Lisa Anne Kammerman

Kammerman Consulting, LLC
4445 Willard Ave, Suite 600
Chevy Chase, MD 20815-3786
+1 240-760-2512
lisa@kammerman.com

Educational Background

- University of North Carolina, Biostatistics, Ph.D.
- University of Southern California, Biometry, M.S.
- University of Southern California, Natural Sciences and Mathematics (Cum Laude), A.B.

Additional Training

- United States Public Health Traineeship, School of Public Health, University of North Carolina
- COSTEP/Public Health Service, Appointment to the Environmental Epidemiology Branch, National Cancer Institute

Professional Experience

Kammerman Consulting, Chevy Chase, Maryland 7/18 to present

I provide regulatory and statistical consulting support to pharmaceutical companies so they can deliver the best possible products to market as quickly and efficiently as possible.

Regulatory insights:
I provide guidance to companies so they can author the best possible regulatory submissions and reduce the number of review cycles. I apply my biostatistical reviewer expertise gained during my 24 years at FDA to conducting statistical reviews of submissions (e.g., protocols, SAPs, briefing documents, CSRs) before they go to the FDA and other regulators. I identify gaps in the submissions and anticipate questions regulators may ask. Having attended countless industry meetings as an FDA team leader, reviewer and an industry statistician, my preparations of teams for their interactions with regulators and for advisory committee meetings anticipates questions that regulators and committee members might ask. I advise responses to regulatory questions arising from information requests and other inquiries.

Endpoint development for patient-reported outcomes and other clinical outcome assessments:
I advise clinical trial designs that use PROs and COAs, so that the data from studies are usable and interpretable. To achieve that goal, I provide guidance on the definition of hypotheses, and the endpoints and statistical analyses that can test them. I review and interpret PRO and COA results, and recommend how to present the COA results to meet the needs of FDA and other regulatory authorities.

Statistical insights and guidance:
In addition to guiding pre-specified statistical analyses, I interpret study findings and recommend exploratory analyses to further the understanding of clinical study findings. I can advise on the level of evidence needed for submissions.

AstraZeneca, Gaithersburg, Maryland 3/14 to 7/18

- Director, Therapy Area Information Science (Oncology and Immuno-oncology), Biometrics and Information Sciences (7/17 to 7/18)

I supervised 12 direct reports, who provided information science support to oncology and immuno-oncology drug projects. Using my strategic leadership skills, I ensured knowledge transfer through an innovative workshop led by the senior staff who were made redundant and rolled out to new information practice hires, thus paving the way for a strong foundation for the future. I also created and sponsored a face-to-face meeting focused on team effectiveness, crucial because of the exits of the most senior members leaving behind a relatively junior group. This meeting was the first of its kind in our department.

To develop an information strategy for oncology and immune-oncology, I interviewed key stakeholders and customers in the Oncology and Immuno-oncology therapeutic area. Stakeholders represented the

global medical development oncology leadership team, biometrics team leaders, immuno-oncology franchise members, and others). I identified key themes and needs, and proposed a strategy needed to enable the future success of oncology and immune-oncology.

- Senior Statistical Science Director, Oncology, Biometrics and Information Sciences (6/15 to 6/17)

  I served two roles in the Oncology statistics group: regulatory statistics expert, and patient-reported outcomes expert. As the regulatory statistics expert, I supported the project teams in their interactions with regulatory agencies by reviewing and commenting on submissions to the agencies, providing strategic advice and preparing them for meetings. As the patient-reported outcomes expert, I developed a guidance document on the use of patient-reported outcomes in clinical studies and I provide patient-reported outcome advice to project teams.

- Senior Principal Scientist, Statistical Innovations Group, Advanced Analytics Center (3/14 to 6/15)

  Regulatory statistics, patient-reported outcomes, clinical outcome assessments and challenging trial design and analytic questions were my areas of expertise. I was the lead for Inflammation, Autoimmunity & Neurosciences (formerly Inflammation, Neurosciences and Respiratory), and led the cross-therapeutic area missing data initiative. I consulted on projects from numerous therapeutic areas including respiratory, lupus, arthritis, diabetes, oncology, inflammation and neurosciences

  I was the Global Product Statistician for AZD3293 (BACE inhibitor), and made significant contributions to the development of the study protocol and to regulatory interactions. I participated in due diligence and helped transition the project when AstraZeneca partnered with Eli Lilly.

