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SUMMARY

Statistical consultant for pharmaceutical and medical device development and litigation support. Over 25 years of statistical consulting as statistician and director in a first-tier pharmaceutical company and in private practice. Accomplishments in world-wide regulatory submissions, life-cycle management, and support of medical education and commercial messages. Extensive knowledge to bridge preclinical, clinical, manufacturing, commercial and regulatory initiatives (US, Japan, Canada and Europe).

EXPERIENCE

BITTMAN BIOSTAT, INC., President ***2003 – present***

- Provide litigation support: critical review of clinical trial protocols, study results and internal and external communications; data analysis to expose trends.
- Consult with clients on clinical trial design, clinical development strategies, and regulatory interactions here and overseas. Projects include clinical trial design, regulatory submissions, preparation for advisory committee and dispute resolution panels, modeling of trial outcomes, meta-analysis, press releases and statistical method development. Therapeutic areas include central nervous system (pain, sleep, epilepsy and psychosis), cardiovascular (hypertension, heart failure, stroke, acute coronary syndromes), metabolic diseases (diabetes and obesity), gastrointestinal, oncology and anti-infectives. Nonclinical contributions include stability assessment and assay validation.
- Chair data safety monitoring boards (DSMB). Prepare DSMB charters. Provide statistical analyses to DSMBs.
- Perform independent quality assurance and software validation; develop standard operating procedures (SOPs).

PFIZER, PHARMACIA, MONSANTO, SEARLE ***Skokie, Illinois, 1984 – 2003***

- Director, Cardiovascular Statistics group. Responsible for protocol and trial design, statistical analysis plan development, and production of deliverables for global program of 15 Phase III hypertension trials and a cardiovascular mortality/morbidity trial of 6,600 patients. Served on Pediatric, Regulatory Submissions, and Package Insert teams and on joint R&D-commercial Publications Working Group. Achieved on-time regulatory submissions.
- Evaluated in-licensed, out-licensed, and co-development candidates.
- Directed statistics in oncology for a hematopoietic growth factor.

- Consulted with and provided leadership to company's Japanese affiliate for a hypertension program. Participated in meetings with Japanese regulatory authorities. Achieved on-time Japanese regulatory submission.
- Performed risk factor modeling for a Phase IV study of 8,000 arthritis patients.
- Designed pivotal anti-thrombosis trial and defended results at FDA, leading to approval. Defended product monograph at Health Canada.
- Represented statistics and programming for selection of contract research organizations (CRO), interaction and governance during shift to large-scale outsourcing. Developed operating guidelines and performance metrics for a CRO partnership on an entire clinical program.

Preclinical Statistics

- Directed a two-year project to specify, document and test an automated Good Laboratory Practices (GLP) data analysis system for toxicology. System in routine use since 1995.
- Oversaw statistical consulting and collaboration with discovery, genomics, biotechnology development, formulations, stability, assay validation, process scale-up, chemical sciences, pharmacokinetics and toxicology.
- Established out-of-state satellite department to support 300 discovery scientists.
- Developed project tracking system, SOPs and annual stakeholder feedback survey.
- Initiated needs assessment at Belgian site to speed-up European integration.

EDUCATION

PhD in Mathematics, University of Wisconsin
MS in Statistics, University of Wisconsin
BA in Mathematics, Middlebury College

PROFESSIONAL ACTIVITIES

Current member of American Statistical Association (ASA), International Biometric Society, Drug Information Association.

ASA Subcommittee on Organizational Membership, 1998-2001.

PhRMA Biostatistics Steering Committee member 1995-1997. Liaison with Biological and Biotechnology Committee, 1998-2002.

Midwest Biopharmaceutical Statistics Workshop. Past Chair and Liaison to ASA Biopharmaceutical Section, 1993-1994. Chair, 1992-1993. Co-chair, 1992 and 1987. Session organizer, 1991 and 1986.