Kaitlyn Fernandez, MS

SUMMARY:

Kaitlyn (Kaitie) Fernandez, MS, is an Associate Director of Biostatistics with more than 15 years of experience leading Phase II and III clinical development programs across respiratory disease, immunology, allergy, and other chronic disease therapeutic areas. Her expertise includes protocol development, statistical analysis planning, regulatory submissions, data visualization, and communication of complex statistical concepts to multidisciplinary teams. She has served as lead statistician on multiple global development programs, including the landmark Learning Early About Peanut Allergy (LEAP) study and the successful global regulatory submission of Tezspire®. In addition to her clinical development leadership, she is recognized for advancing statistical communication through innovative data visualization, engaging scientific presentations, and mentorship of early-career statisticians. Her professional interests include the thoughtful integration of artificial intelligence to enhance statistical programming, scientific writing, and scientific presentations.

CAREER HIGHLIGHTS:

- 15+ years in pharmaceutical and clinical research
- 30+ publications, posters, and oral presentations
- Lead statistician for multiple global Phase II/III programs (including the successful global submissions of Tezspire®)
- Award-winning presenter at JSM, SAS Global Forum, PharmaSUG, and regional SAS conferences

PROFESSIONAL EXPERIENCE:

September 2025 – present

Cytel Inc., Waltham, MA USA (Home-based)
Associate Director of Biostatistics, FSP

- Provides strategic oversight of external statistical vendors supporting DSMB reviews, interim analyses, and periodic safety reporting across global Phase II and III programs
- Mentors junior biostatisticians across multiple clinical development programs, supporting technical growth and statistical best practices
- Coaches statisticians and programmers on presentation and communication techniques
- Develops statistical resourcing strategies across multiple clinical development programs while balancing portfolio priorities and timelines
- Implements feedback from regulatory authorities into key study documents (e.g., statistical analysis plan, blinded sample size re-estimation plan, and clinical study protocol)
- Continues to perform duties of Principal Biostatistician

November 2020 – September 2025

Cytel Inc., Waltham, MA USA (Home-based)
Principal Biostatistician, FSP

- Provided statistical leadership and statistical expertise into clinical development plans, concept sheets, and protocols for clinical development projects

- Led statistical teams on clinical development projects, ensuring alignment of objectives and delivery of statistical output on time and meeting project requirements, coordinating all statistical aspects across clinical trials of each assigned project
- Provided statistical input into study protocols, Case Report Forms, and data management plans, wrote statistical analysis plans, reviewed or created analysis dataset specifications, and performed statistical analyses
- Developed strong collaboration and communication with sponsor cross-functional teams and sponsor Biostatistics management
- Reviewed and contributed to study reports and clinical and statistical sections of regulatory submission dossiers, led electronic submissions of clinical data to regulatory authorities, and participated in meetings with regulatory authorities.
- Managed biostatistician and statistical programmers with respect to statistical strategy, deliverables, and processes.
- Organized out-of-scope services and performed ad hoc analyses as needed
- Created and led cross-organizational open-forum lecture series for all FSPs within Cytel where biostatisticians, programmers, data managers can share and collaborate on operational techniques and best practices.
- Facilitated monthly partnership meetings providing all team members the opportunity to share and deepen connections across our virtual team

April 2018 – November 2020

Rho, Inc., Durham, NC USA
Senior Biostatistician II

- Managed project teams, including data managers, programmers, and fellow biostatisticians
- Assisted in the interview and selection of qualified personnel
- Acted as independent statistician for DMC studies
- Assigned as primary statistical contact and lead statistician for commercial Phase II and Phase III studies
- Developed and drafted statistical methods sections or statistical analysis plans for FDA submission
- Designed summary table, listing, and figure specifications for proposed research protocols (including experience with integrated ISS databases)
- Created and reviewed Analysis Dataset Reviewer's Guide, define file, BIMO dataset, BIMO Dataset Reviewer's Guide for ISS FDA submission
- Assisted in the preparation of proposals and budgets (e.g., definition of the scope of work, estimates for the bid, attending bid defenses)
- Continued to perform duties of Senior Biostatistician I

