CURRICULUM VITAE October 2023 Vasilis Bill Pikounis http://billpikounis.net/

SKILLS I have 34 years of experience as an open-consulting statistician, including the last 32 years at major pharmaceutical companies. I believe and practice modern data analysis — resistance & robustness, good data graphs, resampling, simulations, high-dimension reduction, predictive models, machine learning, analytics, and data science — and believe in the importance and practice of valid interpretation and presentation of trends, patterns, structures, and relationships from such analyses. Since January 2005 I have built, led, and managed groups of statisticians dedicated to support of pharmaceutical research. My oral and written communications skills have been critical to establish and grow successful collaborations with scientists, engineers, and decision-makers in discovery, basic research, development, and manufacturing environments.

I strive for ongoing self-development of my skills in leadership, crafting strategy, management, data analysis, written & oral communications, data graphs, computer software construction, design of experiments, data management, and statistical research. I am committed to communicating the value of statistics to scientists and decision-makers through orientation and education, coupled with the use of computer technology to deliver benefit. I enjoy the process of building long-term collaborative relationships. I am adaptable and at ease with either non-rigid or rigid structure to projects. Accelerated acquisition of skills is a critical value for me.

I am a self-taught programmer of various computer languages and environments. I am comfortable with the development of back-end numerically-intensive programs, front-end user-friendly interfaces, and the integration of all such components together for the delivery, maintenance, and continuous improvement of beneficial, reliable and efficient software tools.

My current technical interests of focus for practical learning and application include Bayesian problem-solving, multivariate modeling, automated workflows including reporting and documentation, and scientific web applications, primarily using R Studio platforms and technologies.

For general problem solving and improvements, I seek ways to cultivate viable paths to get from ideas to successful execution for myself and for teams. Recognized leadership accomplishments to assist company goals in high performance collaboration with colleagues include: directing an overhaul of job ladders and job descriptions for statisticians; rebalancing an inherited organization for appropriate geographical-based support; authoring cross-company and enterprise SOPs and Quality Standards; consolidation of campuses; developing a recruiting system and standards to scale for high-volume hiring; creating and coordinating hybrid conceptual-practical statistics training for hundreds of discovery and manufacturing scientists; and launching a dedicated business office and a scientific computing team with scope to serve the entire statistics organization.

EMPLOYMENT HISTORY

Head, Manufacturing and Applied Statistical Sciences (Senior Director) Also oversee functions of Scientific Business Office and Scientific Computing Operations Janssen R & D, a division of Johnson & Johnson, January 2018 – present

Role created as part of a reorganization and expansion of responsibilities. I lead and manage functions and services related to the Manufacturing of all pharmaceutical products: small molecule (pill, tablet), large molecule (biologics), and vaccines. I supervise direct reports and staff of teams of statisticians and computing personnel based in Belgium, The Netherlands, China, Prague, Great Britain, and the USA (New Jersey, Pennsylvania). The organization currently consists of approximately 25 permanent employee individuals and external partners (8 full-time equivalents). Recruiting efforts emphasize diversity of perspectives and experiences.

Essential contributions from 2018 to present as Manufacturing Statistician Leader to Chemistry, Manufacturing and Controls (CMC) sections of approved CARVYKTI (LCAR-B38M cilta-cel), a chimeric antigen receptor T cell (CAR-T) therapy.

The Scientific Computing Operations team focuses on scientific and operational computing needs of Statistics & Decision Sciences (SDS) within Janssen via platforms for high performance computing, infrastructure reliability and flexibility, knowledge sharing, and applications development and delivery.

From March 2018 – March 2022, I oversaw the Scientific Business Office (SBO) of my umbrella organization, until it was elevated to a peer organization reporting to the head of Statistics & Decision Sciences (SDS), as I report to as well. The SBO team centrally supports scientific and business functions of Statistics & Decision Sciences (SDS) within Janssen to enable operational excellence in areas of staffing, communications, compliance, recruiting, knowledge management, budgeting, people development, and resource management. The office primarily drives the cost, quality, and timing of all interactions for SDS through comprehensive process evaluation, development, execution, and maintenance.

