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BIOPHARMACEUTICAL REPORT

Chair: Heather Thomas and Richard Zink **Editors:** Ilya Lipkovich and Julia Jingyu Luan

CONTENTS

FEATURED ARTICLES

Biopharmaceutical Software Working Group
Alex Dmitrienko (Mediana Inc), J. Kyle Wathen (Johnson & Johnson), Gautier Paux (Sanofi), Thomas Brechenmacher (IQVIA), Kaushik Patra (Alexion), B. Nebiyou Bekele (Gilead), Dacheng Liu (Boehringer Ingelheim).....2

Be Bold
Christy Chuang-Stein, Chuang-Stein Consulting, LLC.....14

Biopharm Section recollections
Stephen J. Ruberg, Analytix Thinking, LLC.....15

BIOPHARMACEUTICAL SECTION NEWS

Transition Report
Heather Thomas and Richard Zink 9

Summary of the Biopharmaceutical Section Executive Committee Transition Meeting
Janelle K. Charles, BIOP Secretary 12

CONFERENCES

JSM 2018 Biopharmaceutical Section Poster Award winners.....16

JSM 2019: Biopharmaceutical Section Program at a Glance
Margaret Gamalo, Eli Lilly.....17

75th Annual Deming Conference on Applied Statistics.....18

42nd Annual Midwest Biopharmaceutical Statistics Workshop.....19

Note from the editors

Welcome to the first issue of the Biopharmaceutical (BIOP) Report for 2019! This issue's featured article by the members of BiopharmSoft group (led by **Alex Dmitrienko**, Mediana Inc and **J. Kyle Wathen**, Johnson and Johnson) provides an overview of the group's goals and a description of two topics related to its main activities: a general framework for clinical trial simulation and practical guidelines for the development of biopharmaceutical software.

In anticipation of the 40th anniversary of the ASA Biopharmaceutical section (in 2020) we start a series of vignettes from some of the key contributes to the section who reflect on the past and offer insights for the future. This issue contains vignettes by **Christy Chuang-Stein** (Chuang-Stein Consulting, LLC) and **Stephen J. Ruberg** (Analytix Thinking, LLC).

This issue also presents updates on some other Biopharmaceutical Section activities, such as a transition report (**Heather Thomas** and **Richard Zink**) and a summary of the executive committee transition meeting (**Janelle K. Charles**).

We also provide brief information on upcoming statistical conferences and announce the JSM 2018 Biopharmaceutical Section Poster Award winners.

We would like to thank Jeff Maca for his service as the BR Editor in 2018 and his continuing support in 2019, and welcome the new members of the editorial board: **Ilya Lipkovich** (Editor) and **Julia Jingyu Luan** (Associated Editor).

We hope you enjoy reading this issue and welcome feedback and suggestions on improvement and topics of interest you would like to see in the future issues.

BIOPHARMACEUTICAL SOFTWARE WORKING GROUP

Alex Dmitrienko (Mediana Inc), J. Kyle Wathen (Johnson & Johnson), Gautier Paux (Sanofi), Thomas Brechenmacher (IQVIA), Kaushik Patra (Alexion), B. Nebiyou Bekele (Gilead), Dacheng Liu (Boehringer Ingelheim)

1. INTRODUCTION

This article introduces one of the recently created working groups (Biopharmaceutical software working group or BiopharmSoft) and outlines its scope and general vision. We also provide a detailed description of two topics that play a central role in BiopharmSoft's list of goals, namely, a general framework for clinical trial simulation and practical guidelines for the development of biopharmaceutical software.

To provide some background information, the Section's Executive Committee voted to create BiopharmSoft in August 2018. The new working group intends to initiate a community-led effort aimed at building and validating software tools for biopharmaceutical applications. As the first step, we have started working on a detailed plan for developing free statistical software tools. The initial suite of tools includes open-source software, including R-based software and free Windows-based software packages with a graphical user interface, e.g.,

- Mediana package (an R package for general simulation-based power and sample size calculations in fixed-sample trial settings).
- Mediana Designer (a free Windows-based software tool for traditional and simulation-based power/sample size calculations in fixed-sample and group-sequential trial settings).
- PlatformTrialSimulator (an R package for simulation of platform clinical trials, including designs with multiple interventions entering the trial).

These software tools and those that will be built in the near future support novel simulation-based approaches, including Bayesian approaches, to the design and analysis of early-stage and late-stage clinical trials. BiopharmSoft will work on software packages that will be used by statisticians and packages intended for a broad audience of drug developers. These packages can be used to facilitate the decision-making process by providing an efficient framework for assessing multiple design and analysis approaches at either the clinical trial or the development program level. The working group will actively reach out to other groups across the biopharmaceutical industry to discuss and set up collaborations that will facilitate the development of free software aimed at biopharmaceutical applications.

The BiopharmSoft core team is currently composed of 14 members:

Alun Bedding (Roche), Neby Bekele (Gilead), Thomas Brechenmacher (IQVIA), Greg Cicconetti (AbbVie), Alex Dmitrienko (Mediana Inc) [Chair], Jessica Hu (FDA), Matthew Kowgier (Roche), Dacheng Liu (Boehringer Ingelheim), Brian Millen (Eli Lilly), Christoph Muysers (Bayer), Kaushik Patra (Alexion), Gautier Paux (Sanofi), Paul Schuette (FDA), Kyle Wathen (J&J) [Vice Chair].

The working group also includes three members at large: Keaven Anderson (Merck), Yilong Zhang (Merck) and Richard Zink (Target PharmaSolutions).

For more information about the working group and software tools mentioned above, please visit BiopharmSoft's page at *http://biopharmnet.com/biopharmsoft.*

2. GENERAL FRAMEWORK FOR CLINICAL TRIAL SIMULATION

It was explained above that one of the most important goals of BiopharmSoft is to develop software tools that enable efficient simulation-based approaches to designing complex clinical trials at different stages of development. Several recent publications deal with the broad topic of clinical trial simulation (CTS), see, for example, O'Kelly et al. (2017), Mayer et al. (2019), Morris, White and Crowther (2019). The 21st Century Cures Act (Subtitle C, Sec 3021) and PDUFA VI (Section 4) promote the use of complex innovative designs (CIDs). In particular, PDUFA VI states that "FDA will conduct a pilot program for highly innovative trial designs for which analytically

derived properties (e.g., Type I error) may not be feasible, and simulations are necessary to determine trial operating characteristics." This topic was discussed at the FDA public workshop on promoting the use of complex innovative designs in clinical trials (FDA, 2018). Dr. John Scott (Director, Division of Biostatistics, CBER, FDA) and other presenters encouraged trial sponsors to embrace simulation-based approaches to enable complex trial designs such as designs with multiple adaptations, Bayesian trial designs and small-sample designs. The FDA further established the CID pilot program in August 2018, see *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm617212.htm.*

The CID is defined as "highly innovative trial designs for which analytically derived properties may not be feasible, and simulations are necessary to determine trial operating characteristics." In addition, the recent FDA draft guidance on adaptive designs (FDA, 2018) describes that simulations "often play a critical role in planning and designing clinical trials in general, and are particularly important for adaptive trials."

