

Charter of Nonclinical Biostatistics Working Group of the Biopharmaceutical Section of the American Statistical Association

ARTICLE I. NAME

The name of this forum is Nonclinical Biostatistics Working Group (NCBWG) of the Biopharmaceutical Section (BIOP) of the American Statistical Association (ASA).

ARTICLE II. SCOPE

The special interest of the NCBWG is the application of statistics, data science, visualization and computing methods specific to nonclinical development subject matter areas related to Drug Discovery, Toxicology/Safety and CMC (Chemistry, Manufacturing and Controls).

a. Primary interests of NCBWG are:

- i. the biological, chemical, physical and engineering sciences involved with drug discovery, drug safety and pharmaceutical sciences for formulations, product development, and manufacturing.
- ii. regulatory issues governing statistical practices associated with (i)
- iii. to work in collaboration with other BIOP committees in influencing and facilitating efforts to increase nonclinical statistics engagements and visibility across BIOP, and to raise awareness of the importance of such engagements in developing interests of nonclinical statistics among statisticians and data scientists.

b. In pursuit of these primary interests, the NCBWG shall:

- i. operate under the direction of the BIOP Executive Committee.
- ii. promote the improvement of federal policy and regulators governing nonclinical statistical practices and associated guidance across the product lifecycle;
- iii. improve the practices of statistics as related to design, computing, evaluation and reporting in the nonclinical space;
- iv. promote research that adds tools to improve decision making and further the understanding of scientific studies in the nonclinical space;
- v. engage as feasible with other ASA sections inside and outside BIOP;
- vi. seek opportunities to leverage development programs, tools, or experts external to ASA that can offer benefits towards growing the impact of biopharmaceutical statisticians and data scientists.

ARTICLE III. FUNCTIONS

To support the interests specified in the above scope, NCBWG may perform any of the following functions, together with such others as are appropriate and sanctioned by the steering committee:

- a. assist in the advancement of knowledge in the scientific fields related to nonclinical pharmaceutical development including:
 - plan, organize and support biennial Nonclinical Biostatistics (NCB) conference.
 - plan appropriate sessions on the applications of statistics in the nonclinical subject matter areas at JSM and other scientific meetings.
 - promote the general development of statistics and support the general aims of the American Statistical Association.
- b. support student outreach by financing scholarships, best paper awards and building nonclinical statistics awareness within the student community;
- c. cooperate with government, academia, business and industry in the discussion and resolution of important statistical issues;
- d. establish and maintain liaisons and collaboration with other WorkGroups within BIOP ;

ARTICLE IV. GOVERNANCE

- a. The management of NCBWG is the responsibility of the steering committee, comprised of six members and a chair
- b. Each steering committee member serves a 3-year term with extension for steering committees members granted at the discretion of NCBWG chair.
- c. The duties of the chair are as follows:
 - managing the periodic steering committee meetings.
 - managing the membership and election of steering committee members.
 - leading the steering committee in pursuing the mission of NCBWG.
 - appointing a delegate to lead organizing committee of NCB conference.
 - approving the creation of new scientific working groups (SWG) that are managed by NCBWG
 - supporting maintenance of NCBWG webpages and publicizing the work of the steering committee in promoting pharmaceutical nonclinical statistics.
 - leading and managing the logistics of the biannual business meetings, called

the Nonclinical Biostatistics Leaders' Forum (NCBLF).

- maintaining current mailing list of the NCBLF members.