Head, Manufacturing, Toxicology and Applied Statistical Sciences (Senior Director) Janssen R & D, a division of Johnson & Johnson, July 2016 – December 2017

Role created as part of a reorganization. I led and managed functions and services related to the Manufacturing and Safety of all pharmaceutical products: small molecule (pill, tablet), large molecule (biologics), and vaccines. I supervised direct reports and staff of teams of statisticians and computing personnel based in Belgium, The Netherlands, New Jersey, and Pennsylvania. The organization consisted of approximately 40 permanent employees and partners.

Head, Nonclinical Statistics & Computing (Senior Director)

Janssen R & D, a division of Johnson & Johnson, June 2011 – June 2016

I led and managed nonclinical statistics functions and services for all pharmaceutical products: small molecule (pill, tablet), large molecule (biologics), and vaccines. I supervised direct reports and staff of teams of statisticians and computing personnel based in Belgium, California, The Netherlands, New Jersey, and Pennsylvania. The organization consisted of up to approximately 45 permanent employees and partners. This grew with concentrated recruiting efforts from an initial size of 25 in the five-year term. Developed a comprehensive Interview Guide and recruiting process.

Statistical Services and Solutions provider with Centocor and Johnson & Johnson, January 2005 – May 2011 Director, Nonclinical Statistics

Director in Nonclinical Statistics organization. Established and led a dedicated support group for Discovery and Development needs in pre-clinical and non-clinical areas. Hired five permanent-hire direct reports. Periodic hiring and supervision of interns and contract personnel. Primary focus of service was for biotech products, particularly biologic / large molecule entities for immunology and oncology therapies.

Essential contributions as Manufacturing Statistician Leader to Chemistry, Manufacturing and Controls (CMC) sections of two commercially approved products, SIMPONI and STELARA, pre- and post-filing and approvals. Recognized with company Standards of Leadership awards for both of these medicines. The contributions involved the evaluation of drug product release and stability data, for purposes of shelf-life expiry, setting specifications, comparability amongst formulations, and various quality control issues across a wide variety of assays. Participated in original filings through initial approval, updates, and responses to regulatory reviews both domestic and international.

Statistical Solutions provider with Merck & Co, October 1991 – January 2005 Summer Intern with Merck & Co., May – August 1989

Last title of Associate Director. Provided quality statistical services to scientists in a variety of client areas that span discovery, basic research, and pre-clinical / non-clinical development stages of

drug development. Long-time collaborations with Animal Pharmacology on therapies of inflammation, obesity, and diabetes. Long-term ties also to Antibiotic Discovery & Development. Open consulting provided for numerous other departments, including regulatory needs for post-approval responses and pre-approval submissions. Multiple periodic collaborations on process, quality control, formulation, and delivery needs. Substantive contributions included the medicines of CANCIDAS and EMEND.

Recruitment and direct supervision of contract computer and statistics personnel from 1997 - 2004. Recruited and directly supervised interns in most summers (8 out of 11) from 1994 - 2004. Helped as needed with administrative and managerial functions in the department, with continuous striving for increased efficiency in such tasks. Interim manager of Biometrics-Rahway group from July-December 1996, and March 1998-November 1999.

Led the ongoing development of Intranet Department Web site. Provided leadership and contributions to numerous in-house software applications that provide innovative, comprehensive, modern data analysis and statistical results to scientists. Emphasis was on useful interfaces and documentation for customers. Software was reliable and maintainable according to good software engineering principles. Built-in usage accounting provided evidence of at least 20-person equivalence in productivity, as the software applications served over 130 users within over 45 departments internally in the 2004 calendar year alone.

Member of Merck's Institutional Animal Care and Use Committee (IACUC), January 2002 – January 2005. Organized the contributions of leading academic statisticians through seminar and consultation visits, typically twice annually. Coordinated seminars and courses for up to 150 attendees.

Statistical consultant with Biostatistics Division at University of Florida, August 1987-July 1991

Provided open-consulting services (20 hours per week) in Data Analysis Lab to medical researchers at the J. Hillis Miller Health Center. Assumed professional responsibility for all work performed, including data analysis and written & oral communications.