Clinical Scenario Evaluation

In this section we will provide a high-level review of practical approaches to creating efficient CTS frameworks. To facilitate CTS planning, it is helpful to take advantage of general frameworks that have been tested in dozens of clinical trials, e.g., the Clinical Scenario Evaluation (CSE) framework (Benda et al., 2010).

The CSE framework introduces a disciplined approach to quantitative assessments of candidate trial designs and analysis methods in clinical trials. The framework relies on the following components known as data, analysis and evaluation models:

- Data models define the process of generating trial data, including the distributions of the outcome variables and their parameters.
- Analysis models specify the analysis strategies such as statistical tests that are applied to the trial data generated from the data models.
- Evaluation models define the criteria for evaluating the performance of the analysis strategies such as the definition of the probability of success.

The decomposition of clinical trial simulation into three main components facilitates a structured assessment of the operating characteristics of designs and analytical options. By carefully selecting plausible data models, applicable analysis models and clinically relevant evaluation models, a trial's sponsor can design a simulation study that supports a comprehensive evaluation of the pros and cons of selected analysis methods and assess their sensitivity to potential deviations from the original treatment effect assumptions. Examples of efficient CSE-based simulations are provided in Dmitrienko, Paux and Brechenmacher (2015), Dmitrienko et al. (2016) and Dmitrienko and Pulkstenis (2017).

The following principles were formulated in recent publications to set up a template for performing CSE-based simulations in a broad class of clinical trials:

- Data models should be selected based on a broad range of treatment effect assumptions, including both optimistic and pessimistic sets of assumptions. It is also important to explore a range of operational parameters, e.g., different patient enrollment and dropout patterns, especially in time-to-event trials.
- When defining analysis models, it is important to consider several applicable analysis methods, such as several statistical models, several multiple tests or several adaptive strategies.
- Evaluation models should be defined using commonly used metrics such as marginal and disjunctive power (probability that at least one null hypothesis in the family of primary hypotheses is rejected) as well as other meaningful criteria.
- Sensitivity assessments should play a central role in any CSE-based simulation to examine the robustness of the optimal analysis model against deviations from the main set of treatment effect assumptions. Qualitative sensitivity assessments are based on a small number of data models that correspond to clinically distinct treatment effect scenarios whereas quantitative sensitivity assessments consider a large set of data models that are slightly different from the main model (these models are obtained using random perturbations of the main data model).

The CSE framework also provides a foundation for developing optimal approaches to identifying trial designs and analysis methods. In fact, a comprehensive

simulation-based evaluation of candidate data and analysis models plays a key role in choosing optimal models with a robust performance across multiple sets of treatment effect assumptions. CSE-based optimization strategies have been studied in several recent publications, e.g., Dmitrienko and Paux (2017a, 2017b) and Paux and Dmitrienko (2018), applied the CSE framework to finding multiplicity adjustments that optimize appropriate evaluation criteria in Phase III trials with complex objectives. This general approach was illustrated using the APEX trial (Cohen et al., 2016) that employed a multi-population design with efficacy evaluations performed in the general patient population and two pre-defined subpopulations. The Type I error rate was controlled in the trial using the hierarchical testing strategy, which led to a negative trial outcome. A comprehensive simulation-driven assessment of alternative multiplicity adjustments, including the Hochberg test (Dmitrienko and D'Agostino, 2013), was undertaken and demonstrated that flexible multiplicity adjustments with a data-driven testing sequence would have been clearly superior to the basic hierarchical test in this trial.

Reproducibility and simulation report

In addition to the CSE framework discussed above, another important criterion for evaluating the quality of a simulation study is the ability to reproduce the results. One could argue that CTS may be difficult to reproduce, as simulation studies usually require a case-by-case implementation. This issue is of particular importance when a trial design assessed using CTS is submitted to a regulatory agency or ethical committees/independent review boards. In order to reduce the burden of CTS review, best practices for CTS assessment and communication need to be adopted. O'Kelly et al. (2017) proposed best practices for projects that involve modeling and simulation under the initiative of the Special Interest Group for Modeling and Simulation of the European Federation of Statisticians in the Pharmaceutical Industry. This document defines the key elements that should be presented (or justified to be omitted) when CTS is used in a project. Simulation reports should be comprehensive enough to expedite the review and enable reproducibility of the findings. In general, simulation reports should at least include:

- An overview of the objectives of the CTS exercise.
- A description of the CSE models used, i.e., parameters of the data, analysis and evaluation models.
- A description of the computing environment and software used, which may include some key programming elements.
- A specification of the number of iterations and seed for pseudo-random data generation.
- A detailed summary of the operating characteristics.

Additionally, the simulation code and technical details may be provided.

The software tools mentioned in the Introduction, e.g., Mediana package or Mediana Designer, implement the CSE approach to support disciplined clinical trial simulation in late-stage clinical trials. Both tools have also been designed to facilitate the reproducibility of simulation studies in clinical trials and support useful features such as an automatic generation of detailed simulation reports.

3. GUIDELINES FOR BIOPHARMACEUTICAL SOFTWARE DEVELOPMENT

This section will discuss the general goal of creating practical guidelines and specifications for biopharmaceutical software tools. We will focus on key topics such as software validation, software coding standards, acceptance testing, etc.

Validation and verification

First of all, in the software development field, the terms verification and validation are used interchangeably. In contrast, in the biopharmaceutical world, there is a distinction between software verification and software validation, see FDA (2002, Section 3.1). While it is common to talk about software validation in the biopharmaceutical industry, validation is a very broad term, and in this context, it is more appropriate to focus on software verification. One of the most important components of the process of software verification is the software requirements specification document that should contain an explicit definition of the software functionality. The document should include at a minimum software inputs, output and expected results. A second task in software verification is software testing. Software testing is intended to demonstrate that the software output matches the requirements as specified in the requirements document.

