

# GILBERT SHANGA, PhD, MBA

20+ years of R&D experience handling data from phases I-IV in various therapeutic areas (Respiratory, Pain, Skin, OHC, NRTs, MVS). Highly motivated, exemplary performing professional statistician, easily adaptable natural influencer. A business oriented strategic thinker with a problem-solving mindset that believes in making data driven forward looking decisions.

## Personal Info

### Address

298 Winding Hill Dr.  
Hackettstown, NJ, 07840

### Phone

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## Skills

- Exemplary interpersonal communication skills
- Strong team leadership capabilities
- Third-party Vendor relations and management

## Software

SAS, PASS, nQuery, Spotfire, Power BI, R, GastroPlus,

## Work History

2021-09-

### Director, Biostatistics

Present

*Haleon, Warren, NJ*

- Effectively and efficiently allocate statisticians and statistical programmers to projects.
- Contribute to the Departmental strategy as part of the leadership team to deliver on the vision and mission.
- Co-ordinate and lead Biostatistics and Data Management activities for projects.
- Lead functional and cross-functional process improvement initiatives. Two examples are the DEI initiative & Diversity in Clinical Trials.
- Provide technical leadership and expertise to guide Statisticians when challenges arise in clinical studies and liaise with other business units and/or statistical experts for those situations.
- Provide expert statistical knowledge and leadership for activities to support the business outside of clinical studies, such as due diligence, complaint/challenge and training.
- Provide scientific and technical statistical leadership on studies from NCDP through to publication.
- Interacts with senior internal and external stakeholders on statistical issues.
- Work as a Study Statistician on more complex projects, including submission projects and as required partake in escalation/troubleshooting activities.
- Provide Third Party oversight of strategic and tactical partners as related to statistics, statistical programming and data management.
- Accountable for the successful execution of projects and provide leadership of oversight of Third-Party Vendors.
- Coaching and mentoring junior staff across BDM.
- Review/approve protocols, SAPs, CSRs & publications.

2005-11 –  
2021-09

- Provides expert statistical input and leadership in relation to clinical trials, RWD/RWE and other statistical work across multiple categories, including detailed regulatory interactions like a preparations for a recent FDA advisory committee on possible adolescents abuse of NRT sprays.
- Develop, train, written standards for QTLS and Estimands.

## **Manager, Biostatistics**

*GlaxoSmithKline Consumer Healthcare, Warren, NJ*

- Review/approve protocols, SAPs, CSRs, and publications.
- Developed scalable IVIVC models in lieu of BE studies for manufacturing sites and formulations changes.
- Lead the QTLs initiative in line with ICH E6 R2 requirements for data integrity and subject safety.
- Lead departmental process improvement initiatives of streamlining and ownership of written standards.
- Provided statistical leadership on RWD/RWE and MDR PMCF studies.
- Effectively and timely responded to requests from regulatory agencies and other stakeholders.
- Prepared integrated summaries of safety and efficacy.
- Lead statistician on FDA Advisory Board Meetings
- Oversaw Junior statisticians by providing mentoring.
- Provided vendor oversight for Statistics deliverables.
- Authored SAPs for analyses done in house.
- A trusted SME on complex Statistics methodologies
- Developed a vendor selection process.
- Due diligent vendor qualification assessments
- Statistics lead of clinical support for market expansions.
- Internal Statistics consultant on studies & literature
- Oversee the data disclosure efforts.
- Developed vendor payment models.

2004-06 -  
2005-11

## **Senior Statistician**

*Unilever, Trumbull, CT*

- Enabled the delivery of effective technically defensible, informative, and timely study designs.
- Leveraged critical thinking in statistical design, sampling, and data analyses.
- Worked on retrospective meta-analysis to gain efficiencies of evaluating Anti-Aging technologies.

- Scouted, identified, and championed novel, value-added data-analytical methodologies.