EDUCATION

University of Florida	1991	Ph.D. in Statistics
University of Florida	1987	Master of Statistics
University of Florida	1985	B.S. in Statistics, minor in Classics

COMPUTER SKILLS

Lead author and maintainer of the R contributed package **cg**, available from http://cran.r-project.org/web/packages/cg/index.html. A companion paper on the package is published in the Journal of Statistical Software.

Proficient in R, and related RStudio technologies of Shiny, Markdown, Tidyverse, and ggplot2 (Grammar of Graphics). Past proficiency with other software languages such as Perl, VBA, and SQL. Familiar with other software languages and packages. Comfortable learning new applications and scripting in all operating systems and environments.

SOCIETY MEMBERSHIPS and DESIGNATIONS, AWARDS

American Statistical Association (ASA), 1985-present

President, Princeton-Trenton Chapter of the American Statistical Association, May 2001 – May 2002 (President Elect May 2000 – May 2001, Past-President May 2002 – May 2003)

Vice President, Philadelphia Chapter of the American Statistical Association, August 2006 – July 2007

President, Philadelphia Chapter of the American Statistical Association, August 2007 – July 2008 (Past President August 2008 – July 2009)

Quantitative Sciences in the Pharmaceutical Industry (QSPI) section of the Society for Clinical Trials, 2013-2017. Elected nonclinical statistics member of the QSPI core steering committee, 2013-2015. Elected and served as Vice-Chair for 2015-2016 term.

Fellow of the American Statistical Association, <u>class of 2014</u>.

Citation: For highly effective application of statistical principles in nonclinical and preclinical research of biological therapeutics; for numerous activities that have enhanced the stature of nonclinical statistics in the pharmaceutical industry; and for service to the ASA Biopharmaceutical Section and local chapters.

Philadelphia Chapter of the ASA, Chapter Service Award, 2015: At most once every three years, ASA chapters have the opportunity to recognize special members for their service.

Citation by the ASA, presented at a Joint Statistical Meetings (JSM) awards ceremony in August 2015: In recognition of many years of extensive service to the Philadelphia Chapter. As President, he instituted modernizing practices that continue to increase access to and participation in Chapter activities, and supported statistics education in schools.

Citation in July 2015 chapter newsletter: "This year, the chapter has chosen ASA Fellow Bill Pikounis for this award. Immediate Past President David Radley writes that Bill was chosen "in recognition of the many years of extensive service to the Philadelphia Chapter. As President, he instituted practices and activities that helped move our Chapter forward into the 21st century. He continues to be very active in the Chapter's activities." Former President Mac Turner added details. "Bill was an efficient and effective member of the ASA-P Executive Committee serving as Vice-President, President, and Past President from 2006 through 2009. He helped to set up informative and lively educational meetings in addition to establishing links to local high school statistics teachers. During his tenure he brought in new members to ASA-P and encouraged those members to become active in providing direction to the chapter. Many of the people recruited by Bill have gone on to become officers in the chapter and several have gone on to serve as Vice-President and President. After he left office, Bill has continued to actively participate in chapter activities including judging at the Delaware Valley Science Fair and managing and reporting on the chapter elections. Congratulations, Bill, and thank you for your outstanding efforts on our behalf."

Janssen R&D Fellow, an internal designation within Johnson & Johnson: Elected in 2015 by peerreview of application. The Janssen Fellows designation "differentiates and recognizes a different set of skills with a focus on contributing to scientific breakthroughs. Janssen Fellows are focused on furthering research and moving concepts forward to facilitate adopting new technical ideas into current practices, and the expectation is that the Janssen Fellows are internal intellectual leaders, or 'internal experts' who drive impact across programs/projects."

OTHER PROFESSIONAL RESPONSIBILITIES

Invited Panelist at the 2019 JSM Diversity Workshop and Mentoring Program in Denver, CO.

Invited Panelist at 2018 5th annual IABS workshop on Statistical Approaches for CMC Development and Lifecycle Management of Biotherapeutics and Vaccines: "Industry, Academic, Regulatory Panel perspectives"

Co-lead coordinator for Quantitative Sciences in the Pharmaceutical Industry (QSPI) / FDA 1-day summit which was held at the White Oak, MD campus March 2014.