Test-driven development (TDD) is a software process that focuses on short development cycles where software requirements are turned into test cases and thus a software tool is developed and/or improved by ensuring that each test will pass. The software development industry has utilized test driven development since the late 1990's. However, many biopharmaceutical software developers do not embrace the test-driven approach or do not formally release tests with R packages. As a simple example of TDD, suppose that an R developer was required to implement a function to square the input argument and return it. The developer would go through the following process:

- Define the function signature, for example
  `Square <- function(x) {return(-1)}`
  that clearly returns an incorrect result.
- Create several tests with known correct answers and execute the test with the expectation that all tests fail, e.g., the returned value is not equal to the expected result.
- Implement the necessary changes to make all tests pass, for example
  `Square <- function(x) {return(x*x)}`
- Rerun all tests.
- If all tests pass, the returned results all equal the expected results, the process is completed but, if any test fails, correct the bugs in the function and re-run the test until all tests pass.

For many applications performing simulations, there is an inherent random component. The TDD example above is great for deterministic functions, however, more planning is required for functions that contain a random element. For example, it would be more difficult to test a function that generates the age of a patient where the goal is to generate patients that are normally distributed with a mean of 50 years and standard deviation (SD) of 3 years. A test that calls the function and computes the mean/SD and compares them to a fixed tolerability range for both parameters would be considered a minimal test. By contrast, a test that calls the function multiple times and performs a statistical test, such as a Chi-squared test, to check that the resulting distribution matches the target distribution would be a more comprehensive test.

TDD encourages smaller and simpler code units (functions) that are easier to test and increases confidence in the code. In addition, TDD decreases the likelihood of bugs being introduced because it provides an easy way of testing via previously developed tests. While there are several approaches to help with TDD in R, the testthat (Wickham, 2018) and RUnit (Burger, Juenemann and Koenig, 2018) packages provide a simple to use structure for developing code in a TDD fashion.

Software coding standards

Software coding standards is a subset of coding best practices and should be considered prior to commencing development. Dictionary.com defines the word code as "a system used for brevity or secrecy of communication, in which arbitrarily chosen words, letters, or symbols are assigned definite meanings." This definition contrasts with one of the overall goals of coding standards, which is to increase readability. When developing code, the developer should strive to write code that is easy to read, understand and follow, rather than code that focuses on "brevity or secrecy of communication." Coding standards vary depending on the development language, eg R vs C++, however, there is a lack of commonly agreed upon coding standards in R that are widely accepted and utilized in the biopharmaceutical world. Coding standards typically address the following topics:

- Commenting: Create short and informative descriptions for blocks of code or functions. Often, the developer does not have sufficient time to add comments or detailed documentation and thus ends up with undocumented, difficult-to-ready code. Our recommendation, at a minimum, is to include a brief description of the intent of all functions or blocks of code, with a description of input parameters and returned values.
- Naming Convention: Utilize a clear and consistent naming convention within a software project can greatly increase the readability and maintainability of the code. Avoid using generic names that have no meaning without commenting. For example, variable names such as age, weight or height would be much easier

to follow than generic variables like x1, x2 and x3. The use of CamelCase or using underscores to separate words (e.g., WeightPounds or weight_pounds) can make code easier to read and follow. It is better to avoid using dots in variable names (e.g., or weight.pounds) as dots should be reserved for object-oriented programming. Also, using WeightPounds would be better than Weight as it is instantly recognizable with a known unit of measurement.

- Simple code: Avoid complicated logic, such as multiple nested if-else logic, as it tends to be very error prone and difficult for multiple developers to follow. Complicated logic is much more difficult to test. In addition, complicated logic written by an initial developer may be confusing to subsequent developers. Note also that striving to write simple code does not imply that putting as much functionality into one line of code improves the simplicity factor. It is often easier to follow code that is broken into several lines, rather the one very complicated line of code.

We believe that any statistician can learn to write code that is clean and easy to read, but it does require some time to develop the skills. With good coding and documentation practices, it is a lot easier to test, maintain and update software tools.

In addition, biopharmaceutical statisticians are encouraged to utilize modern version control tools and practices, including Git and online platforms such as github.com and gitlab.com. Many online resources are available to learn Git, such as *https://git-scm.com/book/en/v1/Getting-Started-About-Version-Control* or *https://backlog.com/git-tutorial.*

See also Hogbin (2015). A version control system tracks changes to the software code and can be used to identify the revisions made by each contributor and merge multiple versions of the same program. Git-based tools and online platforms provide issue-tracking ability, which is very important in community-driven development projects as it is easy for all contributors to see issues as they arise.

User acceptance

Before a software product is released, it is beneficial to have a beta release and gather feedback from potential users. It is very important to gather, record, and provide the feedback that is received regarding the user-friendly attributes of the interface (especially in the context of applications with graphical user interfaces). Other important factors to evaluate at this stage include the input options, presentation of the output, clarity of help files or examples, clarity of software code in the case of an R package, and installation issues as well as bugs. We recommend that developers of biopharmaceutical software should plan ahead to collect user feedback. Gathering user feedback can be helpful to provide guidance around the next steps for the software development project, next versions and future enhancements to the software.

It is important to remember that, after a product is released, the next phase of software development begins. Software developers need to be prepared to begin the phase of collecting user feedback, such as questions on usage or new functionality that is requested. It is very useful to provide a formal process for bug reporting, tracking and resolution. In a community-driven development project, this part of the software lifecycle is extremely important as it improves the software's usability, reliability and functionality and avoids developing new packages because an existing package does not cover a specific user requirement. Post-release formal management of communication flows between users and developers of biopharmaceutical software tools are rare yet easy to enable. For example, github.com or gitlab.com provide an avenue for report and tracking bugs as well as feature requests, see training examples.

Examples

The following examples will be used to illustrate the key points presented above. The Windows application for clinical trial simulations (Mediana Designer) has been built by following the recommendations presented earlier in this section. As the very first step, a very detailed set of software design specifications was prepared (the most important specifications are described in the technical manual available on the application's web page) and a comprehensive set of unit tests was constructed to ensure that each function in the simulation library was compliant with the specifications. These tests can be thoughts of as "local" tests and were subsequently accompanied by "global" tests that focused on the interactions among the individual functions. The global tests were carried out using detailed comparisons to commercially available and

open-source software to test the internal logic using hundreds of scenarios. Detailed test summaries can be downloaded from the application's web page. The next step involved user acceptance testing. Over 30 testers from across the biopharmaceutical industry have reviewed beta versions of Mediana Designer and provided valuable feedback that helped address multiple issues in the application's interface and in the simulation library. The software tool is undergoing an additional set of user acceptance tests as part of the public beta testing before the production version (Version 1.0) will be released.