Food and Drug Administration, Silver Spring, Maryland 11/89 to 2/14

- Master Reviewer, GS-15, Divisions of Biometrics II and III, Center for Drug Evaluation and Research (CDER) (1999 – 2014). Assigned to special projects, and supported Divisions of Gastrointestinal and Inborn Errors Products, and Reproductive and Urology Products.

  As a Master Biometrics Reviewer, I served as a regulatory review scientist with responsibility for the review of scientifically complex human drugs and biologics across numerous therapeutic areas. I consulted and reviewed applications with particularly challenging statistical and regulatory review issues. I presented my findings at FDA Advisory Committee meetings, Scientific Rounds and regulatory briefings.

  I was the Office of Biometrics leader in developing strategic initiatives in the use of patient-reported outcomes in clinical studies, for the assessment of both efficacy and safety. In addition to mentoring statisticians and consulting with medical divisions, I collaborated with NIH as a member of the FDA-NIH Interagency Clinical Outcomes Assessment Working Group. I represented the Office of Biostatistics at professional meetings as an invited speaker, and was a coordinator and instructor in workshops.

  I belonged to several working groups that developed and recommended new guidelines. I was a co-chair of the group that wrote the guidance document, "Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products -- Content and Format" and was a co-chair of a group that was drafting a guidance on the design and analysis of clinical studies of medical products intended for the treatment of rare diseases. I was a member of the groups that wrote guidance documents on End-of-Phase 2A meetings, patient-reported outcome measures, non-inferiority studies and adaptive designs.

  I was a member of FDA's institutional review board, which is responsible for assuring the safety of human subjects included in studies conducted by FDA scientists. I was also a member of the Regulatory Science Research Committee, and the Science Prioritization and Research Committee. The latter committee reviews proposals seeking funding through the Critical Path mechanism and drafted the science priorities important to CDER. I was also a member of the Division of Scientific Investigation's advisory group that oversaw the development of a risk-based method for selecting study sites for inspection.

- Team Leader, Division of Biometrics II, CDER, Food and Drug Administration, Rockville, Maryland - (10/96 to 10/03). Supported the Division of Reproductive and Urology Products and the Division of

Pulmonary Products.

- Team Leader, Division of Biometrics IV, CDER, Food and Drug Administration, Rockville, Maryland - (3/96 to 10/96). Supported the Division of Reproductive and Urology Products.
- Supervisory Mathematical Statistician, Statistical Application and Research Branch, CDER, Food and Drug Administration, Rockville, Maryland - (2/93 to 3/96). Supported the Division of Antiviral Drug Products which was later divided into two groups; the Division of Antiviral Drug Products and the Division of Special Pathogen and Transplant Products.
- Mathematical Statistician, Food and Drug Administration, Rockville, Maryland - (11/89 to 2/93)

Children's National Medical Center, Washington, D.C. 9/86 to 11/89
Research Biostatistician

School of Medicine, George Washington University 7/88 to 11/89
Assistant Professor, Department of Pediatrics

George Washington University 1/88 to 9/89
Assistant Professorial Lecturer, Division of Continuing Education

School of Medicine, George Washington University 12/86 to 7/88
Instructor, Dept. of Child Health and Development

Westat, Inc., Rockville, Maryland 1/85 to 8/86
Biostatistician

University of North Carolina, Chapel Hill 8/83 to 12/84
Biostatistician, Oral Cancer Project, Department of Biostatistics, School of Public Health

University of North Carolina, Chapel Hill 8/80 to 8/83
Project Manager, Length of Hospitalization Study, Dept. of Biostatistics, School of Public Health

National Cancer Institute, Bethesda, Maryland 5/80 to 8/80
Biostatistician, Environmental Epidemiology Branch

Harvard School of Public Health, Boston, Massachusetts 10/77 to 9/79
Coordinator of the Biostatistical Consulting Service

