

WILLIAM D. MIKRUT, M.Sc.

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EXECUTIVE SUMMARY

I am a highly skilled, motivated professional with over 28 years' experience in the Biostatistics and Data Management arena, the last 25 years in the biotech/CRO industry. I have working experience in various clinical indications; primarily specializing in oncology, dental anesthetics, dental S. mutans/cavity reduction, pain, GI, Lupus, and infectious disease. I have extensive experience working with FDA having been directly involved in eight successful (approved) NDAs, sNDAs, and BLA submissions. I have twice built an entire data management, programming, and statistical department from the ground up (computer network system, integrating data management software (paper and EDC), SAS programming, biostatistics, SOP development, etc.). I have exceptional interpersonal, communication, and managerial skills having supervised biostatisticians, SAS programmers, data management, IT, and medical writing personnel. I am comfortable multi-tasking with senior executives, M.D.'s, R&D, regulatory personnel in a fast paced, dynamic environment.

PROFESSIONAL EXPERIENCE

Vantage Data Designs, Inc.

July 2006 - Present

President and Principal Biostatistician

Consultant to various biotechnology companies providing statistical and data management expertise:

- Clinical trial designs (study objectives, study endpoints, sample size calculations, determine appropriate statistical methodologies, write statistical section of the protocol, develop statistical analysis plans).
- Clinical trial execution (randomization, stratification, implementation of IWRS, case report form development, statistical analysis plans, review and sign-off on data management plans, available to answer study conduct questions that may impact the statistical integrity of the trial).
- Provide GCP clinical data management services (case report form design, database building/validation, data entry, data query resolution, MedDRA/WHO coding, data listings review, database lock, SAS datasets ready for statistical analysis) using Medidata RAVE and Medrio EDC systems.
- SAS programming expertise (SDTM and ADAM datasets, summary tables, subject listings, graphs, etc.).
- Statistical data analysis (hypothesis testing, data modeling, safety trends, etc.) of clinical trial data via SAS statistical software.
- Interpret statistical output and apply these interpretations to the clinical study report as appropriate.
- Represent companies at FDA meetings requiring statistical expertise and follow-up dialog as necessary.
- Create, review, and approve abstracts and posters for display at various professional conferences.
- Help assess, select, and audit full-service CRO's for small biotech companies.
- Assess new product potential as a member of sponsor due diligence team.
- Liaison with and/or participate as a member of Data Safety Monitoring Boards (DSMB).
- Strategic planning and execution of NDA/BLA regulatory filings.
- Preparation of Integrated Summary of Efficacy (ISE) and Integrated Summary of Safety (ISS).
- Electronic and CDISC Submission advice.
- Ex-member of the San Diego Hospice and Palliative Care Institutional Review Board (IRB).

Vical, Inc. San Diego, CA

March 2003 – June 2006

**Senior Director, Biostatistics and Clinical Data Management
and
Product Development Team Leader – Allovectin-7 Program**

- Oversaw the Biostatistics, Data Management, SAS Programming functions for the company.
- Product Development Team Leader for Allovectin-7, Vical Inc. late stage (Phase 3) oncology vaccine program for metastatic melanoma.
- A key member of the team that designed and negotiated a successful “Special Protocol Assessment” with FDA. This was a Phase 3 registration trial design in metastatic melanoma utilizing unique primary endpoint (“durable” response rate), modifications to the RECIST criteria, endpoint adjudication processes, sample size, interim analysis, and randomization.
- Member of the Allovectin-7 Business Development partnering presentation team. Successfully negotiated a clinical/commercial partner for the Allovectin-7 program.
- Designed, planned, implemented, analyzed, and interpreted various types of data (clinical, non-clinical, and manufacturing) for the company.
- Evaluated workloads, resources, technology, and budgets for efficient operations of the department.
- Consulted with Vical, Inc. medical officers, senior management, consultants, and project teams on strategic study design and other project related issues.
- Communicated with key FDA personnel on future clinical development strategies (trial designs, appropriate statistical methodologies, data monitoring committees, response adjudication processes, etc.).
- Developed and implemented standard operating procedures for the department.
- Oversaw the activities of contracted statistical consultants, contract SAS Programmers and data management CROs involved with Vical clinical studies.
- Ad-hoc Product Development team member for Vical Inc. other clinical programs (CMV, IL2 Electroporation, and Anthrax).

ILEX Oncology, Inc., San Antonio, TX

January 1996 – February 2003

Vice President, Data Operations

- Began with the company at the pre-IPO stage as one of the first 20 FTE employees.
- Started and led the Biostatistics, Data Management, Programming, Medical Writing, Clinical Technologies, and Medical Coding departments for the company. Oversight included all of ILEX Oncology’s proprietary pipeline products as well as contract research projects.
- Evaluated workloads, resources, technology, and budgets for efficient operations for a staff of approximately 30 professionals (statisticians, programmers, data managers, IT, and medical writers) responsible for approximately 60 clinical studies (Phases 1-4).
- Consulted with ILEX Oncology medical officers, senior management, and clients on strategic study design and project related issues.
- Strategically involved in the Biologic Licensing Application (BLA) with ILEX Oncology’s lead product, Campath. In addition, involved in the post-marketing activities (IST’s, pharmacovigilance, and marketing) of Campath after FDA approval.
- Served as primary leader in the statistical analysis, data management, report writing, and ODAC preparation for two of ILEX Oncology’s FDA submissions (Campath and Mitoguazone).
- Participated as a key member in the clinical development strategy of Clofarabine which was approved for pediatric ALL and AML in January 2005.