In addition to building reliable software packages, it is important not to lose sight of the user's perspective. We would like to emphasize that our goal is to build useful software tools with detailed user manuals, case studies and other instructional materials, including instructional videos. For example, all R packages are required to have vignettes but most of the vignettes are extremely short and far from being user-friendly. We encourage developers of biopharmaceutical software to set aside time to develop comprehensive documentation with useful examples that shed light on all key features of the software tool. Mediana's online manual, available at *http://gpaux.github.io/Mediana,* serves as an example of a recommended approach to creating user manuals.

Returning to Mediana Designer, over 50 case studies were created to explain how this tool could be used to run power and sample size calculations under most common settings. By modifying parameters of the case studies, the user can very quickly find solutions to hundreds of related problems. In addition, free instructional videos (to explain the interface) and technical videos (to introduce the underlying statistical methodology) will be soon developed and posted to the Section's YouTube channel: *https://community.amstat.org/biop/media-contents/youtube.*

For more information on Mediana Designer, validation procedures and documentation, see *http://biopharmnet.com/mediana-designer*.

BiopharmSoft members are actively involved in developing free training videos for the Section's membership and other clinical trial statisticians. J. Kyle Wathen has created a multi-part video series on Bayesian clinical trial simulations that provides, among other things, detailed examples of test-driven approaches to building R packages. The series can be found on the Section's YouTube channel. Other members, including Alex Dmitrienko and Gautier Paux, are beginning to work on a video series on CSE-based approaches to clinical trial simulations.

4. CONCLUDING REMARKS

We have been inspired by the R project and by numerous volunteers who have developed great software tools for biopharmaceutical applications. BiopharmSoft is excited to help coordinate multiple software development efforts across the biopharmaceutical industry. The working group will continue developing free software tools, preparing publications, organizing conference presentations and creating training courses to introduce the software tools designed by the working group to the biostatistical and clinical trial communities.

BiopharmSoft has started setting up a network of testers and reviewers with over 30 statisticians around the biopharmaceutical industry contributing to testing Mediana Designer. BiopharmSoft is also soliciting ideas for new software tools. Our ultimately goal is to cultivate a community focused on the development of software tools for biopharmaceutical statisticians by biopharmaceutical statisticians. If you are interested in contributing to this initiative, please contact us at *biopharmsoft@biopharmnet.com*. ■

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TRANSITION REPORT

Heather Thomas (BIOP Chair 2018) and Richard Zink (BIOP Chair 2019)

Greetings! The past year was another busy year for the Biopharmaceutical Section (BIOP) and 2019 is proving to be just as busy with very active committee work and preparations for annual meetings and workshops. In this article, we will provide a quick summary of the most important initiatives and events that took place in 2018 as well as early 2019, and our plans for the rest of the year.

INITIATIVES AND ACTIVITIES

Biopharmaceutical Section Scholarship

The first Biopharmaceutical Section scholarships were awarded in 2018. The scholarships are aimed at students enrolled in a Master's or Doctoral program in statistics or biostatistics. Consideration for the awards are based primarily on notable academic achievement or applied project work related to the area of biopharmaceutical statistics and consider general academic performance, leadership, volunteering, and service. A committee was established to advertise the scholarships and oversee the selection process. Three scholarships of $1,000 each were awarded in 2018 to the following well deserving recipients:

- Christopher R. Barbour, Montana State University
- Theyaa Chandereng, University of Wisconsin
- Will A. Eagan, Purdue University

The recipients were honored at the ASA Biopharmaceutical Section Business Meeting at the Joint Statistical Meetings (JSM) in Vancouver, Canada.

Given the success of the first ever Biopharmaceutical Section Scholarship awards in 2018, it was decided to continue the scholarship in 2019. The Scholarship committee plans to do more outreach to academic department chairs and student organizations in 2019 and will open the application process in March. The winners will be announced prior to JSM and honored again at the ASA Biopharmaceutical Section Business meeting at JSM in Denver, Colorado.

Biopharmaceutical Section 40th Anniversary Committee

It was determined that in 2021, the Biopharmaceutical Section will celebrate its 40th anniversary as a section. The Executive Committee voted in 2018 to establish a 40th anniversary committee in 2019 to begin planning for some celebratory activities in 2021. Ideas being considered are:

- Logo competition for the 40th anniversary open to the section membership
- Activities at JSM and the ASA Biopharmaceutical Regulatory-Industry Statistics Workshop
- Special session at the 2021 ASA Biopharmaceutical Regulatory-Industry Statistics Workshop

We look forward to this amazing milestone and celebrating our success as a section!

Biopharmaceutical Section Regulatory-Industry Statistics Workshop Sponsorship

The Task Force for the Biopharmaceutical Section Regulatory-Industry Statistics Workshop brought a proposal to the Executive Committee for consideration in 2018 to allow for sponsorship for the Workshop. The Executive Committee voted to allow for sponsorship at the Workshop and we are happy to report that we already have a few sponsors lined for the 2019 Workshop.

Other Initiatives

Other initiatives discussed in 2018 for execution in 2019 include:

- The implementation of a YouTube channel as a communication tool to the membership to share webinars, leadership or statistical trainings, and other statistical information relevant to the Biopharmaceutical Section.
- Combining various committees within the Section that were liaising with other sections or groups to form a single Outreach Committee.

CONFERENCES AND WORKSHOPS

JSM

The Section had a successful presence at JSM in Vancouver, Canada in 2018. The Section sponsored 4 invited sessions, 14 roundtables, 18 topic-contributed sessions and 21 contributed sessions as well as 4 short courses. For JSM 2019, we expect to have a similar presence for invited sessions, topic-contributed sessions, contributed sessions, short courses, and roundtables. Our Program Chair, Margaret Gamalo-Siebers and numerous volunteers have been hard at work planning these activities. We hope to see you all in Denver!

ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop

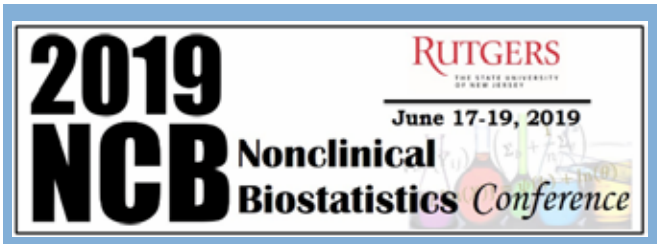
The 2018 Regulatory-Industry Statistics Workshop held in Washington, D.C. in September was a huge success! The Workshop was co-chaired by Satrajit Roychoudhury and Yun Wang and they did a fantastic job. The theme chosen by the steering committee (Evolution of Statistical Science: Translating Data to Innovative Health Care) reflected the increasing interest in the development of proper estimands, use of real-world evidence, master protocols, and related topics. The Workshop's steering committee put together an exciting program with two plenary sessions that featured presentations from industry and regulatory statistical experts, 43 sessions, 39 roundtable discussions, and 8 half-day courses. Registration sold out prior to the meeting for the second year in a year. There was also a well-attended poster session.