University of Southern California 9/75 to 10/77
Biometrician, High Risk Infant Follow-up Project, Women's Hospital, Los Angeles County

University of Southern California Hospital 6/76 to 9/76
Computer Programmer, Edmonson Cancer Res. Center, Biostatistics Unit, Los Angeles County

Honors and Awards

2017	Global Medicines Development Awards Finalist, Patient-reported outcomes guidance document
2015	Global Medicines Development Awards Finalist, Respiratory Biologics Missing Data Taskforce
2015	Global Medicines Development Awards Finalist, B&I SAVOR Advisory Committee Team
2015	FDA's Group Recognition Award: "For superior achievement of the Agency's mission through teamwork, partnership, shared responsibility, or fostering collaboration and coalition to achieve FDA goals: 1st Pediatric Clinical Investigator Training Workshop".
2014	CDER Director's Special Recognition Award: "For providing substantial and innovative thinking and leadership in critical scientific areas, in particular, rare diseases, labeling, and patient-reported outcomes in clinical studies."
2011	CDER's Special Recognition Award: "For creating and publishing a comprehensive draft guidance on adaptive design strategies for implementation by the Agency." (Member of Adaptive Designs Guidance Group.)
2011	CDER's Special Recognition Award: "For creating and publishing a comprehensive draft guidance on non-inferiority design strategies for implementation by the Agency." (Member of

Non-inferiority Designs Guidance Group.)

2007	CDER's Team Excellence Award: "For exceptional teamwork performance during the review and first cycle approval of the BLA NME Myozyme, the first ever approved treatment for Pompe Disease."
2005	FDA's Group Recognition Award: "For sustained and superior efforts in the review of palifermin, a first in-class biologic that is the first agent approved under the continuous marketing application pilot."
2004	CDER's Team Excellence Award: "For sustained and outstanding performance and impactful statistical review performances in therapeutic Biologics during the transition period from CBER to CDER."
1998	FDA's Award of Merit: "For exceptional performance in the review of two important AIDS therapies resulting in an Agency record for drug approval times."
1998	Center Director's Special Citation: Innovations Recognition Committee. Member of committee that planned recognition ceremony in honor of FDA's Innovations in American Government award.
1997	Principal investigator, RSR award, Active Control Studies. Objective of project is the creation of a computerized database containing abstracts of the statistical literature on dose-response, equivalence, and non-inferiority trial designs and analysis.
1996	FDA's Group Recognition Award: Issues in AIDS Clinical Trials Workshop Committee. Member of committee that planned a two-day workshop on AIDS clinical trials issues. Workshop was attended by individuals from FDA, NIH, and industry, and by individuals with HIV.
1992	Food and Drug Administration's Group Recognition Award: ddI Project Group. Statistical reviewer for ddI, a nucleoside analogue approved for the treatment of HIV infection. This review process was the prototype for the accelerated approval regulations.
1975 to 1977	California State Fellowship
1975	Mortar Board Senior Honor Society
1971 to 1975	California State Scholarship

