



Connecting ISoP with Statisticians: An Introduction to the Biopharmaceutical Section of the American Statistical Association



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Introduction

The **American Statistical Association (ASA)** is a co-sponsor of **SxP (Statistics and Pharmacometrics)**, an interest group also co-sponsored by ISoP. The ASA is made up of many regional chapters and topically focused sections. The **Biopharmaceutical Section (BIOP)** of the ASA was established in 1981. The special interest of the Biopharmaceutical Section is the application of statistics to the development and use of therapeutic drugs, biologics, devices, other medicines, and related technologies in humans and animals. SxP was originally formed to bridge between ISoP and ASA. Both groups use novel statistical approaches to answer similar questions, however, we often use different nomenclature and make different assumptions in our modeling. This poster will provide some history about BIOP, explain its objectives and organization, and how to get involved in BIOP or to contact its members.

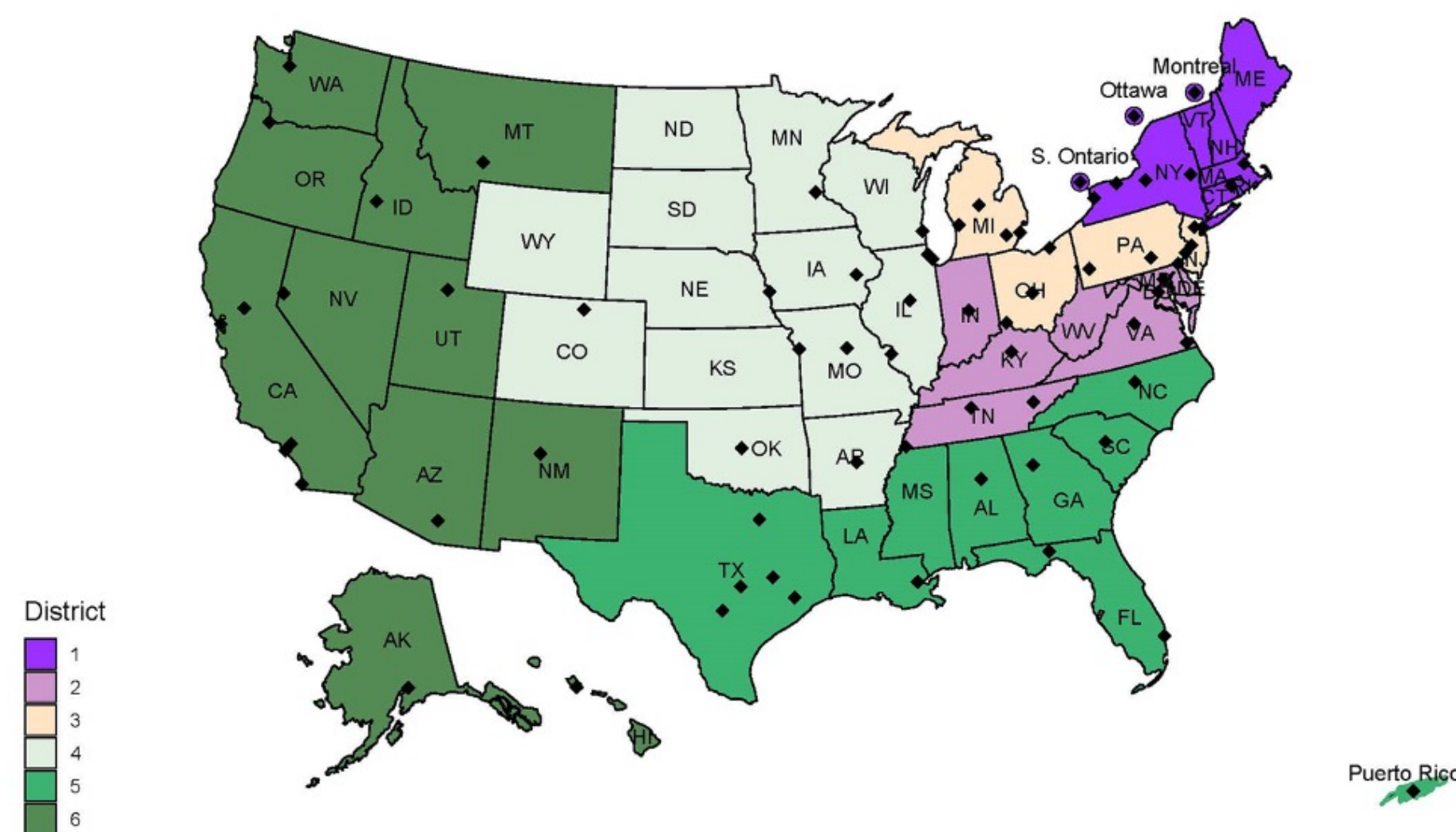
ASA

The American Statistical Association is organized as a collective of:

1. Chapters (including Student Chapters)

Regional communities for statisticians and data scientists, created chapters to support local-level ASA member involvement. Activities include:

- Organize meetings and networking events
- Provide continuing education offerings
- Engage in outreach efforts to local schools to stimulate interest in statistics as a career
- Provide information about the application of statistics



2. Sections & Interest Groups

Subject-area and/or industry-related and provide benefits specific to their members' interests (e.g., health care, manufacturing, defense, and national security)

Biopharmaceutical Section (BIOP)

The Biopharmaceutical (BIOP) Section of the American Statistical Association (ASA) was established in 1968 as a sub-section of the Biometrics Section. It was initially called the Pharmaceutical Subsection and was first subsection of the ASA. After 12 years, given its tremendous growth in membership, the subsection was inducted into the ASA as a full section in 1981. The Biopharmaceutical Section is now one of the most active sections of the ASA.

