

# GILBERT SHANGA, PhD, MBA

16+ years of R&D experience handling data from phases I-IV in various therapeutic areas. Highly motivated, exemplary performing professional statistician, easily adaptable natural influencer. A business oriented problem-solving mindset that believes in making data driven forward looking decisions.

## Work History

### Personal Info

#### Address

298 Winding Hill Dr.  
Hackettstown, NJ, 07840

#### Phone

(203) 543-4917

#### E-mail

gshanga@yahoo.com

### Skills

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

### Software

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

#### 2021-09- Present **Director, Biostatistics**

*GlaxoSmithKline Consumer Healthcare, Warren, NJ*

- Provide scientific and technical statistical leadership on studies from non-clinical development planning through to publication, where appropriate
- Interacts with senior internal and external stakeholders on statistical issues
- Provides 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
- Work as a Study Statistician on more complex projects, including submission projects and as required partake in escalation/troubleshooting activities
- Co-ordinate and lead all Biostatistics and Data Management (BDM) activities for projects, where appropriate
- Lead functional and cross-functional process improvement initiatives
- Provide Third Party oversight of strategic and tactical partners as related to area of responsibility
- Provide expert statistical knowledge and leadership for activities to support the business outside of clinical studies, such as due diligence, complaint/challenge and training
- Coaches and mentors junior staff across BDM
- Provides expert statistical input and leadership in relation to clinical trials, real-world evidence and other statistical work executed by the Consumer Healthcare division across multiple categories, including detailed regulatory interactions.
- Accountable for the successful execution of the delegated projects and provide leadership of

oversight of Third-Party Vendors.

- Deputize for Head of BDM on reviews/approvals and other interactions.

## **Manager, Biostatistics**

2005-11 –  
2021-09

*GlaxoSmithKline Consumer Healthcare, Warren, NJ*

- Reviewed and approved 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 | <b>Ph.D.: Statistics</b><br><i>Kansas State University, Manhattan, KS</i>                    |
| 2015 | <b>MBA</b><br><i>Montclair State University, Montclair, NJ</i>                               |
| 1998 | <b>MS: Mathematics &amp; Statistics</b><br><i>Western Illinois University, Macomb, IL</i>    |
| 1996 | <b>BS.: Mathematics &amp; Statistics</b><br><i>The University of Nairobi, Nairobi, Kenya</i> |
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## 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](https://clinicaltrials.gov).
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## Affiliations

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American Statistical Association

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## Additional Information

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- President and CEO of Hamisi Community Development Fund, Inc., a non-profit organization  
<https://www.hacodefu.org/>