Elected to ASA Council of Sections representative from the Biopharmaceutical Section, 2015-2017 term.

Overall Program Chair for 2013 Midwest Biopharmaceutical Statistics Workshop (36th annual), held in Muncie, Indiana, May 2013.

Program Committee for useR! 2012 conference, held in Nashville, Tennessee.

Invited Discussant at 2011 Joint Statistical Meetings, held in Miami, Florida, for session "Topics in Nonclinical Biostatistics for Biologics, Including Vaccines."

Co-Chaired and headed the Chemistry, Manufacturing, and Controls (CM&C) Track at the 2011 Midwest Biopharmaceutical Statistics Workshop, held in Muncie, IN.

Organizing team for the October 2011 Non-Clinical Biostatistics Conference, held in Boston, Massachusetts.

Core Committee Organizer for inaugural Non-Clinical Biostatistics Conference 2009, held in Boston, Massachusetts.

Co-Chaired and headed the Pre-Clinical Track, called "Modern Scopes of Preclinical Statistics", at 2010 Midwest Biopharmaceutical Statistics Workshop, held in Muncie, IN. Also organized and chaired a session on "Immune Response and Related Antibody Assays" within that track.

Refereed manuscripts for journals including: Biologicals, Statistics for Biopharmaceutical Research, American Statistician, Biometrical Journal, Journal of Biopharmaceutical Statistics, and Biometrics.

Served as a statistics judge for the annual <u>Delaware Valley Science Fair</u> on multiple occasions since 2006. (The Philadelphia Chapter of ASA coordinates a special award for statistical excellence in student posters.)

PUBLICATIONS (most recent listed first, and first authorships bolded)

- Oleynick, J., Shoung, J. M., & Pikounis, B. (2020). "Linear Splines for Shelf Life Analysis of a Drug Product Stored in Hybrid Storage Conditions." *Statistics in Biopharmaceutical Research*, 1-5.
- Li, Q., & Pikounis, B. (2019). "Shiny Tools for Sample Size Calculation in Process Performance Qualification of Large Molecules." *In Pharmaceutical Statistics: MBSW 39, Muncie, Indiana, USA, May 16-18, 2016* (pp. 71-86). Springer.
- Pikounis, B., & Bijnens, L. (2016). "How To Be a Good Nonclinical Statistician." In Nonclinical Statistics for Pharmaceutical and Biotechnology Industries (pp. 33-50). Springer International Publishing.
- 4. **Pikounis, B.**, and Oleynick, J. (2013). "The cg Package for Comparison of Groups", *Journal of Statistical Software*, Vol. 52, Issue 1, 1-27. Available at <u>http://www.jstatsoft.org/v52/i01</u>.
- 5. Li, Q., Shen, B., Bin, L., Goldberg, K., and Pikounis, B. (2012). "On Response-Constrained Optimal Experimental Conditions in a Polynomial Mixed Model Setting", *Statistics in Biopharmaceutical Research*, Volume 4, Issue 2, 174-184.
- Lubiniecki, A., Volkin, D., Federici, M., Bond, M., Nedved, M., Hendricks, L., Mehndiratta, P., Bruner, M., Burman, S., Dal Monte, P., Kline, J., Ni, A., Panek, M., Pikounis, B., Powers, G., Vafa, O., Siegel, R. (2010). "Comparability Assessments of Process and Product Changes Made During Development of Two Different Monoclonal Antibodies", *Biologicals*, Volume 38, 1045-1056.
- Shealy, D., Cai, A., Staquet, K., Baker, A., Lacy, E., Johns, L., Vafa, O., Gunn, G., Tam, S., Sague, S., Wang, D., Brigham-Burke, M., Dalmonte, P., Emmell, E., Pikounis, B., Bugelski, P., Zhou, H., Scallon, B., Giles-Komar, J. (2010). "Characterization of Golimumab (CNTO148), a human monoclonal antibody specific for human tumor necrosis factor α", *mAbs*, Volume 2, Issue 4, 428-439.