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## Education

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- 2003      **Ph.D.: Statistics**  
*Kansas State University, Manhattan, KS*  
*Thesis Topic: Analyses of Crossover Designs when Treatments have Unequal Variances*
- 2015      **MBA**  
*Montclair State University, Montclair, NJ*
- 1998      **MS: Mathematics & Statistics**  
*Western Illinois University, Macomb, IL*
- 1996      **BS.: Mathematics & Statistics**  
*The University of Nairobi, Nairobi, Kenya*
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## Highlight Accomplishments

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- Developed scalable IVIVC Models in lieu of BE studies.
  - Successful JV integrations with Novartis CH and Pfizer CH
  - Enabled strategies that improved first time acceptance of study results disclosures to clinicaltrials.gov.
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## Affiliations

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American Statistical Association

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## Selected Publications

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- Rasmussen, S.C., Becker, W.D., **Shanga, G. M.**, (2018) Single Dose Bioequivalence of Two Mini-Nicotine Lozenge Formulation. *Clinical Pharmacology in Drug Development* 7(5):498-505
- Wheatley, J. R., Amis, T. C., Lee, S. A., Ciesla, R., **Shanga, G.** (2019) Objective and Subjective Effects of a Prototype Nasal Dilator Strip on Sleep in Subjects with Chronic Nocturnal Nasal Congestion. *Advances in Therapy* 36(7):1657-1671
- Schenkel, E. J., Ciesla, R. and **Shanga, G.** (2018) Effects of nasal dilator strips on subjective measures of sleep in subjects with chronic nocturnal nasal congestion: a randomized, placebo-controlled trial.

- Ward, J., Ciesla, R., Becker, W. and **Shanga, G. M.** (2018) Randomized Trials of Nasal Patency and Dermal Tolerability With External Nasal Dilators in Healthy Volunteers. *Allergy & Rhinology (Providence, RI)*. eCollection
- Nidels, M, **Shanga, G. M.**, Bishop, A. and Becker, W.D. (2018) Nicotine Lozenges in the Relief of Behaviorally Provoked Craving. *American Journal of Health Behavior* 42(3):69-80
- Hagen, M., **Shanga, G.**, Caron, S. and Debnath, G., (2023) Nasal Cast deposition for xylo- and oxymetazoline formulations using two different nasal pumps. *Rhinology Online*
- Maihöfner, C., Haas, A, Sethi, V., **Shanga, G.**, Wilcox, T.K., Csoke, E. and Fabrikant K. (2023) Patients Experience and utilization patterns of Diclofenac gel in Germany: A real-world study with prospective longitudinal survey and retrospective analyses of pharmacy data. *Current Medical Research and Opinion (Online ahead of print)*
- Munoz, C.A., Gendreau, L., **Shanga, G.**, Magnuszewski, T., Fernandez, P. and Durocher, J. (2012) A clinical Study to evaluate denture adhesive use in Well-fitting dentures. *Journal of Prosthodontics* 21(2):123-9
- Bishop, C., Johnson, S.M., Wall. M.B., Janiczek, R.L., **Shanga, G.**, Wise, R. G., Newbould, R. D. and Murphy, P. S. (2016) Magnetic resonance imaging reveals the complementary effects of decongestant and Breathe Right Nasal Strips on internal nasal anatomy. *The Laryngoscope* 126(10):2205-11
- Bosma, M. P., McNab, R, Gallagher, A., Baxter, K., **Shanga, G.**, Middleton, A. (2008) Removal of oral debris and bacteria during supervised tooth brushing. *Archives of Oral Biology* 53 Suppl 1:S26-30
- Gfeller, C. F., Wanser, R. Mahalingam, H., Moore, D.J., Wang, X., Lin, C. B., **Shanga, G.**, Grove, G. and Rawlings, A. V. (2019) A series of in vitro and human studies of a novel lip cream formulation for protecting against environmental triggers of recurrent herpes labialis. *Clinical, Cosmetic and Investigational Dermatology* 12:193-208, eCollection
- Gfeller, C., Hardie, G., **Shanga, G.** and Mahalingam, H. (2019) Evaluating the Moisturizing Abilities and Sun Protection Factor of New Lip Balm Formulations. *Journal of Cosmetic Science* 70(1):1-5