January 2016 – April 2018

Rho, Inc., Chapel Hill, NC USA
Senior Biostatistician I

- Served as lead study statistician for multiple federally funded allergy immunotherapy studies
- Supervised and mentored junior level employees
- Led the creation of manuscripts and presentation of study results
- Conducted planned and exploratory statistical analyses and interpreted the results using written, oral, and graphic methods, as appropriate to the audience

- Supported submission of results to ClinicalTrials.gov
- Performed QC on dataset and display output as well as written text
- Supervised validation of statistical analyses, data displays, and written text for reports, primary analyses, and manuscript production
- Prepared statistical reports and displays for client projects, for presentation at meetings or conferences, and for publication in regulatory documents
- Planned and specified the structure of analysis datasets
- Programmed and validated analysis datasets and display output
- Provided statistical expertise for company-wide data integrity initiative
- Continued to perform duties of Biostatistician

June 2012 – January 2016

Rho, Inc., Chapel Hill, NC USA
Biostatistician

- Led team of statistical programmers in analysis of data and data displays
- Performed sample size calculations to determine appropriate number of subjects necessary for the investigation, taking into consideration the interpretability of the results from a statistical and clinical prospective
- Developed and drafted statistical methods sections and summary displays for proposed research protocols
- Created Data Safety Monitoring Board, Investigational New Drug, and monthly study status reports
- Validated programs for statistical analysis, analysis data sets, and data displays
- Participated in protocol and case report form development
- Identified and troubleshot missing, miscoded, or incomplete data and resolved issues with clinical team
- Maintained a steady, open dialogue with study team members regarding study execution as it relates to timelines, data quality, and interpretation of results
- Supported work for multiple abstracts submitted to the American Academy of Allergy & Immunology (AAAAI)

August 2011 – June 2012

Rho, Inc., Chapel Hill, NC USA
Statistical Research Associate

- Learned about the scientific basis of clinical research and how data are generated
- Drafted two statistical analysis plans for federally funded studies
- Created programs for analysis datasets and data displays from provided specifications
- Collaborated with statistical programming on the production of datasets and displays
- Mentored more senior-level statisticians on new graphical techniques

CORE EXPERTISE:

- Phase II-III Clinical Development
- Respiratory Disease (Asthma/COPD) and Food Allergy
- Regulatory Interactions
- Statistical Analysis Plans

- DSMB Support
- Data Visualization
- Cross-functional Leadership
- Scientific Presentations and Communication

EDUCATION:

Master of Science, University of North Carolina, Chapel Hill, NC USA
Biostatistics

Bachelor of Arts, Maryville College, Maryville, TN USA
Applied Mathematics with a minor in vocal performance

COMPUTER SKILLS:

Proficiency in SAS with 15+ years of experience
Familiarity with R
Graphical programming
Clinical data standards familiarity (ADaM)
Microsoft Office Suite
Adobe Acrobat

PROFESSIONAL RECOGNITION:

- Numerous Peer-to-Peer Awards
- Awarded Best Paper in Data Visualization, PharmaSUG 2017
- Invited Speaker
  - SAS Global Forum 2018 and 2019
  - Michigan SAS User's Group 2018
- Marquis Who's Who in America 2024-2025

PERFORMING ARTS:

- Chorus member of the North Carolina Opera, 2012 – 2022
- Chorus member of the Knoxville Opera, 2022 – Present
- Soprano section leader of the Oak Ridge Chorus, 2025 – Present
- Performed at Carnegie Hall, June 2017, June 2021, May 2023, June 2026

ORAL PRESENTATIONS AND SUPPORTED ABSTRACTS:

Fernandez, K, "Multilevel Generalized Linear Mixed Model: Importance of Adjusting for Correlated Outcomes", poster presentation at Joint Statistical Meetings, San Diego, CA, July, 2012

Fernandez, K et. al., "A Suite of Statistical Data Checks to Identify Questionable and Suspicious Data in a Central Management System", poster presentation at Society for Clinical Trials, Philadelphia, PA, May, 2014

