

RESUME
Chris Barker, Ph.D.
Clinical Trial Biostatistician

ADDRESS

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Accomplishments

- Statistical consultant with Pharmaceutical and Medical Device Companies. Currently providing statistical planning and analysis for oncology phase I “3+3” clinical trials. Prepared statistical analyses for a Thorough QT study for Ceftaroline in Community Acquired Pneumonia.
- Extensive hands-on experience in diverse aspects of drug development, including designing, conducting and analyzing clinical trials, Phases, I, II, III, IV, Health Economics, and Outcomes Research and statistical analyses for large Insurance claims databases and registries.
- Statistical leader for the design, conduct and analysis of Phase II and III clinical studies leading to successful worldwide registration of CELLCEPT for kidney transplantation and successful negotiation with FDA and other regulatory agencies worldwide, in all phases of the transplant development program and responding to questions at the successful advisory meeting. Prior experience preparing analyses of Phase III trials included in the successful U.S. registration of AMBIEN.
- Diverse experience in multiple therapeutic areas, including cardiovascular, organ transplantation, Parkinsons’s disease, obesity, osteoporosis and cancers including breast, and colon.
- CRO selection, oversight and verification of the accuracy and statistical integrity of tables, listings and graphs provided by vendors.

PROFESSIONAL EXPERIENCE

President and Owner

Chris Barker Statistical Planning and Analysis Services, Inc. San Carlos, Ca 2008 - Present
Statistical Consultant

Statistical consultant for Bay Area Pharmaceutical and Device companies. I prepare statistical sections of protocols, statistical analysis plans, programming specifications, and verification for phase I, II and III clinical studies, Integrated summary of Efficacy and Safety (ISE, ISS) case report forms and data entry specifications. Currently I prepare statistical analysis plans for Phase I “3+3” study designs. I reviewed and verified the statistical integrity of clinical study reports, including a Thorough QT study. My work has included verification of pharmacokinetic calculations and development of procedures for verifying analyses that use WINNONLIN. Prepared complex statistical analyses for a manuscript submitted to a major cardiovascular journal. I collaborated with regulatory, clinical, QA, bio-analytical, programmers and data managers in monitoring on-going clinical trials, including database locks and un-blinding.

Associate Director of Biostatistics

Johnson & Johnson Pharmaceutical (JnJ)
Research and Development
(after reorganization of Alza and Scios)

Mountain View CA

2005 –2008



Associate Director of Biostatistics

Prepared statistical analysis plans, sample size, and clinical study reports by ICH guidelines, for Natreacor pK and Phase I, II and III clinical trials and JnJ Diligence team Licensing and Acquisition Projects. Supervised the activities of several CRO's in preparation of case report forms, electronic data capture (EDC), data quality checks, IVRS and Tables, listings and graphs. Verified statistical integrity of all tables, listings and graphs and final clinical study report publication for several Natreacor clinical trials. I was the Scios statistical expert for statistical analysis plans and implementation for health economics and Patient Reported Outcomes (PRO's) analyses in any Scios study. Provided pre-IND statistical materials, and drafted the Target Product Profile for a First in Human study of the VEGF-121 molecule for pre-eclampsia. Led a cross-functional team of three programmers and an economist and prepared novel statistical analyses of Health Economics outcomes for abstracts and publications for both clinical trial data and a large (600K+ claims) insurance claims database. The statistical analysis of claims data won a Best Poster Award in 2007 at ISPOR.

Genentech, Inc
Senior Statistical Scientist

South San Francisco

2003 –2005



Planned statistical analyses for a supplemental registration, and responded to FDA questions about post Marketing requirements for HERCEPTIN, in adjuvant and first line treatment in HER2+ metastatic breast cancer. Developed statistical analysis plans, including specifications for Group Sequential Interim Monitoring Boundaries with an alpha spending function for a Genentech supported National Cancer Institute Phase III trial involving ~ 6000 Women. Provided statistical evaluations of proposals for Investigator Sponsored Trials. Prepared abstracts and publications for HERCEPTIN Phase IV studies.