ARTICLE V. NOMENCLATURE

To distinguish between NCBWG internal and external activities, following should be adopted:

- a. Scope pursuant to ARTICLE II, section b, paragraphs ii, iii, iv shall be called Workstreams
- b. Scope pursuant to ARTICLE II, section b, paragraphs v, vi shall be called Workgroups

ARTICLE VI. APPOINTED COMMITTEE POSITION DESCRIPTIONS

- a. Nonclinical Biostatistics Conference chair
 - i. In the year of an NCB conference in the U.S., a future conference chair will be appointed by the NCBLF steering committee. A typical term for conference chair is to serve for two U.S. conferences, or a 4-year term.
- b. Nonclinical Biostatistics Conference webmaster
- c. Scientific Working Groups (SWG)
 - i. Nonclinical SWGs are self-contained inside NCBWG and controlled
- d. Communications and Outreach
- e. Stan Altan Best Paper Award
- f. Student Outreach
- g. Nonclinical Statistics scholarship(s)
- h. Permanent ASA-BIOP nonclinical committee appointees

a. Nonclinical Biostatistics Conference chair

The Nonclinical Biostatistics Conference chair assumes overall responsibility for planning and delivering the biennial U.S. NCB Conference, which showcases the breadth, impact, and technical excellence of nonclinical statistics. The conference program spans early discovery and biomarkers; safety and pharmacology; chemistry, manufacturing, and controls; and data sciences and emerging tools. In collaboration with the steering committee, appoints the co-chair and track chairs and oversees venue selection and end-to-end conference logistics. In the year of an NCB conference, a future conference chair will be appointed by the NCBLF steering committee. A typical term for conference chair is to serve for two U.S. conferences, or a 4-year term.

b. Nonclinical Biostatistics Conference webmaster

The Nonclinical Biostatistics Conference webmaster maintains and updates the conference website to ensure that program information, registration details, deadlines, speaker materials, and logistical updates are accurate and accessible. The webmaster coordinates with conference leadership, track chairs, and vendors to post timely announcements, manage content changes, and support attendees by troubleshooting website issues and ensuring consistent branding and compliance with organizational guidelines.

c. Scientific Working Groups

In conjunction with forum members, the Steering Committee endorses the creation of new workstreams, monitors progress at biannual meetings and recommends improvements to strengthen workstream deliverables. Each workstream is led by a designated leader who collaborates with NCBWG members with a particular interest in contributing to the topic area. Deliverables may include publications, posters, presentations, and software applications.

d. Communications and Outreach

The Communications and Outreach committee provides consistent outreach to BIOP members to increase awareness of nonclinical statistics. It drives communication strategy and visibility by showcasing successes, thought leadership, and technical excellence; supports the nonclinical associate editor of the *Biopharmaceutical Report* by identifying articles and future editors; and promotes nonclinical topics in the broader statistical community, especially in non-NCB years. Channels include the ASA-BIOP newsletter, *Amstat News*, LinkedIn, and email.

e. Stan Altan Best Paper Award

This award recognizes recent publications that make significant contributions to the field of nonclinical biostatistics. It is conferred at the biennial Nonclinical Biostatistics Conference or at another conference featuring topics relevant to the award’s subject matter. Award recipients are presented with a commemorative plaque.

f. Student Outreach

Provide students with information and insights regarding career opportunities in nonclinical biostatistics. Offer a forum for students and early-career professionals to engage actively in ASA-BIOP activities. Bridge the academic–industry divide by fostering dialogue among a diverse community of students, early-career professionals, and industry leaders. Maintain a scholarship program open to students in US graduate programs. Oversee the Best Student Presentation Award, which recognizes the outstanding student presenter at the Nonclinical Biostatistics Conference.

g. Permanent ASA-BIOP nonclinical committee appointees.

The appointees serve as liaisons to the BIOP committees to promote the visibility of nonclinical statistics and to foster cross-functional collaboration and shared values. In particular, the representation on the Finance Committee helps secure funding for conferences, seminars, and other scientific events with a nonclinical statistics focus.

ARTICLE VII. NCBLF MEMBERSHIP

Membership of NCBLF shall constitute members who:

- i. Hold a leadership position of nonclinical statistic at their respective organizations regardless of the organizational job title.
- ii. hold a leadership position of any workstream or committee of NCBWG .
- iii. qualify at discretion of the NCBLF chair.

Article VIII. FUNDING

To support the interests specified in Article III, NCBLF shall exercise the proceeds generated by the biennial U.S. NCB conference.