- Represented ILEX Oncology at three end-of-Phase 2 meetings, two pre-NDA meeting, one pre-BLA meeting, two ODAC meetings, and all teleconferences with FDA for all ILEX Oncology products. Represented third party client companies in a consulting role at six end-of-Phase 2 meetings, and one pre-NDA meeting.
- Recommended and helped implement a new client-server LAN system and our data management systems utilizing/integrating Oracle 7.3, ClinTrial 4.1, and SAS 6.12 software. Involved in validation of those systems.
- Led a technology taskforce that was commissioned to explore all new hardware and software technologies and made recommendations to ILEX Oncology senior management. Led the 21 CRF Part 11 compliance team.
- Wrote all Data Management and Biostatistics SOP's for the company to ensure consistent processes are in place for the department. Passed 21 audits conducted by regulatory or potential third party clients.
- Oversaw the activities of contracted statistical consultants and other experts involved with ILEX Oncology products.
- Presented ILEX Oncology (CRO division) Biostatistics and Data Management capabilities to potential client companies.
- Served as a statistical consultant to four biotechnology companies requiring statistical expertise.
- ILEX Oncology was ultimately acquired by Genzyme in 2004 for approximately \$1.2 billion.

Pharmaco (PPD), Austin, Texas

July 1991 – December 1995

Senior Biostatistician

- Served as a group leader statistician and interacted with Sponsor and/or FDA on larger, more complex studies designed for NDA submissions.
- Primarily involved in the successful FDA applications of Dovonex, LacHydrin, SonoRx, and ProHance.
- Supervised and reviewed the work of other statisticians and SAS programmers. Trained entry-level statisticians in the proper conduct and analyses of clinical data.
- Involved with operational planning and budgeting to ensure profitability of the department.
- Provided business development support (i.e. capability presentations) for the general growth of the department.
- Responsible for stand-alone Biostatistics consulting projects and developed positive relationships to ensure future business with these clients.
- Designed studies, developed statistical analysis plans, created table shells, calculated sample size and wrote statistical sections of protocols.
- Assisted in the development and maintenance of company standard operating procedures.
- Wrote stand-alone statistical reports for various clients.
- Collaborated with medical/technical writers with results and tables needed for clinical/statistical reports.
- Pharmaco was ultimately acquired by PPD in 1996 for approximately \$350 million.

University of Texas Medical Branch at Galveston, Galveston, Texas

August 1988 – June 1991

Biostatistician

- Provided on-campus statistical services to university researchers and graduate students.
- Helped design studies, programmed using SAS, analyzed data, wrote statistical methods and results.
- Approximately 50% of my time was spent working in a collaborative effort with the Pediatrics department on their otitis media and infant feeding studies. The remaining time was for general statistical design, analysis, or interpretation questions from UTMB personnel needing statistical assistance.

CLINICAL RESEARCH AND FDA EXPERIENCE

- Oncology - Solid Tumors: melanoma, pancreatic, prostate, SCLC, NSCLC, bladder, breast, colorectal, head/neck, brain, ovarian, soft tissue sarcoma, oral mucositis associated with chemotherapy.
- Oncology - Lymphoma / Leukemia: CLL, CML, ALL, AML, NHL, PTCL.
- Dental anesthetic and dental microbe/cavity reduction.
- Pain Studies.
- Gastrointestinal indications: Crohn's Disease, Irritable Bowel Syndrome, GERD, Hepatic Encephalopathy.
- Lupus.
- Antibiotics for hospital acquired infections, bronchitis, pneumonia, skin infections.
- Diagnostic imaging agents.
- Topical treatments for acne, toe fungus, poison ivy, atopic dermatitis, plaque psoriasis, scalp psoriasis.
- Cardiovascular.
- Wound healing.
- Sepsis syndrome treatment.
- CNS: Alzheimer's and Parkinson's disease.
- Ophthalmology (Macular Degeneration)
- Traumatic head injury treatments.
- Participated in numerous end-of-Phase 2 meetings, Special Protocol Assessments, pre-BLA meetings, ODAC meetings, and DSMB meetings in collaboration with FDA for product submission and approvals.
- **Successful (approved) NDA/BLA experience (as primary biostatistician)** includes two Oncology submissions (Campath, Clofarabine), two unique dental anesthetic products (Oraverse an anesthetic reversal agent and Kovanaze an anesthetic nasal mist), two Dermatology submissions (Dovonex, LacHydrin), and two Diagnostic Imaging submissions (SonoRx, ProHance),

EDUCATION

Masters of Science. Biometry (1989)
University of Texas Health Science Center
Houston, Texas

Bachelors of Science. Biology (1982)
Northern Illinois University
DeKalb, Illinois

PROFESSIONAL MEMBERSHIPS

American Statistical Association
Drug Information Association
SAS Users Group International
American Society of Clinical Oncology (ASCO)

REFERENCES

Available upon request