MEDTAP International, Inc. (Acquired by
United Biosource)

Redwood City, CA

2001 –2003



Director, Statistical Research

Provided statistical consulting and training for MEDTAP clients and MEDTAP Health Economics and Outcomes Scientific staff in areas ranging from multiple comparisons, multivariate analyses, such as canonical correlation, factor analysis, cluster analysis, and linear mixed effects models resulting in posters abstracts and publications. Planned and prepared statistical analyses of work impact due to schizophrenia using a large (300,000+ insured) Health Insurance Claims database as requested by a client. One publication received a Public Health Service Award. Supervised and scheduled project work of one statistician and one programmer.

ROCHE Pharmaceuticals
Pharma Business Strategy
Health Economics and Strategic Pricing

Palo Alto CA

1995- 2001



Principal Pharmacoeconomic Statistician

First statistician in this newly created position and sole statistician for the department. I supervised the statistical programming of up to four Programmers. Provided training in statistical methods and prepared statistical analyses for up to ten economists for all Roche Phase III clinical trials used in economics models of Cost Effectiveness, Cost Offset and Cost Utility and various PRO and Outcomes publications. The therapeutic areas for these projects included: Transplantation, AIDS Retinitis CMV, Breast, Renal and Colon Cancers, Influenza, Hepatic Cirrhosis, Obesity, Rheumatoid Arthritis, Osteoporosis, Congestive Heart Failure, Parkinson's disease, Cardiovascular and Urological. The statistical work was included in economic models submitted for successful reimbursement decisions by the National Institute for Clinical Excellence (NICE), also Canadian, Australian and other reimbursement agencies.

ROCHE Pharmaceuticals (acquired
Syntex) Palo Alto CA

1994-1995

Principal Statistician

Project Statistician for the CELLCEPT® in Renal Transplantation Dossier registration team, prepared Syntex's single largest dossier for successful international submission and registration in North America, Europe, Asia and Australia. I participated in all key FDA interactions, including End of Phase II, response to FDA questions and responded to questions at the FDA Advisory hearing for CELLCEPT. I prepared responses to regulatory questions arising from US (FDA), the European Rapporteur, and Australian, Canadian and Japanese and other regulatory authorities.

Syntex Pharmaceuticals Palo Alto CA

1990-1994

Research Biostatistician II (Project Statistician)



Determined sample sizes, and established project standards for statistical analysis methods, case report form design, and data collection, data quality, for three planned pivotal Phase III clinical studies of a novel immunosuppressant. Completed statistical analyses and final reports for an AIDS CMV retinitis drug (Cytovene), an ophthalmic, Ketorolac, in accordance within project timelines.

Lorex Pharmaceuticals (a Joint Venture of
Searle and Synthelabo Pharmaceuticals) Skokie, IL

1988-1990

Senior Biostatistician

Prepared sample size, statistical analysis plans, and final clinical study report of a pivotal Phase III clinical trial leading to a successful registration and labeling of a sleep hypnotic, AMBIEN. I prepared statistical analyses of clinical trials included in the successful registration of Kerlone and the antibiotic Maxaquin.

EDUCATION

Ph.D. Biostatistics. University of Illinois Health Sciences Center. Chicago, IL.
M.Sc. Biostatistics. University of Pittsburgh. Pittsburgh, PA.
M.A. Economics. Northwestern University. Evanston, IL.
B.A. Economics. University of Colorado. Boulder, CO.

TECHNICAL EXPERTISE

- Statistical - linear mixed effects models, univariate and recurrent event survival analysis, multivariate analyses including factor analysis and other psychometric methods.
- Statistical Programming – SPLUS, SAS, R, EAST, WINNONLIN and Nquery.
- Operating Environments - UNIX and WINDOWS.

Journal Statistical Reviewer

Journal of Clinical Oncology: 2005 – present.
Journal of Biopharmaceutical Statistics: 2007 – present.
Value in Health: 2007 – present.
Journal of Controlled Clinical Trials: 2009 – present.