- Millar, H., Nemeth, J., McCabe, F., Pikounis, B., Wickstrom, E. (2008). "Circulating Human Interleukin-8 as an Indicator of Cancer Progression in a Nude Rat Orthotopic Human Non–Small Cell Lung Carcinoma Model", *Cancer Epidemiology Biomarkers & Prevention*, Volume 17, Number 8, 2180-2187.
- 9. Cornacoff, J.B., Howk, K., Pikounis, B., Mendenhall, V., and Martin, P. (2007) "Development of a Method for the Evaluation of Sterile Wound Tensile-Strength in Cynomolgus Monkeys Following Treatment with Anti-angiogenic Monoclonal Antibodies", *Journal of Pharmacological and Toxicological Methods*, Volume 57, Issue 1, 74-79.
- 10. **Pikounis, B.**, and Liaw, A. (2005). "The value of R for preclinical statisticians." *R News*, Volume 5, Number 1, 44-47.
- Hickey, E., Abruzzo, G., Bowman, J., Douglas, C., Gill, C., Liberator, P., Misura, A., Pikounis, B. & Bartizal, K. (2005). "Caspofungin versus amphotericin B treatment of Aspergillus fumigatus in kidneys of chronically immunosuppressed infected mice", *Therapy*, Volume 2, Number 6, 615-621.
- Hermanowski-Vosatka, A., Mundt, S., Nunes, C., Strowski, M., Li, Z., Zhang, B., Frazier, E., Le Grand, C., Chen, H., Pikounis, B., Robertson, N., Metzger, J., Strack, A., Olson. S, Schaeffer, J., Wright, S., Balkovec, J., and Thieringer, R. (2005) "11β-HSD1 Inhibition Ameliorates Metabolic Syndrome in Mice." *Journal of Experimental Medicine*, Volume 202, Number 4, 517-527.
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 "Neuroprotective effects of M826, a reversible caspase-3 inhibitor, in the rat malonate model of Huntington's disease." *British Journal of Pharmacology*, Volume 141, 689–697.
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- 16. Brideau, C., Gunter, B., Pikounis, B. and Liaw, A. (2003). "Improved statistical methods for hit selection in high throughput screening." *Journal of Biomolecular Screening*, Volume 8, Number 6, 634-647.
- 17. Gunter, B., Brideau, C., Pikounis, B. and Liaw, A. (2003) "Statistical and graphical methods for quality control determination of high throughput screening data." *Journal of Biomolecular Screening*, Volume 8, Number 6, 624-633.
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- 19. **Pikounis, V.B.**, Antonello, J.M., Moore, D., Senderak, E., and Soper, K.A. (2001). "Practicing What We Preach: The Application of Continuous Improvement in a Preclinical Statistics

Department at a Pharmaceutical Company." *Journal of Official Statistics*, Volume 17, Number 1, 187-206.

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- Shoop, W.L., Zakson-Aiken, M., Gregory, L.M., Michael, B.F., Pivnichy, J., Meinke, P.T., Fisher, M.H., Wyvratt, M.J., Pikounis, B., and Schmatz, D. (2001). "Systemic efficacy of nodulisporamides against fleas in dogs", *Journal of Parasitology*, Volume 87, Number 5, 1150-1154.
- 22. **Pikounis, B.**, Bradstreet, T., and Millard, S. (2001). "Graphical insight and data analysis for the 2,2,2, crossover design." Chapter 7 of *Applied Statistics in the Pharmaceutical Industry*, edited by Millard and Krause, New York: Springer-Verlag.
- 23. **Pikounis, B.** (2001). "One-Factor comparative studies." Chapter 2 of *Applied Statistics in the Pharmaceutical Industry*, edited by Millard and Krause, New York: Springer-Verlag.
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- 33. **Pikounis, V. B.** and Rao, P. V. (1994). "Linear rank tests for the nonresponders problem with censored data." *Biometrika*, Volume 81, Number 4, 691-699.
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PRESENTATIONS & POSTERS (most recent listed first, and first authorships bolded)