We look forward to this year's workshop, which will be held on September 23-25 at the Wardman Park Marriott in Washington, D.C. This year's co-chairs, Judy Li and Renee Rees, have begun organizing this incredible workshop. We would like to give a huge shout-out to all of the many volunteers that devote their time to making this such a great event. The theme of the 2019 Workshop will be "From Small Data to Big Data, from RCT to RWE, the Impact of Statistics." Given that last year's workshop sold out for the second year in a row, it is suggested to register early. We look forward to the Workshop and hope to see you there in September.

ASA Biopharmaceutical Section Nonclinical Biostatistics Conference

The ASA Biopharmaceutical Section Nonclinical Biostatistics Conference (NCB) is a biennial conference held at Rutgers University and is sponsored by the Biopharmaceutical Section in cooperation with the Rutgers University Statistics Department. The 3-day conference is organized by the NCB conference committee and the Nonclinical Biostatisticians Working Group. The conference includes invited and contributed talks on nonclinical biostatistics topics with speakers from industry, regulatory, and academia as well two short courses offered on the first day.

The next conference will take place at Rutgers University on June 17-19 2019. The theme of this year's conference is "Nonclinical Biostatistics – Advancing drug development from discovery to commercialization." ASA President, Karen Kafadar, will be speaking at the conference on evaluating the benefits and biases in cancer screening trials. Registration is already open and is limited to 180 participants so, be sure to sign up early!



Visit the conference website: ***http://community.amstat.org/biop/events/ncb/index***

Visit the NCB student outreach website: ***http://community.amstat.org/biop/workinggroups/ncbwg/students***

Visit the Best non-clinical biostatistics paper website: ***http://community.amstat.org/biop/workinggroups/ncbwg/awards***

Scientific Working Groups

Over the past year, the Executive Committee reviewed several proposals to create Biopharmaceutical Section sponsored scientific working groups aimed at promoting cross-community efforts in advancing statistical and regulatory science. The process of establishing new working groups is overseen by the Scientific Working Group (SWG) Committee. Through the SWG Committee, section members can submit research topics that contribute to the goals of advancing the science, enabling innovation, and leveraging the membership expertise. The establishment of the working group must be approved by the Section Executive Committee and each scientific working group must provide a yearly update report to the Executive Committee.

In 2018, the following scientific working groups received approval by the Executive Committee for establishment:

- Oncology Working Group chaired by Qi Jiang and Olga Marchenko
- Real World Data and Real World Evidence Working Group chaired by Weili He and Martin
- Biopharmaceutical Software Working Group chaired by Alex Dmitrienko and Kyle Wathen
- Pediatric Scientific Working Group chaired by Margaret Gamalo-Siebers and Mark Rothmann

Biopharmaceutical Section Newly Elected Officers

We would like to welcome the following elected officers to the Biopharmaceutical Section Executive Committee for 2019:

- Bruce Binkowitz Chair-Elect for 2019 following as Chair in 2020
- Stephine Keeton Program Chair-Elect in 2019 following as Program Chair in 2020
- Yongming Qu Publications Officer for a 3-year term (2019-2021)
- Veronica Powell Council of Sections Representative for a 3-year term (2019-2021)

We know these individuals will do a fantastic job representing the Section and we wish them the best of luck!

Final Thoughts

We would like to take this opportunity to thank all of the elected officers, committee chairs, and committee members for their commitment, time, energy, and expertise in the smooth running of the Section. Without all of you, the Section would not be able to accomplish everything that it does.

Outgoing elected officers in 2018 included:

- Alex Dmitrienko Past Chair (Chair in 2017)
- Qi Jiang Program Chair
- Jennifer Gauvin Publications Officer
- Rima Izem Council of Sections Representative

We would also like to thank the membership for your support of our very active section. We are looking forward to a productive 2019.

Cheers! ■

Heather and Richard

SUMMARY OF THE BIOPHARMACEUTICAL SECTION EXECUTIVE COMMITTEE TRANSITION MEETING

By Janelle K. Charles, BIOP Secretary

Heather Thomas, Biopharmaceutical (BIOP) Section Chair, welcomed the Executive Committee (EC) to the meeting, attendance was recorded, and the meeting was called to order. There were 15 in-person attendees and 9 attendees by phone. Heather led discussions of three important topics: JSM Business Meeting, WebEx Licensing and the ENAR EC Meeting.

JSM BUSINESS MEETING

Heather provided a breakdown of the attendees at the 2018 JSM Business Meeting/Mixer. Based on the sign-in sheet, there were 123 attendees and Heather had estimated a total of 125 when preparing the food costs for the mixer. There were 23 people at the JSM Business Meeting who expressed interest in being mentors; these names were passed to the Mentoring Committee.

The EC discussed possibly including a new responsibility for the Membership Committee to track attendance and provide summary reports of attendees to future Business meetings, distinguishing BIOP members and non-members. Such summaries could be useful for budgetary and logistical planning. Matthew Guerra, Chair of the Membership Committee, discussed that similar reports had been done by the committee in the past and provided the EC with a brief summary of attendance to prior JSM Business Meetings.

WEBEX LICENSING

Heather presented two options for WebEx licenses for EC consideration to circumvent challenges experienced with previous web conferencing methods. The Starter Package with up to 9 hosts and maximum of 50 attendees costing $13.95 per host per month or the Plus Package with up to 50 hosts and maximum of 100 attendees for $17.95 per host per month. The EC discussed pros and cons of each WebEx package. The EC considered risk of a single host account if multiple meetings need to be held simultaneously. The EC decided to pay for a year of the WebEx Plus Package with one host and potentially expand to more hosts if needed.

ENAR EC MEETING

Heather presented the low in-person attendance by EC members at the ENAR EC Meetings in 2017 (~15 members) and 2018 (~10 members). There are high costs for the EC associated food, conference room, AV, etc. compared to low attendance rate. Additionally, BIOP has no negotiating power in these costs for the face-to-face ENAR EC Meeting. The EC discussed alternatives for future EC meetings separate from the ENAR Spring Conference. The EC decided to pilot a virtual meeting in March/April 2019 timeframe in lieu of the one usually held at the ENAR Spring Conference. After this meeting, the EC will re-evaluate whether to permanently have a virtual meeting in first quarter and make the corresponding changes to the Manual of Operations.