Special Invitations

- Kammerman, L.A. and G.B. Schreiber. "Adjustment for nonresponse in HANES,' presented at the Spring Meeting of the NHANES Users' Group, Washington, D.C., 1986.
- Kammerman, L.A. "Statistical review of ddI (didanosine)," presented at a meeting of the Advisory Committee, Division of Antiviral Drug Products, FDA, Bethesda, Maryland, July 1991.
- Kammerman, L.A. "Statistical comments on the analysis of ACTG 116B/117," presented at a meeting of the Advisory Committee, Division of Antiviral Drug Products, FDA, Bethesda, Maryland, April 1992.
- Kammerman, L.A. "Statistical review of rifabutin" presented at a meeting of the Advisory Committee, Division of Antiviral Drug Products, FDA, Silver Spring, Maryland, June 1992.
- Kammerman, L.A. "Statistical review of FK506", presented at a meeting of the Advisory Committee, Division of Antiviral Drug Products, FDA, Rockville, Maryland, December 1993.
- Kazempour K, L.A. Kammerman, and S. Farr, "Subgroup analysis: a meta-analysis approach", presented at the annual Joint Statistics Meeting, Toronto, Canada, August 1994.
- Kammerman, L.A. "Statistical review of oral ganciclovir", presented at a meeting of the Advisory Committee, Division of Antiviral Drug Products, FDA, Silver Spring, Maryland, November 1994.
- Kammerman, L.A. "Study design issues", presented at the workshop on the Development of Outcome Measures for Therapeutic Trials in Chronic Fatigue Syndrome (CFS), organized by NIAID, NIH and FDA, Bethesda, Maryland, April 1995.
- Kammerman, L.A., moderator, "Design issues", a breakout session of "FDA AIDS Task Force Workshop: Current Issues in Clinical Trials", Bethesda, Maryland, September 1995.
- Kammerman, L.A., moderator, "Round table discussion: Study design issues in AIDS clinical trials", Joint Statistics Meeting, Chicago, August 1996.
- Kammerman, L.A., "Study design and statistical issues for trials of vaginal microbicide for the prevention of HIV transmission", presented at a joint meeting of the Advisory Committee, Division of Antiviral Drug Products and Division of Reproductive and Urologic Drug Products, FDA, Silver Spring, Maryland, September 1996.
- Kammerman, L.A., "Study design issues in trials of the prevention of rejection of organ transplants", Midwest Statistical Meetings, Kalamazoo, 1996.
- Kammerman, L.A., "Run-in periods in clinical trials", CDER Scientific Rounds, February 1998.
- Kammerman, L.A., "A FDA statistician's perspective on statistical consultants in the pharmaceutical

industry", Joint Statistical Meetings, Texas, August 1998.

- Kammerman, L.A., "HRQoL: What are the Analysis Issues?", 1999 Regulatory Issues in Health Related Quality of Life Assessment, PhRMA, Washington, D.C., March 1999.
- Kammerman, L.A., "PRO data: are there special considerations for analysis?", presented at the Drug Information Association Annual Meeting, Denver, July 2001.
- Kammerman, L.A., "New Guidance on the Clinical Trials Section of Labeling", Strategic Document Management: Meeting the Challenges and Building Value, Drug Information Association, Philadelphia, Pennsylvania, February 2002.
- Kammerman, L.A., "Non-inferiority Designs", ICSA, Philadelphia, Pennsylvania, June 2002
- Kammerman, L.A., "Statistical Review and Evaluation of the NDA for Spiriva", presented at a meeting of the Advisory Committee, Division of Pulmonary and Allergy Drug Products, September 2002.
- Kammerman, L.A., "What do PROs mean? Examples from NDAs", presented at "Assessing treatment impact using PROs: challenges in study design, conduct and analysis", Drug Information Association, Arlington, Virginia, May 2003.
- Kammerman, L.A., "The Clinical Trials Section of Labeling", Drug Information Association Annual Meeting, Washington, D.C., July 2004.
- Kammerman, L.A., Discussant, "Benefits and Challenges with ePRO", Drug Information Association, Arlington, Virginia, April 2005.
- Kammerman, L.A., FDA/Industry Workshop, Washington, D.C., September 2005.
- Kammerman, L.A., Discussant, "Endpoints", PhRMA Multi-regional Trial Workshop, Rockville, MD, October 2007.
- Kammerman, L.A., "Aglucosidase Alfa 2000L – Statistical Review", presented at a meeting of the Advisory Committee, Division of Gastrointestinal Products, FDA, Silver Spring, Maryland, October 2008.
- Kammerman, L.A., "Level of Evidence Requirements", presented at a meeting of the Advisory Committee, Division of Gastrointestinal Products, FDA, Gaithersburg, Maryland, May 2009.
- Kammerman, L.A. and D. Lin, "The FDA PRO Guidance", International Chinese Statistical Association, San Francisco, CA, June 2009.
- Kammerman, L.A., "What you need to know about statistical reviews of submission containing PROs", FDA/Industry Statistics Workshop, Washington, DC, September 2010.
- Kammerman, L.A. "Interpreting change and responder analyses for patient-reported outcomes – statistical considerations", Short Course at the FDA/Industry Statistics Workshop, September 2010.
- Kammerman, L.A., "Level of evidence to support marketing applications", Rare Disease Workshop, Rockville, MD, October 2010.
- Kammerman, L.A., "Interpreting change and responder analyses for patient-reported outcomes – statistical considerations", Short Course (with J. Cappelleri and K. Wyrich) at the FDA/Industry Statistics Workshop, Washington, DC, September 2010.
- Kammerman, L.A., "CDER's use of responder analyses and cumulative distribution functions", Second Annual Patient-reported Outcome (PRO) Consortium Workshop, Silver Spring, MD, March 2011.
- Kammerman, L.A., "Bias revealed – examples from regulatory submissions", The Science of Small Trials (a short course), Silver Spring, MD, April 2011.
- Kammerman, L.A., "Patient-reported outcomes: The need for statistical innovation", Drug Information Association Annual Meeting, Chicago, IL, June 2011.
- Kammerman, L.A., "Challenges in the FDA statistical reviews of submissions containing patient-reported outcomes (PROs)", Joint Statistics Meetings, Miami Beach, FL, July 2011.
- Kammerman, L.A., "Interpreting change and responder analyses for patient-reported outcomes – statistical considerations", Short Course (with J. Cappelleri and K. Wyrich) at the International Conference on Health Policy Statistics, Cleveland, OH, October 2011.
- Kammerman, L.A., "Are patient-reported outcome responder analyses for efficacy or interpretation?", FDA/DIA Statistics Workshop, North Bethesda, MD, April 2013
- Kammerman, L.A., "Interpreting change and responder analyses for patient-reported outcomes – statistical considerations", Short Course (with J. Cappelleri) at the International Conference on Health Policy Statistics, Chicago, IL, October 2013.
- Kammerman, L.A., "Interpretation of COA scores", DIA Study Endpoints Workshop, North Bethesda, MD, March 2014.
- Kammerman, L.A., "Key Elements of Statistical Analyses for Studies with Small Populations (Pediatrics)," FDA Public Workshop: Pediatric Clinical Investigator Training, Bethesda, MD, September 2014.
- Kammerman, L.A., "Adaptive Design Studies: Operational and Regulatory Challenges", FDA-Industry Statistics Conference, Washington, DC, September 2014.

