CURRICULUM VITAE

Chao Wang, Ph.D.
President, Pharma Data Associates LLC
e-mail: Chao.Wang@PharmaDataAssociates.com. Phone: 410-370-9508

Summary

- Experienced in establishing and managing the Biometrics (Biostatistics, Statistical Programming, Clinical Data Management, and Database Management) department, including budget forecast and management.
- Submitted or reviewed over 10 BLA/NDA as the primary sponsor statistician or as the primary FDA statistical reviewer.
- Organized and served on the Data Monitoring Committees (DMC).
- Statistical expertise: group sequential trial design and futility analysis, non-inferiority design, missing data imputation, mixed effects models, and survival analysis.
- Medical experience: oncology, analgesic/sedation, dermatology, immunology, nephrology, cardiac, and CNS.

Professional Experience

Jun 2011 - Present

President and Principal Statistician
Pharma Data Associates, LLC

- Provide consultation to the clients' clinical development programs: study design, sample size/power calculation, protocol development, CRF design, EDC/IWRS, statistical analysis plan, SAS programming, CSR review, strategy of ISS/ISE and clinical development program, and FDA electronic submission data package.
- Serve on Data Monitoring Committees for several phase I/II clinical studies. Assisted the development of the stopping boundaries for safety and futility.
- Lead the Biometrics team for the statistics, programming, and data management support for phase II/III studies and ISS/ISE preparation.
- Medical area: pain, CINV, gastroenterology.

Jan 2010 – Jun 2011

Senior Director, Biometrics
Shionogi Inc., Florham Park, NJ

- Created and managed the Biometrics department and the infrastructure.
- Forecasted the headcount and budget.
- Recruited and managed the staff to provide support for the clinical development, medical affairs, manufacturing quality, and pharmacovigilance.
- Reviewed and approved protocols, CSRs, and FDA submission documents.
- Collaborated with the Japanese counterpart on the global standardizations.
- Medical area: metabolic syndrome, Opioid-induced AEs, women's health, CNS, and hematology.

Oct 2009 – Jan 2010	**Executive Director, Biometrics** Abraxis BioScience, Boston, MA o Oversaw the biostatistical support for the clinical development programs. o Provided budget forecast and assisted the review of in-licensing products. o Medical area: oncology.
Mar 2008 – May 2009	**Senior Director, Biometrics** King Pharmaceuticals (legacy Alpharma Pharmaceuticals LLC), Piscataway, NJ o Created and managed the Biometrics department and the infrastructure. o Provided input on project timelines and resource requirements. Forecasted the department budget. o Reviewed and approved study protocols and reports. o Successfully led and managed the preparation of the ISS and the statistical data package in CDISC and the FDA 1999 Guidance formats for the EMBEDA NDA resubmission. Assisted the preparation of the briefing book and Q&A for the FDA Advisory Committee meeting. o Medical area: pain/analgesics.
2003 – 2008	**Senior Director, Biometrics** Eisai, Inc. (legacy MGI Pharma, Inc. 2005-2008 and legacy Guilford Pharmaceuticals, Inc. 2003-2005) Baltimore, MD o Created and managed Biometrics department. Developed SOPs, procedures, and templates. Decided computer hardware and software. Set up vision and expectation for the department staff. o Responsible for the direction and operation of the Biometrics department, supporting 4 late phase/marketed products and 5 early to mid phase products. Made decisions for recruitment for in house needs vs. outsourcing opportunities. o Provided input to the management on project timelines and resource requirements. Forecasted and managed the department budget. o Championed the EDC data management system. o Led the Biometrics team for the clinical development of Lucedra®. Spearheaded the ISS/ISE for 21 clinical trials with the design, analysis, and interpretation of the statistical tables. Interacted with the FDA eSubmission team and managed the preparation of the statistical part of the NDA submission in CDISC format. o Designed and actively negotiated with the FDA for the noninferiority and superiority trials for a cardiovascular drug. o Organized two DMCs for phase III studies in oncology and CV areas. o Prepared and defended a regulatory submission in an Asian country. o Medical area: Sedation, CV, oncology, hematology, and CNS.
2001 – 2003	**Mathematical Statistician** Center for Biologics Evaluation and Research (CBER) The US Food and Drug Administration (FDA). Rockville, MD o Reviewed submissions for over 70 different Biologics License Applications (BLA), Investigational New Drugs (IND), and Investigational Device Exemptions (IDE). Recommended approval/no approval decisions for many

BLAs and pivotal protocols. Represented the FDA Biostatistics at the advisory committee meetings.
- Held meetings with sponsors at various stages to provide statistical input on study design, data analysis and interpretation, and regulatory guidance.
- Represented Office of Biostatistics and Epidemiology in the CBER Review Management Coordinating Committee.
- BLAs reviewed include Herceptin®, Amavive®, ReoPro®, Xolair®, and Enbrel®.
- Areas of review included oncologic, immunologic, CVS, ophthalmic, orthopedic, pulmonary, dermatologic, nephrological, and respiratory diseases treated with monoclonal antibodies, cytokines, gene therapies, recombinant growth factors, and fusion proteins.