Alex Dmitrienko, Past-Chair, announced that there are 4 positions open for the 2019 ASA elections: Chair Elect, Treasurer, Program Chair-Elect, and Council of Sections Representative. Interested persons were to contact Alex for consideration to be added to the elections slate. The final candidates are Weili He, AbbVie and Meg Gamalo-Siebers, Eli Lilly & Company for Chair-Elect, Freda Cooner, Amgen and Jane Qian, AbbVie / Abbott Laboratories for Treasurer, Jonathan Moscovici, IQVIA is running uncontested for Program Chair-Elect, and Abie Ekangaki, Premier Research and Ted Lystig, Medtronic for Council of Sections Representative.

Heather and Alex requested EC members to continue to review and provide suggested updates to the Section's Manual of Operations.

Richard Zink, Chair-Elect, introduced the winners of the 2018 elections whose terms began in 2019:

- **Chair-Elect:** Bruce Binkowitz, Shionogi
- **Program Chair-Elect:** Stephine Keeton, PPD
- **Publications Officer:** Yongming Qu, Eli Lilly

- **Council of Sections Representative:** Veronica Powell, QST Consultations

Additionally, the appointed EC members are as follows:

- Ad Hoc Members: Rakhi Kilaru, PPD and Melvin Munsaka, AbbVie
- Distance Learning Program: Elena Polverejan, Janssen
- Associate Editor, Biopharmaceutical Report: Julia Jingyu Luan, FDA/CDEREC
- Scholarship Award Chair: Abie Ekangaki, Premier Research

Richard highlighted a few areas of focus for 2019:

- Workshop Task Force to reconvene discussions regarding getting sponsorships and potential for term limits for the Workshop Steering Committee
- Scholarship Committee to emphasize raising awareness of the BIOP Scholarship Award
- Outreach Committee to reconsider BIOP involvement in giving talks to undergraduates and high school classes

Alan Hartford, Treasurer, provided a summary of the year-to-date spending and noted that it was tracking as expected based on the 2018 budget. He also presented the 2019 Draft Budget, which was based on the 2018 Budget with the exception of an increase in food costs by 10%. The costs for WebEx was also to be added to finalize the 2019 budget. Additionally, the budget would be impacted with the EC decision to host a virtual meeting in March/April 2019 instead of face-to-face during ENAR.

The EC decided to maintain the contributions to other organizations at $10,000 as well as money for future initiatives. The EC discussed that the $15,000 from conference proceedings may not be realized in the future.

Satrajit Roychoudhury and **Yun Wang,** 2018 Biopharmaceutical Section Regulatory-Industry Statistics Workshop Co-Chairs, provided highlights from the first day of the workshop. The Workshop had been sold out and, despite Hurricane Florence, the impact on attendance and program was minimal; there were only 6 cancellations but approximately 20 waitlisted. There were 8 winners out of 19 applicants for the student travel awards; each to receive $500 on the last day of the Workshop. There will be a shortened review time (3 months instead of 6 months for major papers and 1 month minor review of papers) so the Special Issue of the Statistics in Biopharmaceutical Research expected to be published earlier than the typical timeframe.

Erik Pulkstenis, Council of Sections (CoS) Representative, provided updates of two topics from the JSM EC meeting that were voted on during the transition meeting. Firstly, the EC voted to have BIOP Cos Representatives endorse changes to the Cos Charter expanding language about interest groups and requirement for annual reports from interest groups. Secondly, the EC supported the application for Lifetime Data (LIDA) Interest Group to become a Section.

Abie Ekangaki, presented that the Scholarship Committee aims to advertise the 2019 scholarship widely to get as many applicants as possible. The Committee will work with Rick Peterson at ASA to obtain contact information for academic department chairs and student chapters. The Committee plans to publish article in Amstat News advertising 2019 scholarship award application; application to open in March 2019.

Bruce Binkowitz, Scientific Working Group, introduced the newest proposal received by the Scientific Working Group Proposal committee for the formation of the Pediatric Scientific Working Group. The approval of this proposal during the meeting meant that a total of eight scientific working groups within BIOP.

Heather led the discussion about the feasibility to have updates from working groups at each EC meeting considering the growth in numbers of working groups. The expectation is that the working group charters will serve as a template for the yearly deliverables. The EC discussed requesting annual reports from the working groups.

Alex Dmitrienko, Strategic Initiatives/Outreach Committee, in follow-up to JSM EC Meeting, shared ideas for using a YouTube Channel as a communication tool for the benefit of BIOP members. Alex noted there were no costs involved in hosting a YouTube Channel and confirmed that any ASA logos or other ASA site material may be included on the channel. Alex will provide proposal outlining committee membership for the channel and details for managing the content.

After updates and discussions on a few additional topics, Heather Heather requested all EC members who are transitioning off positions to contact incoming EC members taking over in same roles for onboarding. Heather concluded her last EC meeting as Chair of BIOP by thanking all EC members for their contributions to the Section. The meeting was then adjourned. ■

BE BOLD

By Christy Chuang-Stein, Chuang-Stein Consulting, LLC

"If you are taking a risk, what you are really saying is, 'I believe in tomorrow and I will be part of it.'"

– Linda Ellerbee

This year, I serve on the Florence Nightingale David Award and Lecture Committee, External Nominations and Awards Committee, and Deming Lectureship Committee. The first committee is sponsored jointly by COPSS (Committee of Presidents of Statistical Societies) and the Caucus for Women in Statistics while the last two are sponsored by the American Statistical Association. I enjoy serving on these committees because I get to learn the career paths and achievements of many outstanding members of our profession.

Some of the nominees went through a natural career progression through the ranks. Many, on the other hand, have chosen to leave the comfortable folds of statistics and become a dean or a provost of a college. This stepping-out-of-statistics choice was not limited to academic statisticians. Some statisticians in the pharmaceutical industry have opted to cross over to other disciplinary areas such as regulatory affairs, safety, information technology or project management. They brought their well-honed logical thinking to their new positions and found great success and fulfillment in their new homes.

Statisticians working in the pharmaceutical industry are familiar with go/no-go milestone decisions. We face similar decisions in our career journeys. The timings of the decisions may vary among individuals. Yet, sooner or later, we will face questions like - Should I apply for a higher position within my organization or in a different organization? Will I be good at it? Will I enjoy the prospect of working in a new area? What if I fail in the new position? Will my reputation suffer irreparable damage because of the failure?

Interestingly, some statisticians find it difficult to make a career change. I wonder whether this has something to do with our statistical training. We are good at calculating risks associated with wrong decisions, but we are not as good at articulating gains from right decisions except for, perhaps, the Bayesians. We caution against making go-decisions when the evidence for moving forward is limited. This cautious tendency may have contributed to our unwillingness to make a career change when uncertainties abounded.