Primary interests:

- the biochemical and physical sciences involved with drugs, biologics, devices, other medicines, and related technologies;
- discovery, formulations, product development, and quality control;
- the biological sciences involved in evaluating safety and efficacy of therapeutic drugs, biologics, devices, other medicines, and related technologies;
- experimental human and veterinary medicine in support of therapeutic drugs, biologics, devices, other medicines, and related technologies;
- health promotion and disease prevention and intervention activities;
- and product toxicity and disease surveillance.

See the full charter on the BIOP website:
<https://community.amstat.org/biop/home>

History of BIOP

Year	Achievement
1968	Established as subsection of the ASA
1981	Established as a section of the ASA
1983	Manual of Operations
1986	Short course on "Fundamentals of Clinical Trials" by Dave DeMets and Gordon Lan
1991	Creation of Best Contributed Paper Award
1992	Biopharmaceutical Report. First editor: Avital Cnaan
1994	Creation of Best Student Paper Award
1996	Creation of BIOP Website
1997	ASA Biopharmaceutical Section Regulatory/Industry Statistics Workshop
2007	ASA journal "Statistics in Biopharmaceutical Research (SBR)". First editor: Joe Heyse
2007	First webinar
2009	Best Poster Award
2012	First Podcast
2014	Launch of the Mentoring Program
2016	20th Anniversary of the Regulatory-Industry Statistics Workshop
2017	Nonclinical Biostatistics joins the section
2018	Scholarship award initiated
2019	BIOP YouTube Channel initiated
2021	LinkedIn Presence
2022	RISW moved to Rockville
2023	SxP became a BIOP Working Group

BIOP Conferences

BIOP annually sponsors the **Regulatory/Industry Statistics Workshop (RISW)** which has been successful in uniting statisticians from both the FDA and the pharmaceutical industry, allowing for scientific discussions of statistics applied to drug development.

BIOP also sponsors the biennial **Nonclinical Biostatistics Conference**.

Over its long history, the section continues to offer members valuable benefits such as web-based training series, contributed paper awards and contributed poster awards.

BIOP Sponsored / Supported Meetings

BIOP provides funding to other groups for their conferences that provide value to BIOP members or value to statistics students

- Deming Conference on Applied Statistics
- JSM Diversity Workshop and Mentoring Program
- The Bay Area Biotech-pharma Statistics Workshop (BBSW)
- Boston Pharmaceutical Symposium
- Meeting Within a Meeting (MWM) Free Online Professional Learning for Middle- and High-School Mathematics and Science Teachers Teaching Statistics
- And others

Awards and Scholarship

BIOP provides awards for papers, posters, and presentations given at JSM, our BIOP Regulatory Industry Statistics Workshop, and other meetings, e.g., BCASA 2023 Symposium.

The Biopharmaceutical Section Scholarship Award was established in 2018 by the Biopharmaceutical Section of the American Statistical Association to recognize notable research, academic achievement, and applied project work related to the area of biopharmaceutical statistics. The award will also consider general academic performance, leadership, volunteering, and service. Annually, up to five students will each receive an award of \$3000.

Current BIOP Working Groups

- Alzheimer's Disease
- Cell & Gene Therapy
- Centralized Statistical Monitoring and Quality Tolerance Limits
- Estimands in Oncology
- Nonclinical Biostatistics
- Pediatric Drug Development
- Real World Evidence Scientific Working Group
- Re-Randomization
- Safety Scientific Working Group
- **Statistics and Pharmacometrics Special Interest Group**
- Software Engineering Working Group
- Statistical Methods in Oncology
- Health Technology Assessment Scientific Working Group

Active BIOP Committees

- Outreach and Collaboration Committee
- Mentoring Committee
- Funding Committee
- Next Generation Stewardship Committee
- Fellows Nomination Committee
- Membership Committee
- Scientific Working Group Proposal Committee
- Leadership-in-practice Committee
- Statisticians in Small Biotech
- Publications Committee
- Distance Learning (webinar) Committee

Benefits of Membership

- Connecting with other members of BIOP, one of the largest sections of the ASA
- Numerous avenues for professional development, e.g., ASA Biopharmaceutical Section FDA-Industry Statistics Workshop
- Mentoring Program, for benefit as either Mentor or Mentee
- Scientific Working Groups, as a member of a group or to learn from their output
- Popular webinar series with topics relevant to biopharmaceutical statisticians
- Access to external groups via our outreach initiatives promoting our profession
- Discounted registration fees for various conferences and webinars
- Access to our community news forum and the Biopharmaceutical Report
- Minimal membership fee
- Assistance in preparing an ASA Fellow application
- Resources, online and via our committees and working groups

Get Connected!

If you'd like additional information about a BIOP SWG or committee, please go to our website for contact info:

<https://community.amstat.org/biop/home>



If you join ASA (and hopefully, BIOP too), you will have access to the ASA's community directory. The directory provides contact information for all members. You'd be able to reach out to statistician authors and practitioners of any area piquing your interest.

Your first stop should be SxP with members from both our specialties:

<https://sxpsig.github.io/>



References

- Davis, R., et al (2005). "The History of the Biopharmaceutical Section of the American Statistical Association (ASA), 1966-1988." Biopharmaceutical Report, Vol. 13, No. 1.
- Free, Spencer Jr. (1990). "Some History for the Biopharmaceutical Section." The American Statistician, Vol. 44, No. 22.