Biopharmaceutical Statistics (ISBS)

HONORS AND AWARDS

- 2003 *Best Student Paper Award* (*Bayesian determination of threshold for identifying differentially expressed genes in microarray experiments*), Biopharmaceutical Section of the American Statistical Association

- *Graduate Research Fellowship*, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, 1992-1994
- *East-West Center Scholarship*, East-West Population Institute, East-West Center, Honolulu, Hawaii, 1991

COMPUTER SKILLS

- *Statistical Packages*: Proficient in SAS procedures (general and statistical procedures, SAS macro coding), R, S-Plus, WinBUGS
- *Languages*: TSO/JCL, Visual Basic
- *Applications*: Proficient in \LaTeX , Windows software and databases, relational database, spreadsheet, and presentation software
- *Algorithms*: Markov Chain Monte Carlo simulations, Bayesian simulation
- *Operating Systems*: Windows, Unix/Linux