

Biometrics Statistics Leaders Consortium

Erik Pulkstenis
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Presented to EFSPI July 2022

Membership

- ~ top 15-20 biopharmaceutical companies by R&D spend
- Facilitated by ZS associates



abbvie

Pfizer



AMGEN

Eli Lilly and Company

Lilly

AstraZeneca 



 **NOVARTIS**

 **GILEAD**


 **Bristol Myers Squibb**

Takeda


gsk

Leadership Representation


★ Current Chair




Erik Pulkstenis
VP, Data & Statistical Sciences



Kannan Natarajan
SVP, Global Head of Biometrics & Data Management




Venkat Sethuraman
SVP, Biometrics & Data Science




Lisa Lupinacci
VP, Biostatistics



Cyrus Hoseyni
Global Head of Statistics & Decision Sciences



Jeff Helterbrand
SVP, Global Biometrics Head



Chris Miller
VP, Biometrics – Late-Stage Resp. & Immun.



Amy Xia
VP, Center for Design & Analysis



Xun Chen
VP, Global Head of Biostatistics & Programming




Simon Davies
VP, Global Head of Statistical & Quantitative Sciences




Sara Hughes
SVP, Global Head of Biostatistics



Shanthi Sethuraman
VP, Global Statistical Sciences & Advanced Analytics



Patrick Loerch
SVP, Data Science & Biometrics



Charlie Cao
Head of Biostatistics



Eric Gibson
Global Head Biostatistics, Pharmacometrics



BSLC Objectives

1. A **sought-after key opinion leader** on Biopharma-related statistical and/or R&D topics, within Biopharma organizations, Regulatory agency, and Professional Organizations.
 2. An **agent of change** in the industry, supporting existing working groups with guidance & networks, and sponsoring new working groups to tackle open issues.
 3. A **professional development driver**, upskilling our stakeholders to optimize their contributions to our organizations and/or the industry, and elevating our discipline to continue being a driving force in data, analytics, and inference
- Does not seek to duplicate other group, initiatives or activities
 - Not a scientific topical working group
 - Often a pre-competitive place for discussion

BSLC Facilitating Communication / Collaboration

- For collaboration among senior/executive leaders of statistics/biometrics organizations within biopharmaceutical companies.
- To promote visibility, health, and impact of the profession.
- To generate industry solutions or drive conversations that are pre-competitive in nature.
- To serve as a unified leadership voice (when appropriate) on key issues and collaborate with regulatory authorities to provide a venue for regulators and other parties to reach out to hear the unified leadership voice.
- To engage with the broader medical/regulatory/scientific community on issues related to drug development.

In the future, BSLC aims to interact with many different stakeholders, advancing statistics and statistical thinking outside of our member organizations

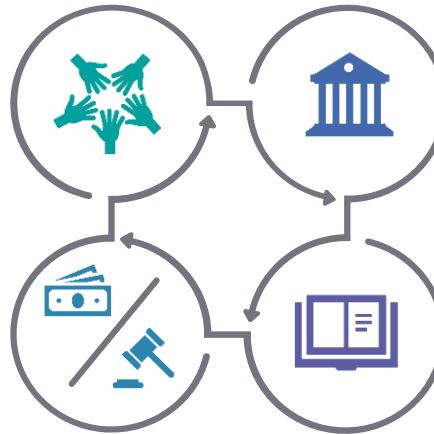
Statisticians

- ❑ **Upskill employee capabilities** (business & strategic acumen, technical expertise, interpersonal skills)
- ❑ **Provide perspectives** on techniques & methodologies to improve outcomes
- ❑ **Raise awareness** of industry efforts & activities to promote efficiencies & best practices
- ❑ **Promote diversity** in hiring & talent development

Clinical and Commercial Colleagues

- ❑ **Improve ability** to articulate role & value of different data & methods
- ❑ **Enable informed decisions** based on quality data & inferences, with well-defined success criteria
- ❑ **Upskill ability** to “ask the right questions” - effectively structuring questions & option analysis

BSLC Vision



Regulatory Authorities

- ❑ **Openly discuss** possible solutions to major issues facing the industry
- ❑ **Harmonize** different opinions across regulatory agencies
- ❑ **Optimize** the R&D process through identification of pain points in industry-regulatory interactions

Academia

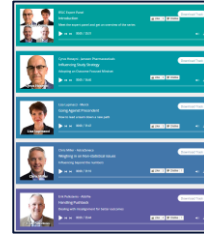
- ❑ Promote **student talent development** through pre-competitive challenges (hackathons)
- ❑ **Encourage student diversity** in the statistics & data science fields
- ❑ **Engage academic faculty** on major industry issues

Since 2019, the BSLC has been evolving, setting new objectives and taking on new initiatives to drive impact for both member organizations & the broader industry



Publication on Trials in COVID-19 (June 2020)

A publication in rapid response to the COVID-19 pandemic containing overall trial impact assessment and recommendations to overcome associated statistical issues



Influencing Skills Podcast (Launching mid-2022)

A podcast training series on influencing skills, conflict resolution, and strategic thinking, to aid career progression for Biopharma statisticians

Member Organizational Benchmarking Report (Aug 2019)

A benchmarking report on biometrics organizational structure, outsourcing behavior, technological capabilities, and employee skillsets



Industry Working Group Support (2020 - Ongoing)

Support to industry working groups engaging in areas such as RWE, DCT, and Novel-Novel Combo trials, through identification of additional members, networking facilitation, and strategic advice



BSLC Messages to EFSPI

- BSLC returns the invitation
- BSLC offers collaboration and support

*Please contact us if you are interested to learn more about BSLC
or partner on an initiative!*



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