I picked up the game of duplicate bridge after my retirement from Pfizer. My husband and I play regularly at our local bridge clubs. I often reviewed the hands played afterwards. I found that players who are willing to take a risk and bid for higher-level contracts tend to have higher scores in the long run. Could it be that life is like a series of bridge hands? One can play it safe and be good. But, could one become great if one is willing to take calculated risks? Data have suggested this to be the case.

So, next time, when you face a career decision, take a risk. The decision to move forward may open doors to other opportunities that you have never imagined before. The change may seem daunting at the beginning, but it could also be energizing. Someone once told me, if you want to be a diamond, you need to be willing to be cut. Or, as John A. Shedd said, a ship in a harbor is safe, but that is not what ships are built for.

Be Bold, my friends. ■

BIOPHARM SECTION RECOLLECTIONS

By Stephen J. Ruberg, Analytix Thinking, LLC

I was asked by long-time friend and colleague, Ilya Lipkovich, to write a short essay on the Biopharm Section for this Report because of my "experience." I immediately saw through his invitation and realized that he (and perhaps his co-Editor) wanted an older person's perspective! As such, I will focus on some of my recollection of those early days of the Section, allowing the reader to suspect some recall bias as any good statistician should do.

Following the passage of the Kefauver-Harris Amendment to the Food Drug and Cosmetic Act [1] in 1962 and the ensuing regulatory framework that emerged throughout the 1960's, the pharma industry was largely engaged in the conduct of clinical trials to satisfy the evidentiary requirements of drugs already on the market. This was known as the DESI era [2]. For those interested in the early years and the writings of those directly involved in the creation of the Biopharm Section, our own web-page has interesting details and some references for further reading [3]. In 1981, when I joined the industry, the DESI era was in its waning years, and the industry pivoted to more forward-looking and systematic drug development creating the Phase 1-2-3-4 paradigm that is largely in place today. This was precisely the time where the Biopharm Section got its foothold in the ASA and began its ascendancy to be a major player in ASA and in industry.

In the 1980's, the relationship between FDA and pharma industry was much more distant and adversarial than today, and communications were slow and more opaque than what occurs in our present-day, hyper-connected world (imagine a world with no e-mail, no internet, not even word processing!). The Biopharm Section was an essential construct that fostered the interchange of ideas about data, evidence and the rule of (probability) law. Section sessions at JSM provided a valuable forum for increasing the rigor with which the industry conducted, analyzed and interpreted clinical trials since, at the time, there was a paucity of journals dedicated to statistics in drug development (recall Biometrics was–and still is –more academic with a broader focus and remit). Such interactions naturally led to greater understanding between pharma and FDA, and the Section's influence spread to other regions and regulatory agencies around the world. Thus, the Section played a key role in building the bridges between industry and regulators that we enjoy today. Also, during the 1980's and into the 1990's, it is worth noting that the Pharmaceutical Manufacturers Association (PMA–now known as PhRMA) had a scientific working group for biostatistics that also played an important role in advancing the science of statistics in drug development and the positive interactions with regulators. However, as PhRMA moved to dissolve its various scientific working groups in the early 2000's, including biostatistics, the ASA Biopharm Section took up an even greater mantle of leadership with fervor and success.

Another key role of the ASA Biopharm Section that might be taken for granted today is the relationship between industry and academia. Again, through workshops, conferences and eventually journals, the Biopharm Section engaged the academic community to bring its considerable intellectual resources to bear on the problems of design of and inference from clinical trials. In this way, the Section was a leader in channeling ASA to more practical and applied problems from its deep historical roots in academia and more theoretical statistics.

For me, the ASA Biopharm Section has always been a place of vibrant learning and networking organization to influence the profession of Statistics and the application of rigorous statistical thinking in drug development. Its influence stretches into many other areas of clinical and basic research and the regulatory science that oversees what the industry does. I am happy to see the Biopharm Section flourishing (e.g. the Regulatory Industry Statistics Workshop meeting is a spectacular success grown from humble beginnings) as others will write for this Report. Our collective challenge is to continue that influence within regulatory agencies and academia for the betterment of society. ■

1. Drug Amendments Act of 1962, Public Law 87–781, 76 STAT 780. *http://prescriptiondrugs.procon.org/sourcefiles/1962Amendments.pdf* (accessed March 10, 2015).
2. Stephen J. Ruberg (2016) Making what's advanced today routine tomorrow, *Journal of Biopharmaceutical Statistics*, 26:1, 55-70, DOI: 10.1080/10543406.2015.1092035
3. *https://community.amstat.org/biop/aboutus/history*

JSM 2018 BIOPHARMACEUTICAL SECTION POSTER AWARD WINNERS

On behalf of the 2018 Biopharmaceutical Section Poster Awards committee, we would like to announce the JSM 2018 Biopharmaceutical Section Poster Award winners:

FIRST PLACE

"Determination of optimal cut-off points for biomarkers in oncology research," by Tian Chen etc. BMS

SECOND PLACE

"Non-Inferiority Margins in Superiority/Non-inferiority Seamless Clinical Trials," by Ellen B. Gurary etc., Boston University

THIRD PLACE

"Power and Type I Error for Sizing Binomial Endpoints with Unequal Randomization Ratios," by Rong Wang etc. Pfizer

In addition, if you plan to attend the 2019 JSM and plan to present a poster, you may consider participating in the Poster Competition sponsored by the ASA Biopharmaceutical Section. All authors who present posters sponsored by the Biopharmaceutical Section are qualified to compete for this award. Three awards with cash prizes of $1000, $600 and $400 will be given for 1st, 2nd and 3rd place, respectively.

If you have submitted an abstract for poster presentation at 2019 JSM through the Biopharmaceutical Section, you are encouraged to participate in the Poster Competition by submitting your poster to Jingyi Liu, Chair for the Poster Awards, through email (*liu_jingyi@lilly.com*) by July 1, 2019. ■

JSM 2019: BIOPHARMACEUTICAL SECTION PROGRAM AT A GLANCE

By Margaret Gamalo, Eli Lilly

The 2018 Joint Statistical Meetings will convene at the Colorado Convention Center in Denver, Colorado from July 27 to August 1. The theme of the 2018 meetings is "Statistics: Making an Impact." The ASA Biopharmaceutical Section has been instrumental in helping to put together an outstanding program, including sponsoring numerous courses, sessions, roundtables and posters.

Two short courses are sponsored by the Biopharmaceutical Section and will be presented this year:

- Analysis of Clinical Trials: Theory and Applications
- Futility Analyses in Confirmatory Clinical Trials – Methods and Procedures

These courses has wide interest and will be helpful for young statisticians embarking on a career in the Pharmaceutical Industry.