- Kammerman, L.A., "Pediatric Study Designs and Analyses," DIA Annual Meeting, Philadelphia, 2016.
- Kammerman, L.A., "Key Elements of Statistical Analyses for Studies with Small Populations (Pediatrics)," FDA Public Workshop: Pediatric Clinical Investigator Training, Bethesda, MD, September 2016.
- Presenter and discussant, Duke Clinical Research Institute Think Tank, "Issues in Pediatric CV Drug Development", Tysons Corner, VA, 2016.
- Panelist, "OB Science Day – Professional Development", Office of Biostatistics, Center for Drug Evaluation and Research, FDA, Silver Spring, MD, 2016.
- Invited Expert and Presenter, "Clinical Outcome Assessments: Establishing and Interpreting Meaningful Within-Patient Change", Duke-Robert J. Margolis, MD Center for Health Policy, Washington, DC, 2017.
- Invited Expert, "Developing and Implementing Personalized Clinical Outcome Assessments", Duke-Robert J. Margolis, MD Center for Health Policy, Washington, DC, 2017.
- Kammerman, L.A., "Interpreting change and responder analyses for patient-reported outcomes – statistical considerations", Short Course (with J. Cappelleri and K. Wyrich) at the International Conference on Health Policy Statistics, Charleston, SC, January 2018.