Fernandez, K et. al., "Including Treatment Assignment in Statistical Risk-Based Monitoring", oral presentation at Joint Statistical Meetings, Seattle, WA, August, 2015

Jepson B and **Lawson K**, "Automated DSMB Presentation in SAS: Yeah, I'd Submit That! How to auto population PowerPoint presentations so you don't have to", oral presentation at PharmaSUG, Baltimore, MA, March, 2017

Jepson B and Lawson K, "Automated DSMB Presentation in SAS: Yeah, I'd Submit That!", oral presentation at SAS Global Forum, Denver, CO, April, 2018

Lawson K, "Statistical Data Checks to Identify Questionable and Suspicious Data", oral presentation at SAS Global Forum, Dallas, TX, April, 2019

Andres Menzies-Gow et al, "Late Breaking Abstract – DESTINATION: tezepelumab long-term safety and efficacy versus placebo in patients with severe, uncontrolled asthma", oral presentation at European Respiratory Society, Milan, Italy, 2023

Daiana Stolz et al, "Inhaled corticosteroid dose reduction with tezepelumab in patients with severe, uncontrolled asthma over 2 years", oral presentation at European Respiratory Society, Milan, Italy, 2023

Guy Brusselle et al, "Long-term safety and efficacy of tezepelumab in adolescents with severe, uncontrolled asthma", oral presentation at European Respiratory Society, Milan, Italy, 2023

Fernandez K and Kowalczyk, K, "GAM Plots, AI, SAS, and R: A tutorial exploring baseline associations with negative binomial responses", oral presentation at Joint Statistical Meetings, Cambridge, MA, August, 2026

PUBLICATIONS:

Sampson HA, Konstantinou GN, Kattan JD, Masilamani M, Strong BD, Bahnson T, **Fernandez K**, Nowak-Wegrzyn AH. Progression towards increasing tolerance to less extensively heat-denatured milk products. *J Allergy Clin Immunol.* 2014;133(2):AB108.

Nowak-Wegrzyn AH, Strong BD, **Fernandez K**, Bahnson T, Sampson HA. Increasing tolerance to less extensively heat-denatured (baked) milk products in milk-allergic children. *J Allergy Clin Immunol.* 2015;135(2):AB234.

Sampson HA, Masilamani M, Kattan JD, Strong BD, **Fernandez K**, Bahnson T, Nowak-Wegrzyn AH. Humoral and cellular immune responses in milk-allergic children on an extensively heated (baked) milk-containing diet. *J Allergy Clin Immunol.* 2015;135(2):AB27.

Du Toit G, Roberts G, Sayre PH, Bahnson HT, Radulovic S, Santos AF, Brough HA, et al. Randomized trial of peanut consumption in infants at risk for peanut allergy. *N Engl J Med.* 2015;372(9):803-813.

Scadding GW, Eifan AO, Lao-Araya M, Penagos M, Poon SY, Steveling E, Yan R, et al. Effect of grass pollen immunotherapy on clinical and local immune response to nasal allergen challenge. *Allergy.* 2015;70(6):689-696.

Du Toit G, Sayre PH, Roberts G, Sever ML, **Lawson K**, Bahnson HT, Brough HA, et al. Effect of avoidance on peanut allergy after early peanut consumption. *N Engl J Med.* 2016;374(15):1435-1443.

Feeney M, Du Toit G, Roberts G, Sayre PH, **Lawson K**, Bahnson HT, Sever ML, et al. Impact of peanut consumption in the LEAP Study: feasibility, growth, and nutrition. *J Allergy Clin Immunol.* 2016;138(4):1108-1118.

Scadding GW, Calderon MA, Shamji MH, Eifan AO, Penagos M, Dumitru F, Sever ML, et al. Effect of 2 years of treatment with sublingual grass pollen immunotherapy on nasal response to allergen challenge at 3 years among patients with moderate to severe seasonal allergic rhinitis: the GRASS randomized clinical trial. *JAMA.* 2017;317(6):615-625.