1995 – 2001 **Project Statistician**

Amgen, Inc. Thousand Oaks, CA

- Led the US biostatistics team for the development of ARANESP® program. Responsibilities included phase 1-3b studies designs, protocols and CRF development, writing statistical analysis plans, conducting statistical analyses, coauthoring clinical study reports, performing ISS/ISE, and reviewing the statistical and clinical sections of the BLA and MAA submissions. The designs of studies included parallel comparison, crossover, non-inferiority, single- and multi-dose PK, and bioequivalence. Cooperated with the UK team on the resource, timing, standardization, review and other issues. Helped preparing briefing documents and participated pre-Phase 3 and pre-BLA submission meetings with the FDA.
- Led the biostatistical support for the EPOGEN® program. Responsibilities included writing statistical analysis plans, conducting analyses, and authoring statistical reports for clinical phase 2-3 studies, and working with investigators on the study designs, analyses, and publications for Amgen sponsored post-marketing studies.
- Primary contributor to the pediatric sBLA for EPOGEN®. This included analyzing and reporting individual studies, summarizing overall efficacy and safety, and reviewing the submission.
- Interacted with the DMC for the design modification of a phase III group sequential study in the CV area. Presented interim analyses to the DMC. Interacted with the FDA reviewers and the journal reviewers on the statistical interpretation of the results when the study was prematurely terminated.
- Medical area: nephrology and CV.

1992 – 1995 **Biostatistician**

Allergan Inc. Irvine, CA

- Responsible for the statistical aspects in several clinical development programs.
- Contributed to several phase 3 studies for BOTOX® and ALPHAGAN®. Duties included CRF designs, statistical analyses for individual study reports, and overall summary reports.
- Assisted the ISS/ISE for several NDA submissions including TAZORAC®.

- Medical area: ophthalmology, dermatology, and CNS.

Education

1992, 1990	**Ph.D. and M.S., Biostatistics** School of Public Health, University of California, Los Angeles
1986	**M.S., Experimental Neurobiology** Shanghai Brain Research Institute, Academia, Sinica

Professional Training (Select List of Post Graduate Courses Taken)

- FDA Reviewer Training
- Winning at FDA – a Strategic Guide
- NDA Preparation – an Overview
- Role of Data Safety Monitoring Board
- Drug Laws and Regulations
- CDISC ADaM
- Effective Negotiation Skills
- Group Sequential Trial Designs
- Survival Analysis for Recurrent Events
- Linear and Nonlinear Mixed Effects Model
- Bayesian Statistics
- Principles of Clinical Pharmacology
- Adaptive Clinical Trials Designs
- Analysis of Repeated Categorical Data

Awards

- Food and Drug Administration (FDA) 2003 Outstanding Service Award for *Excellence in Statistical Computing Involving Complex Statistical Problems and Graphical Presentation of Clinical Data*.
- FDA Center for Drug Evaluation and Research (CDER) 2004 Group Award for *Exceptional Performance in the Priority Review of the Etanercept Supplemental Applications, the First Biological Therapy for Ankylosing Spondylitis*.
- FDA Center for Biologics Evaluation and Research (CBER) 2003 Reward & Recognition for *Producing a Graphics Oriented Patient Profile to Facilitate Clinical Review of Safety Data*.
- FDA CBER 2002 Reward & Recognition for *Performing Excellent Review Work and Highly Successful Collaboration with Clinical Reviewers on the BLA Treatment for Psoriasis.*
- FDA CBER 2001 Reward & Recognition for *Carrying Additional Workload and Performing Outstanding Statistical Analysis Work.*
- One Guilford and three Amgen Excellent Service Awards.

Research Presentations

Wang, C., "Survival Analysis of 4-Period, 4-Treatment Crossover Design with Repeated Measures in Each Period – A Case Study," A presentation given in the 14th Annual Meeting of the Society For Clinical Trials, Orlando, Florida, 1993.

Madden, R. K., Wang, C., and Paugh, J. R., "Comparative Study of Two Non-Invasive Tear Film Stability Techniques," *Current Eye Research*, April, 1994.

Nissenson, A. R. et al, "Novel Erythropoiesis Stimulating Protein (darbepoetin alfa) for Treatment of Anemia in Hemodialysis Patients," *Journal of the American Society of Nephrology*, 2003.

Wang, C. And Okamoto, D., "Group Sequential Trials: How the Guidelines Change in Practice," *Amgen Clinical Development Symposium*, 1997.

Wang, C., "How to Stop a Trial Early for Futility," *Amgen Clinical Development Symposium*, 1998.

Wang, C., "Justification of the Margin for Non-inferiority Trials," *Amgen Clinical Development Symposium*, 2000.

Trotman, M.-L., Soloff, D., Baker, N., Fulton, C., Olson, K., Dewey, C., Hornsby, E., Matcham, J., and Wang, C., "Standardizing Data for Analysis: A Paradigm Shift in Thinking from a Single Study to a Complete Submission," *Amgen Clinical Development Symposium*, 2000.

Soloff, D., Schaap, J., Matcham, J., Baker, N., Cobb, B., Olson, K., Trotman, M.-L., Wang, C., Fulton, and Whitcomb, L., "An Automated Approach to Populating Clinical Study Reports with Tables: NESP Biostatistics Insertion Program," *Amgen Clinical Development Symposium*, 2000.

Yao, B. and Wang, C., "Analysis of Missing Data in Clinical Trials – Experience from NESP Filing," *Amgen Clinical Development Symposium*, 2000.

Wang, C., "Experience of Determining the Per Protocol Evaluable Patients for the Clinical Study Report," *Amgen Clinical Development Symposium*, 2000.

Other Activities

- Referee for Journal of Biopharmaceutical Statistics, 2002.
- Co-chair for "Issues of Missing Data in Clinical Trials" session at the 38th Annual Meeting of the Drug Information Association, 2002.

Professional Affiliations

- Drug Information Association
- American Statistical Association