Participation in National Scientific Meetings, Technical Conferences, Workshops, Seminars

- Snapinn, S., L. Kammerman, R. Shachtman, A. Kronhaus, M. Sanz, D. Quade. "The relationship between age and length of hospitalization," presented at the Annual Meeting of the American Public Health Association, Montreal, Canada, 1982.
- Kammerman, L.A., G.B. Schreiber, H. Nisselson, and P.D. Williams. "Imputation for item nonresponse in NHANES II," presented at the Annual Meeting of the American Public Health Association, Las Vegas, Nevada, 1986.
- Chatoor, I., E. Ruley, B. Kerzner, G. Bock, C. Bock, E. Menvielle, A. Abbot, and L. Kammerman. "The interaction of organic and psychological factors resulting in growth failure in infants with renal disease," presented at the Annual Meeting of the Academy of Child and Adolescent Psychiatry, Washington, D.C., 1987.
- Ruckman, R.N., N.A. Nunes, D.J. Messersmith, and L.A. Kammerman. "Immediate effects of ethanol on embryonic chick heart function during cardiogenesis," presented at the Annual Meeting of the American Pediatric Society/Society for Pediatric Research, 1988.
- Luban, N., M. MacDonald, R. Przygocki, S. Bors, L. Kammerman. "Blood use and transfusion transmitted disease in extracorporeal membrane oxygenation (ECMO)," presented at the annual meeting of the American Society of Hematology, San Antonio, Texas, 1988.
- Ruckman, R.N., T. Wondrafresh, C.O. Brasseaux, L.A. Kammerman, R.M. O'Donnell, and M Stratmeyer. "Effects of ultrasound on the developing heart," presented at the Annual Meeting of the Section on Cardiology, American Academy of Pediatrics, Chicago, Illinois, 1989.
- Higgins, J.J., L.A. Kammerman, and C.K. Fitz. "Stroke in children: a ten year experience at a children's hospital," presented at the Annual Meeting of the Child Neurology Society, San Antonio, Texas, 1989.
- Kammerman, L.A. "A cumulative sum (CUSUM) technique for monitoring clinical variables", presented at the Joint Statistical Meetings, San Francisco, California, August 1993.
- Kammerman, L.A. and K. Kazempour, organizers, "Subgroup analysis in clinical trials", a special contributed papers session at the annual Joint Statistics Meeting, Toronto, Canada, August 1994.
- Discussant, Design of studies for Alzheimer's, PhRMA/FDA workshop November 1998.
- Kammerman, L.A. "Positive control studies for human prescription drugs: an overview", presented at the ENAR Stat meetings, Charlotte, North, Carolina, March 2001.
- Kammerman, L.A. "Non-inferiority designs: selecting the margin", presented at the Society for Clinical Trials, Denver, Colorado, 2001.
- Kammerman, L.A. "A reviewer's perspective of statistical consultants", presented at the Drug Information Association, San Antonio, Texas, 2001
- PERI course instructor, 2001
- Panel Discussant, Workshop on Non-inferiority Studies", CASE, CDER, October 2001.
- Chair/organizer, "Current State of the Art in HRQoL Measurement and Future Directions", FDA/Industry Workshop, January 2002, Bethesda, Maryland.
- Co-chair/organizer, "Patient Reported Outcomes", DIA, June 2005.
- Panel Discussant, "Breakout Session 5: Data Quality", DIA/FDA CDER/CBER Computational Science Meeting, Bethesda, MD, March 2010.
- Moderator, Statistical Issues in Rare Diseases, Drug Information Association's U.S. Conference on Rare

Diseases and Orphan Products, Washington, DC, October 2011.
- Discussant, "Patient-reported Outcomes", DIA/FDA Statistics Forum, North Bethesda, MD, April 2012.
- Discussant, "Responder definitions and non-inferiority margins for patient-reported outcomes," FDA/Industry Workshop, Washington, DC, September 2012.
- Organizer, "Town Hall on Late Breaking Person Reported Outcomes Topics: PCORI Methods Report and Other Issues Related to Efficacy and Safety Endpoints," FDA/Industry Workshop, Washington, DC, September 2012.
- Discussant, "Parenteral Nutrition-associated Liver Disease", GREAT Workshop, Silver Spring, MD, October 2012.
- Discussant, "Mixed Methods in Assuring Content Validity", Fourth Annual Patient-reported Outcome (PRO) Consortium Workshop, Silver Spring, MD, 2013.
- Moderator, "Clinical Trial Design and Statistical Issues for Crohn's Disease," Silver Spring, MD, 2013
- Organizer and chair, "Moving Beyond the Traditional Psychometric Validation of New Phase 3 Clinical Outcome Assessments," DIA Annual Meeting, San Diego, 2014.
- Organizer and chair, "Open-label, Long-term Study Extensions: Study Designs and Ethics," DIA Annual Meeting, Philadelphia, 2016.
- Discussant, "Validation of PRO Instruments in Ongoing Phase 3 Studies," Joint Statistics Meeting, Chicago, 2016.
- Presenter, "Case Studies: (1) Missing PRO data and (2) Use of Existing PRO Instruments," ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington, DC, 2016.
- Panelist, "Developing PRO Instruments in Clinical Trials: Issues, Considerations, and Solutions," ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop, Washington, DC, 2016.
- Organizer and panelist, "Developing PRO Instruments in Clinical Trials: Issues, Considerations, and Solutions," webinar, DIA Statistics Community, March 2017.
- Presenter, "Developing and Evaluating PRO Instruments in Clinical Trials: Statistical Issues for Applications using Registration Trials," DIA Annual Meeting, Chicago, 2017.
- Presenter, "Industry Initiatives: Cultural Shifts Impacting COA Development and Implementation in Clinical Trials," DIA Annual Meeting, Chicago, 2017.