Scadding G, Eifan AO, Calderon MA, Shamji MH, Penagos M, Wurtzen PA, Sever ML, et al. Response to nasal challenge correlates with seasonal outcomes during grass pollen immunotherapy with either subcutaneous or sublingual immunotherapy. *J Allergy Clin Immunol.* 2017;139(2):AB385.

Lawson K, Bahnson HT, Brittain E, Sever ML, Du Toit G, Lack G. Letter of response to Greenhawt et al. "LEAPing through the looking glass: secondary analysis of the effect of skin test size and age of introduction on peanut tolerance after early peanut introduction." *Allergy.* 2017;72(8):1267.

Du Toit G, Sayre PH, Roberts G, **Lawson K**, Sever ML, Bahnson HT, Fisher HR, Feeney M, Radulovic S, Basting M, Plaut M, Lack G; Immune Tolerance Network Learning Early About Peanut Allergy Study Team. Allergen specificity of early peanut consumption and effect on development of allergic disease in the Learning Early About Peanut Allergy study cohort. *J Allergy Clin Immunol.* 2018;141(4):1343-1353.

Nowak-Węgrzyn A, **Lawson K**, Masilamani M, Kattan J, Bahnson HT, Sampson HA. Increased tolerance to less extensively heat-denatured (baked) milk products in milk-allergic children. *J Allergy Clin Immunol Pract.* 2018;6(2):486-495.e5. doi:10.1016/j.jaip.2017.10.021.

Du Toit G, Sayre PH, Roberts G, **Lawson K**, Sever ML, Bahnson HT, Fisher HR, et al. Allergen specificity of early peanut consumption and effect on development of allergic disease in the Learning Early About Peanut Allergy study cohort. *J Allergy Clin Immunol.* 2018;141(4):1343-1353.

Nowak-Wegrzyn A, **Lawson K**, Masilamani M, Kattan J, Bahnson HT, Sampson HA. Increased tolerance to less extensively heat-denatured (baked) milk products in milk-allergic children. *J Allergy Clin Immunol Pract.* 2018;6(2):486-495.

Tsilochristou O, Du Toit G, Sayre PH, Roberts G, **Lawson K**, Sever ML, Bahnson HT, et al. Association of *Staphylococcus aureus* colonization with food allergy occurs independently of eczema severity. *J Allergy Clin Immunol.* 2019;144(2):494-503.

Shamji MH, Larson D, Eifan A, Scadding GW, Qin T, **Lawson K**, Sever ML, et al. Differential induction of allergen-specific IgA responses following timothy grass subcutaneous and sublingual immunotherapy. *J Allergy Clin Immunol.* 2021;148(4):1061-1071.

Feeney M, Du Toit G, Roberts G, Sayre PH, **Lawson K**, Bahnson HT, Sever ML, Radulovic S, Plaut M, Lack G. Impact of peanut consumption in the LEAP Study: feasibility, growth, and nutrition. *Oilseeds Focus.* 2021;7(1):48-51.

Menzies-Gow A, Wechsler ME, Brightling CE, Korn S, Corren J, Israel E, Chupp G, Bednarczyk A, Ponnarambil S, Caveney S, Almqvist G, Gołąbek M, Simonsson L, **Lawson K**, Bowen K, Colice G; DESTINATION Study Investigators. Long-term safety and efficacy of tezepelumab in people with severe, uncontrolled asthma (DESTINATION): a randomised, placebo-controlled extension study. *Lancet Respir Med.* 2023;11(5):425-438.

Chupp GL, Lugogo NL, Wechsler ME, **Lawson K**, Lindsley A, Spahn JOED, Ambrose C. Long-term efficacy of tezepelumab in patients with severe, uncontrolled asthma by baseline body mass index. *Chest.* 2023;164(4):A9-A14.

Singh D, Brightling CE, Rabe KF, Han MK, Christenson SA, Drummond MB, Papi A, et al. Efficacy and safety of tezepelumab versus placebo in adults with moderate to very severe chronic obstructive pulmonary disease (COURSE): a randomised, placebo-controlled, phase 2a trial. *Lancet Respir Med.* 2025;13(1):47-58.