Barbara Elashoff, MS

Biostatistics Consultant

Providing strategic biostatistical consulting for clinical trials & regulatory submissions in pharmaceuticals, medical devices & diagnostics.

Master of Science Degree in Biostatistics, 1995
Harvard University

Bachelor of Arts Degree in Economics, 1992
Vassar College

Accomplished biostatistician with 30 years of experience in pharmaceutical, medical device, and diagnostics industries. As an FDA reviewer, evaluated the statistical design and analyses for hundreds of Phase 2/3 clinical trials. Experience across a wide variety of therapeutic areas including pulmonology, autoimmune, metabolic, cardiovascular, ophthalmology, oncology and analgesia. Proven track record of successful regulatory submissions including NDAs, PMAs, 510(k)s, and BLAs.

Email: barbara@blackcatbio.ai linkedin.com/in/barbara-elashoff/

Core Expertise

- Phase 1/2/3 clinical trial design & analysis
- Adaptive trial design, external control arms, biomarker development
- Sample size calculations, protocol development, Statistical Analysis Plans
- SDTM and ADaM data creation
- MedDRA and WHO Drug data mapping
- Due Diligence
- Draft FDA memos addressing Agency feedback and inquiries

Pharmaceutical Industry Experience

Director of Biostatistics - Alexion Pharmaceuticals (2020-2021)

- Lead statistician for pivotal Phase 3 trials in andexanet alfa cardiovascular program
- Calculated sample size and power for interim analysis that led to early trial termination for overwhelming efficacy benefit
- Demonstrated and validated a correlation between a biomarker (anti-fXa level) and a clinical outcome (mortality)

Director of Biostatistics - Principia Biopharma (2019-2020)

- Lead statistician for Phase 2 and 3 studies in rare autoimmune diseases
- Identified predictive biomarker pattern in early Phase 2 data (N=30) that forecasted Week 28 outcomes with >85% sensitivity and >80% specificity, leading to FDA Breakthrough Therapy Designation
- Authored protocols, Statistical Analysis Plans, and clinical study reports

CEO - Patient Profiles (2010-2014)

- Co-Founded and led a start-up company that developed centralized statistical analytics software (*'Detect'*) for error detection & risk-based monitoring
- *Detect* has been adopted enterprise-wide by some of the largest pharmaceutical companies, including Celgene, BMS and Astellas
- Patient Profiles was acquired in 2014 by Medidata Solutions

Additional Pharmaceutical Consulting Experience:

- Designed and analyzed Phase 1 ECG study
- Provided power calculation for SBIR grant for cardiovascular study
- Created external control arm data for several Phase 2 oncology studies
- Collaborated with Friends of Cancer Research on NSCLC case study published in Journal of Clinical Oncology
- Designed and analyzed Phase 2/3 trials for ophthalmology (uveitis), metabolic (Cushing's Disease), and analgesic (pain patch and post-surgery pain) programs
- Led the creation of integrated safety and efficacy summaries for BLA submission of LAVIV autologous cell therapy
- Managed biostatistical due diligence for pharmaceutical investments at Pivotal Life Sciences (2023-2025)

Medical Device & Diagnostics Experience

SVP Clinical Science - Canary Medical (2021-2023)

- Designed and executed clinical trials for the world's first "Smart Knee" medical device
- Led statistical validation of algorithms for FDA-regulated software as medical device (SaMD)
- Developed biomarkers and recovery curves using sensor data from total knee arthroplasty patients
- Managed regulatory submissions and clinical evidence generation for digital health products

Director of Biostatistics - Myraqa, Inc. (2006-2010)

- Designed and analyzed analytical studies for multiple IVD platforms: PCR, SNP and CNV arrays
- Guided statistical approach for De Novo submission, persuading FDA reviewers to adopt sponsor’s multiple-imputation strategy for handling missing data
- Provided regulatory and statistical guidance for companion diagnostics, including ApoE gene test for Alzheimer's therapy
- Analyzed clinical studies for point-of-care cardiac devices and HPV diagnostics

Founder - Elashoff Consulting, LLC (2000-2006)

- Designed and analyzed genome-wide diagnostic studies for autism-related CNVs and SNPs
- Lead statistician for XDx (CareDx) IMAGE trial comparing Allomap algorithm to traditional biopsy in heart transplant patients (published in NEJM)
- Performed simulation studies for trisomy/Down's syndrome testing
- Statistical design for multi-gene algorithm clinical trial in thyroid nodule patients