Outside professional Advisory and Consulting Activities
- JAYCOR, San Diego, California - (3/82 to 12/82)
- Consultant and statistical programmer in the estimation of radiation exposure levels for unbadged workers involved in nuclear tests.
- KRON Medical Corporation, Chapel Hill, North Carolina - (9/81 to 12/81)
- Analyzed data from a marketing research study. Response rates to mass mailings were analyzed in order to determine the targeting of subsequent mailings.
- Harvard School of Public Health - (10/77 to 9/79)
- As the coordinator of the Biostatistical Consulting Service, provided statistical assistance on problems in many areas of public health including health services, behavioral sciences, environmental health, toxicology and other clinical and laboratory areas.
- Department of Nuclear Medicine, Los Angeles County - University of Southern California Medical Center - (6/76 to 6/77)
- Analyzed data and estimated kinetic parameters for Paget's bone disease patients. Used methodology developed for pharmacokinetics.

Special Assignments and Advisory Activities
- Co-chair, Guidance for the Clinical Studies Section of Labeling, Working Group of the MPCC, FDA - (10/96 to 3/06)
- Co-chair, Active Controls Working Group, Office of Epidemiology and Biometrics, FDA - (6/94 to 3/06)
- Member, FDA tamoxifen audit working group (1/95-10/97)
- Member, GRP Track 2, FDA - (1/98 to 1/05)
- Member, Pregnancy Registry Working Group, FDA - (1/97 to 1/05)
- Member, Urinary Incontinence Work Group, FDA (11/97 to 1/05)
  A joint effort with PhRMA to draft guidelines for the development of drugs for the treatment of urinary incontinence
- Member, FDA's Innovations in Government Award Ceremony Planning Committee, CDER (1/98 to 3/98)
- Member, Health Outcomes Working Group, FDA (8/98 to 2/14)
- Member, HRQL Course Development Working Group, FDA (10/98 to 3/99)

- Member, Women's Health Subcommittee of the MPCC, CDER (10/98 to 2/01)