- 1. Pikounis, B. (2022). "Bayesian Solutions in Action, including examples of the Beta Distribution", *Midwest Biopharmaceutical Statistics Workshop*, Indianapolis, IN. **[INVITED]**
- Pikounis, B., Banton. D., Oleynick, J., Behrle, J., Shoung, J.M. (2019) "Infusing Bayesian Strategies for Pharmaceutical Manufacturing and Development." *Joint Statistical Meetings (JSM)* 2019, Denver, CO.
- 3. **Pikounis, B.,** Sondag, P., Li, Q., Oleynick, J., Behrle, J., Shoung, J.M. (2018). "Out of Specification Evaluations for Biopharmaceuticals." *Non-Clinical Statistics 2018 Conference*, Paris, France. **[ACCEPTED ABSTRACT]**
- 4. Li, Q., and Pikounis, B. (2016). ""Shiny Tools for Sample Size Calculation in Process Performance Qualification of Large Molecules.", *Midwest Biopharmaceutical Statistics Workshop 39*, Indianapolis, IN.
- 5. Li, Q., Pikounis, B., and Yeager, T. (2015). "Sample Size Calculation for Comparability Studies Under Nested Mixed Model", 2015 Joint Statistical Meetings, Seattle, WA.
- 6. Li, Q., Pikounis, B., and Smith, J. (2012). "Determinations of Dilution Series and Sample Sizes in Quantal Bioassays", *2012 Joint Statistical Meetings*, San Diego, CA.
- 7. Li, Q., Wang, X., Harris, I., and Pikounis, B. (2011). "Latent Class Analysis of Multivariate Longitudinal Data: Uncovering Response Patterns in a Stem Cell Study", Poster at 2011 Joint Statistical Meetings, Miami, FL.
- 8. **Pikounis, B.,** Li, Q., Smith, J, and Toth, S. (2011). "Lethal Dose calculations of Botulinum neurotoxin". Poster at 34th annual *Midwest Biopharmaceutical Statistics Workshop*, Muncie, Indiana.
- 9. **Pikounis, B.** (2010) "Perspectives of Nonclinical Statistics in Biotech Drug Research & Development", *Sino-American Pharmaceutical Professional Association Greater Philadelphia Chapter Fall Conference*, Fort Washington, PA. **[INVITED]**
- 10. **Pikounis, B.** and Oleynick, J. (2010). "The cg package for comparison of groups". *useR! 2010 conference* in Gaithersburg, Maryland.
- 11. Oleynick, J., Ni, A., Pikounis, B. (2009). "Determining Acceptance Limits for the Limiting Sedimentation Coefficient", Poster at *Non-Clinical Biostatistics Conference 2009*, Boston, MA.

- 12. **Pikounis, B.** and Goldberg, K. (2006). "Consideration of Parallel-Line and Logistic models for Potency estimation", *Joint Statistical Meetings*, Seattle, WA.
- Pikounis, B. (2005). "Complementing Statistical Services with Software Solutions." Princeton-Trenton Chapter of the American Statistical Association, Fall meeting, Lawrenceville, NJ. [INVITED]
- 14. **Pikounis, B.** (2004). "What Good is Statistical Thinking?" *Joint Statistical Meetings*, Toronto, Ontario, Canada. **[INVITED]**
- 15. **Pikounis, B.** (2003). "Evaluation of arthritic progression ordinal data." *Joint Statistical Meetings*, San Francisco, CA.
- Iliff, S.A., Murphy, L.M., Mariano, M.A., Trainor, C.E., Pikounis, B. And Anderson, L.C. (2003). Comparison of laboratory values of blood collected from rhesus macaques using two different techniques. *American Association for Laboratory Animal Science Meeting (AALAS)*, Seattle, Washington.
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- 18. **Pikounis, B.** (2002) "The Mix of Statisticians, Software, and Scientists." *Midwest Biopharmaceutical Statistics Workshop*, Muncie, Indiana. **[INVITED]**
- 19. **Pikounis, B.** (2002) "Effective Dose Estimation with Multi-Factor Models." *Joint Statistical Meetings*, New York City, New York.
- 20. **Pikounis, B.** (2001) "Enterprise solutions for statistical analysis of gene expression data." *S*-*PLUS International Users Conference*, Philadelphia, Pennsylvania. **[INVITED]**
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