Statistical Reviewer - U.S. Food and Drug Administration (1995 - 2000)

- Reviewed NDAs and INDs for pulmonary, allergy, reproductive, and analgesic therapeutics
- Led multi-disciplinary team to develop FDA guidance document for pediatric growth studies with inhaled corticosteroids
- Presented statistical reviews at FDA Advisory Committees
- Taught biostatistics to FDA medical reviewers

Selected Publications

Elashoff B, Shoham Das. (2025) Large-Scale AI Verification of Power Calculations in Phase 3 Clinical Trials. Bay Area Biotech-Pharma Statistics Workshop (BBSW) Annual Conference.

Cushner FD, Yergler JD, **Elashoff B**, Aubin PM, Verta P, Scuderi GR. (2025) Staying Ahead of the Curve: The Case for Recovery Curves in Total Knee Arthroplasty. J Arthroplasty.

Yocum D, **Elashoff B**, Verta P, Armock G, Yergler J. (2023) Patient reported outcomes do not correlate to functional knee recovery and range of motion in total knee arthroplasty, Journal of Orthopaedics.

Davi R, Chandler M, **Elashoff B**, Ferris AS, Howland A, Lee D, Majumdar A, Stewart M, Strianese L, Stuart E, Yin X, Yver A. (2019) Non-small cell lung cancer (NSCLC) case study examining whether results in a randomized control arm are replicated by a synthetic control arm (SCA), Journal of Clinical Oncology.

Crespo-Leiro, M. G., Stypmann, J., Schulz, U., Zuckermann, A., Mohacsi, P., Bara, C., Ross, H., Parameshwar, J., Zakliczyński, M., Fiocchi, R., Hoefer, D., Colvin, M., Deng, M. C., Leprince, P., **Elashoff, B**., Yee, J. P., & Vanhaecke, J. (2016) Clinical usefulness of gene-expression profile to rule out acute rejection after heart transplantation: CARGO II, European Heart Journal.

Grosu DS, Hague L, Chelliserry M, Kruglyak KM, Lenta R, Klotzle B, San J, Goldstein WM, Moturi S, Devers P, Woolworth J, Peters E, **Elashoff B**, Stoerker J, Wolff DJ, Friedman KJ, Highsmith WE, Lin E, Ong FS. (2014) Clinical investigational studies for validation of a next-generation sequencing in vitro diagnostic device for cystic fibrosis testing, Expert Review of Molecular Diagnostics.

Deng MC, **Elashoff B**, Pham MX, Teuteberg JJ, Kfoury AG, Starling RC, Cappola TP, Kao A, Anderson AS, Cotts WG, Ewald GA, Baran DA, Bogaev RC, Shahzad K, Hiller D, Yee J, Valantine HA; IMAGE Study Group. (2014) Utility of gene expression profiling score variability to predict clinical events in heart transplant recipients, Transplantation.

Khush K, Pham MX, Teuteberg, JJ, Kfoury AG., Starling RC., Deng MC., Cappola TP, Kao A, Anderson AS, Cotts WG, Ewald GA, Baran DA, Bogaev RC, Hlatky M, **Elashoff B**, Hiller D, Yee J, Valentine HA, (2013) Racial Disparities after Heart Transplant: Evidence from IMAGE. The Journal of Heart and Lung Transplantation.

Pham, MX, Teuteberg, JT, Kfoury, A, Starling, RC, Deng, MC, Cappola, TP, Kao, A, Anderson, AS, Cotts, WG, Ewald, GA, Baran, DA, Bogaev, RC, **Elashoff, B**, Baron, H, Yee, J, Valantine, HA, (2010) Comparison of Peripheral Blood Gene Expression Profiling and Endomyocardial Biopsy for Rejection Surveillance After Cardiac Transplantation, New England Journal Of Medicine.

FDA Guidance Document (2000) Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children.

Witte, RS, Elson, P, **Bono, B**, Knop, R, Richardson RR, T, Dreicer, R, and Loehrer, PJ, (1997) ECOG Phase II Trial: Ifosfamide in the Treatment of Previously Treated Advanced Urothelium Carcinoma, Journal of Clinical Oncology.