- Member, Health Related Quality of Life Measures Course Development Working Group, FDA (9/98 to 6/99)
- Member, Common Technical Document Table-of-contents Working Group, FDA
- Presenter, CDER Scientific Rounds, "Study Enrichment"
- Panelist, CDER Scientific Rounds, presented by ODE V, "Prevention: Claims, Outcomes, and Analysis Issues" (10/00)
- Organizer and Presenter, CDER Scientific Rounds, presented by Office of Biostatistics, "Are we using active control studies appropriately?" (5/01)
- Member, Sex and Gender Differences, Office of Women's Health, FDA
- Consultant to medical and statistical divisions regarding PRO instruments, FDA (1/98 to 2/14)
- Member, Statistical Policy and Coordinating Committee (SPCC), Office of Biostatistics, CDER, (1/99 to present)
- Chair and Organizer, "FDA Active Controls Working Group", members represented four centers.
- Member, CDER RSR Committee (1/01 to 1/12)
- Member, End-of-phase 2A Meeting Guidance Committee, CDER (1/07 to 1/10)
- Member, Research in Human Subjects Committee, FDA (1/06 to 12/13)
- Member, Non-inferiority Guidance Committee, CDER (1/07 to 2/14)
- Member, Adaptive Design Guidance Committee, CDER (1/07 to 2/14)
- Subject Area Expert, Risk-based site investigations, CDER (10/08 to 2/14)
- Member, Science Prioritization and Review Committee, CDER (1/09 to 2/14)
- Co-chair, Rare Diseases Working Group, FDA (1/10 to 7/13).
- Member, FDA/NIH Interagency Outcome Assessments Committee (10/10 to 2/14)
- Member, Pediatric Review Committee, CDER (7/11 to 2/14)
- Co-editor, Special Issue on Patient-reported Outcomes, Statistical Methods in Medical Research, published in 2014 (2/12 to 11/14)
- Member, DIA Adaptive Designs Working Group, Case Studies Substream (11/14 to present)
- Lead, AstraZeneca's Missing Data Best Practices Project (2/14 to 10/16)
- Lead, B&I, Oncology patient-reported outcomes working group, (7/16 to 6/17)

Publication List

Refereed Articles

1. Leviton, A., J. Schulman, L. Kammerman, D. Porter, W. Slack, and J.R. Graham. "A probability model of headache recurrence," Journal of Chronic Diseases, 33:407-412, 1980.
2. Grimson, R.C., L.A. Kammerman, and J. Soukup. "Statistical procedures for assignments of upper bounds for radiation doses to an unbadged individual in a group for which some individuals are badged," Health Physics, 45:723-729, 1983.
3. Ludwig, I.H., M.M. Parks, P.R. Getson, and L.A. Kammerman. "Rate of deterioration in accommodative esotropia correlated to the AC/A relationship," Journal of Pediatric Ophthalmology and Strabismus, 25:8-12, 1988
4. Abraham, J., H.M. Stiles, L.A. Kammerman, and D. Forrester. "Assessing periodontal pathogens in children with varying levels of oral hygiene," Journal of Dentistry for Children, 189-193, May-June 1990.
5. MacDonald, M.G., B.H. Herman, L.A. Kammerman, Z. Bors, and A. Arthur-Smith. "Cerebrospinal fluid and plasma beta endorphin-like immunoreactivity in full-term neonates and in premature neonates with and without apnea of prematurity," Developmental Pharmacology and Therapeutics, 15:8-15, 1990.
6. Lotze, A., J.A. Whitsett, L.A. Kammerman, M. Ritter, A.N. Taylor, and B.L. Short. "Surfactant protein-A (SP-A) concentrations in tracheal aspirate fluid in infants requiring extracorporeal membrane oxygenation (ECMO)," Journal of Pediatrics, 116:435-40, 1990.
7. Higgins, J.J., L.A. Kammerman, and C.K. Fitz. "Survival characteristics of stroke in a population at a children's hospital," Journal of Neuropediatrics, 22:190-193, 1991.
8. Bui, K.C., G. Martin, L.A. Kammerman, C. Hammerman, V. Hill, and B.L. Short. "Plasma thromboxane and pulmonary artery pressure in neonates treated with extracorporeal membrane oxygenation," Journal of Thoracic and Cardiovascular Surgery, 104:124-9; 1992.
9. Behrman, R.E., L.A. Kammerman, and D.M. Feigal. "Continued zidovudine or didanosine for human immunodeficiency virus infection," correspondence, The New England Journal of Medicine, 327:1598-1599, 1992.
10. Mittleman, M., D.S. Karcher, L.A. Kammerman, L.S. Lessin. "High Ia (HLA-Dr) and low CD11b (M01) expression may predict early conversion to leukemia in myelodysplastic syndromes," American Journal of Hematology, 43:165-171, 1993.

11. Kazempour, K., L.A. Kammerman, and S. Farr. "Survival effects of nucleoside analogues in patients with CD4<50 cells/mm3," Journal of AIDS, September 1995.
12. Proschan, M., E. Brittain, and L. Kammerman, "Minimizing the use of minimization", Biometrics 2011.
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