Among the 28 invited submissions to the section, the invited program includes five Biopharmaceutical Section sponsored sessions and 10 co-sponsored sessions

- Impact of Using Surrogate Endpoints on Drug Development
- Recent developments in novel clinical trial design and analysis for precision medicine
- Recent evaluations of methods for handling non-compliance/dropouts in clinical trials for better guidance driven application
- Pragmatic randomized clinical trials: challenges and impact on clinical practice and health policies
- Evidence Beyond Traditional Clinical Trials
- Statistical Methods, Challenges and Impacts on Early Phase Trials
- The p-value controversy: where do we go from here?
- How Advanced Analytic Tools Deliver Insights for Clinical Investigations through Real World Data
- Innovative Bayesian Approaches in Clinical Trials and Practical Considerations
- Time-to-event Models in Complex Observational Studies
- Experimental Design Applications in the Pharmaceutical Industry
- Recent Advances in Propensity Score Methods for Observational Studies with Multiple Treatments
- Complex Innovative Designs in Practice of Early Phase Drug Development
- Database lock to Data Safety Monitoring Board Meeting – More than a click of a button.
- Advances in Clinical Outcome Assessments

Additionally, among 45 submissions, the section is sponsoring 16 Topic Contributed sessions on a variety of topics such as optimization in pediatric development, estimands, big data and deep learning, adaptive designs, precision medicine, basket and platform trials, probabilistic decision making, real-world evidence, immunotherapy trials, patient-focused trials, and Bayesian methodology.

The Biopharmaceutical Section received 140 contributed abstracts. The most by any section in the American Statistical Association. One-hundred twelve of these abstracts compose 16 contributed sessions. The remaining were distributed to other speed session or contributed posters. The section is supporting 2 speed sessions of 20 abstracts each and many contributed posters which will be displayed either on the JSM Opening Mixer or Technical Poster Sessions scheduled throughout the week-long conference.

We look forward to seeing you at the 2019 Joint Statistical Meetings in Denver, Colorado this summer.■

75TH ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

December 2-6, 2019; Atlantic City, NJ (*https://demingconference.org*)

The 75th Annual Deming Conference on Applied Statistics will be held from Monday Dec. 2 to Wednesday Dec. 4, 2019, followed by two parallel 2-day short courses on Thursday Dec. 5 and Friday Dec. 6 at the state-of-the-art Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ.

The purpose of the 3-day Deming Conference on Applied Statistics is to provide a learning experience on recent developments in statistical methodologies in biopharmaceutical applications. The conference is composed of twelve three-hour tutorials on current topics in applied biopharmaceutical statistic and FDA regulations, as well as two one-hour distinguished keynotes on Monday and Tuesday. The books, on which these sessions are based, are available for sale at an approximately 40% discount. Attendees will receive program proceedings of the presentations. There will also be poster sessions.

The conference is sponsored by the American Statistical Association Biopharmaceutical Section. Walter Young has chaired this conference for 50 consecutive years. The program committee include: Alfred Balch, Joseph Borden, Ivan Chan, (Din) Ding-Geng Chen, Kalyan Ghosh, Satish Laroia, Xiaoming Li, Sofia Paul, Manoj Patel, Naitee Ting, Yibin Wang, Wenjin Wang, William Wang, Li-an Xu, Walter Young, Pinggao Zhang.

The full program as well as a downloadable printed version will be available on our website by June 1st and online registration will open in August. For more information about the conference, please email Din Chen at *dinchen@email.unc.edu* or visit *https://deming conference.org*. ■

42ND ANNUAL MIDWEST BIOPHARMACEUTICAL STATISTICS WORKSHOP

May 20–22, 2019 • Renaissance Hotel, Carmel (Indianapolis), Indiana

Statistics: Making an Impact

HALF-DAY SHORT COURSES

- *Accelerating Drug Discovery Through Precision Medicine and Innovative Designs* – Concepts, Rationales, and Case Studies by WEIDONG ZHANG (Pfizer), SANDEEP MENON (Pfizer/ Boston University/Tuffs University)
- *An Introduction to Biomarkers for Statisticians – A Brief Guide to Utilizing the Most Appropriate Analytical Tools* by ENA BROMLEY, LIN LI (BioStat Solutions)

MONDAY PLENARY SESSION

- *Statistical Leadership in The Changing Landscape of Drug Development* – ALOKA CHAKRAVARTY, Director (Acting), (FDA)
- *Curtain Raiser* – TRACK CHAIRS AND SESSIONS CHAIRS

The main tracks will include the **Clinical** which will cover topics on subgroup analysis, master protocols, and advanced topics in survival analysis; **Preclinical, Discovery** and **Biomarkers** which will include topics on Design, Analysis and Interpretation of Biomarker Studies; **Chemistry, Manufacturing and Controls** which will include topics on Biosimilars and Comparability, Stability, Bioassay, Reference Standards, and Sampling/SPC During PPQ, CPV; **Real World Evidence** which will include topics on Statistical Approaches to Big Data Research in EMR and Current Thinking and Practice on the Role of Real World Evidence in Decision Making; **Programming and Data Visualization** which will focus on New Tools and Cross-Functional Collaboration. Each track will have three sessions of at least two hours in length with 3–5 speakers. Speakers have time to discuss topics in more detail than at many conferences, and participants will have many opportunities to ask questions and partici¬pate in discussions. Additionally, speakers from the FDA, other governmental agencies, and academia will be invited to give presentations.

A student-focused session organized by Veavi Chang and Brian Millen of Eli Lilly and Barry Katz of IUPUI will be part of the workshop.

STEPHEN RUBERG (Analytix Thinking, LLC) is this year's banquet speaker. He will discuss *The Need for Analytical Science.*

Contributed posters are being accepted for the poster session, to be held on Tuesday, with Ying (Grace) Li of Eli Lilly serving as the chair. The poster session focuses on drug development. Posters will be considered on any biopharmaceutical statistical topic. Students may submit posters for the Charlie Sampson and Mir Ali Poster Award. Deadline for submission is April 12, 2019.

Find more information at *www.mbswonline.com.*

Questions not addressed on the website can be sent to the Publicity Chair Melvin Munsaka (*melvin.munsaka@abbvie.com*) or the Workshop Chair, Vipin Arora (*varora@lilly.com*).

MBSW was co-founded by Charles B. Sampson and Mir Masoom Ali and is co-sponsored by the ASA Biopharmaceutical Section. MBSW, which was founded as a conference to meet the needs of U.S. pharmaceutical industry statisticians in the Midwest has, welcomes attendees from across the United States and around the world. ■