

Charles S. Davis, Ph.D.

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Education

1987	Ph.D. Biostatistics	University of Michigan, Ann Arbor, MI
1977	M.S., Statistics	McMaster University, Hamilton, Ontario
1974	B.A., Mathematics	Houghton College, Houghton, NY

Career Summary

1/09- President, CSD Biostatistics Inc., San Diego, California

12/05-12/08 Biostatistical Consultant, dba CSD Biostatistics, San Diego, CA

- Provide biostatistical expertise, as well as strategic and scientific leadership, in support of medical product development and medical research
- Current clients include large pharmaceutical companies; start-up (private) and public (small, midsize, large) biotech companies; and start-up and public device and diagnostic companies
- Serve as chairperson or member of independent Data Monitoring Committees (DMCs)

8/01-12/05 Elan Pharmaceuticals, San Diego, California

- Vice President, Biometrics (4/04-12/05); Senior Director, Biometrics (8/01-3/04)
- Led a group of 11 statisticians, 5 statistical programmers, 12 data management professionals, 5 medical writers, and 1 administrative assistant
- Built the Biometrics department (Biostatistics, Statistical Programming, Data Management, Medical Writing) from 0 to more than 30 employees in three years
- Provided statistical expertise for Elan's Clinical Development department (US and UK), as well as for Research, Biopharmaceutical Development Services, and Medical Affairs
- Major areas of involvement include:
 - FDA approval of Tysabri for MS
 - FDA and EC approval of Prialt for severe pain
 - FDA approval of the Sepsis EAA System for identifying patients at risk for sepsis
 - FDA approvable letter for Zelapar for Parkinson's disease
 - Key involvement in corporate decisions concerning acquisitions and licensing opportunities
 - Significant contributions to patent and manuscript publication strategies

7/87-8/01 Department of Biostatistics, University of Iowa, Iowa City, Iowa

- Assistant Professor (1987-91), Associate Professor (1991-96), and Professor (1996-2001)
- Taught graduate courses in "Categorical Data Analysis", "Analysis of Repeated Measurements", "Statistical Methods in Clinical Trials", "Biometrics and Bioassay", "Design and Analysis of Experiments", as well as the service course "Introduction to Biostatistics"
- Founded the Biostatistics Core of the University of Iowa Holden Comprehensive Cancer Center in 1994, and served as director from 1994-2001
- Author of the textbook "Statistical Methods for the Analysis of Repeated Measurements" (Springer, 2002), coauthor of "Categorical Data Analysis using the SAS System" (first edition: 1995, second edition 2000), and author/coauthor of four book chapters and more than 80 peer-reviewed papers in statistical and medical journals

- Member of the Health Sciences Institutional Review Board (IRB-01) from 1997-2001 and of the Cancer Center Protocol Review Committee from 1995-2001
- Consultant to numerous pharmaceutical companies and federal government agencies

7/84-9/85 Miles Laboratories, Elkhart, IN

- Manager of the statistical consulting group responsible for supporting the company's Diagnostic, Biotechnology, Consumer Products, and Canadian pharmaceutical divisions

6/81-7/84 American Critical Care, McGaw Park, IL

- Statistician (1981-1983) and Senior Statistician (1983-1984) responsible for statistical analysis and report preparation for clinical trials of an ultra-short acting beta-blocker

7/77-6/81 Mayo Clinic, Rochester, MN

- Statistician for a variety of medical research projects

Honors

- Elected as Fellow, American Statistical Association (ASA) (2004)
- ASA Council of Chapters Traveling Course Instructor (2004)
- Guest Lecturer, Committee of Presidents of Statistical Societies Visiting Lecturer Program (1995-1997)
- Winner of the Statistics in Medicine 10th Anniversary Paper Competition (1990), the Lewis D. Holloway Award for Research in Health Science Education (1992), and the Excellence in Continuing Education Award, ASA (2000)

Other Professional Activities

- Chair, Biometrics Section, ASA (1999-2001); Associate Editor, *Controlled Clinical Trials* (1994-1998); Associate Editor, *The American Statistician* (2001-2005); Executive Committee, Biopharmaceutical Section, ASA (1994-1996); Regional Advisory Board, Biometric Society (1993-1995); Board of Consultants, *Journal of Urology* (1995-2001)
- Taught categorical data analysis short courses (1 day-1 week) at the ASA Annual Meeting; Centers for Disease Control; National Center for Health Statistics; Fudan University (Shanghai, China); Shanghai Medical University; Toronto Area Biostatistics Association; University of Kansas; and at several major corporations (Procter & Gamble, 3M, Sterling Drug, Warner-Lambert, Sanofi Pharmaceuticals, etc.)
- Taught short courses (1-3 days) on the analysis of repeated measurements at the ASA Annual Meeting; Biometric Society Conference (ENAR); Midwest Biopharmaceutical Statistics Workshop; Deming Conference on Applied Statistics; Northeastern Illinois ASA Chapter Annual Conference; Southern California ASA Chapter; Kansas/Western Missouri ASA Chapter; Mid-Missouri ASA Chapter; Seoul National University (Korea); Chonnam National University (Korea); Midwest Research Institute; Annual Meeting of the Association of GCRC Statisticians; Biopharmaceutical Applied Statistics Symposium (BASS Conference); Wyeth Pharmaceuticals; TAP Pharmaceuticals; SCIREX Corporation; Purdue Pharma
- Taught a two-day workshop on the design and analysis of clinical trials at the Shanghai Institute of Planned Parenthood Research, Shanghai, China

NOTE: A list of publications is available upon request