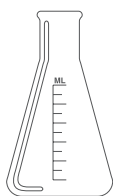


Biopharmaceutical Section



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Chair: *Matilde Sanchez-Kam*

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Note from the Editors

This spring's issue of *Biopharmaceutical Report* provides us the opportunity to showcase our section's contributions to the American Statistical Association as we celebrate the 175th anniversary of ASA, the second-oldest continuously operating professional association in the country.

Erik Pulkstenis (MedImmune), on behalf of the ASA Biopharmaceutical Section Executive Committee, provides updates on two exciting ongoing endeavors - the *ASA 175th Anniversary* and the *World of Statistics*. He shares information on opportunities for the section to participate in both activities. We encourage you to check out the article and website to learn more.

This issue's featured articles focus on meta-analysis. The first article, "Meta-analysis in the Context of Due Diligence" by **Charles Liss** (AstraZeneca), lays out a statistician's role in a due diligence setting to review data for integrity and quality, and to make an assessment of the probability of successful completion of a development program. It provides details on the process, methodology, and limitations of meta-analysis in that particular setting. Since due diligence is a fairly common practice in the pharmaceutical industry, and clearly may have large implications for the financial health of the companies involved, we hope the article will stimulate discussions in this important area of statistical practice.

The second article, "Statistics and Its Role in Global Public Health – A Snapshot View" by **Janelle Charles** (FDA) and **Stephine Keeton** (PPD), aims to increase awareness of the contributions of statisticians through innovative statistical methods to the improvement of global public health. Also, it touches on meta-analysis of multiple studies, primarily randomized clinical trials which are combined to estimate the overall risk in evaluating product safety.

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The "Note from the Chair", **Matilde Sanchez-Kam**, focuses on one of her main goals for the year, which is to retain and increase the section membership. To this end, she provides more details on some of the initiatives she is championing including a mentoring program and formation of scientific working groups. Please read it to see how you can participate in and support these initiatives.

Let us keep celebrating the 175th anniversary of the ASA! ■

Note from the Chair

In this current issue of the *Biopharmaceutical Report*, I will provide more details on some of the initiatives I would like to champion during my year as Section Chair. The Biopharmaceutical Section is one of the most active sections of the ASA. The greatest resource of our section is our members, especially the volunteers who avidly support our many activities. Thus, one of my main goals is to retain and increase our membership. The following initiatives will further this goal.

To increase the benefits of membership, the Biopharm Section is initiating a mentoring program as recommended by our Membership Committee, which is led by Jennifer Gauvin. This activity will increase networking between members and support members' career development. A separate Mentoring Program Committee headed by Amarjot Kaur will implement the mentoring program. The call for volunteers/participants will be in May and matching will occur by June 15. The program will kickoff at the JSM. Please refer to the separate announcement by the Mentoring Program Committee in this issue regarding details on the mentoring program.

Another exciting opportunity for members is the formation of scientific working groups (SWGs). SWGs will encourage collaboration among industry, regulatory and academic statisticians allowing for scientific discussions of statistical issues in drug development. As a pilot for this initiative, we have established a Safety Working Group led by Qi Jiang and Olga Marchenko. The team is focusing initially on CV risk assessment in Type 2 diabetes drugs. I have also formed a committee led by Bruce Binkowitz and Ram Suresh to develop guidelines on forming such scientific working groups.

We also plan to highlight the benefits of membership to the Biopharm Section by collaborating with local ASA chapters (such as the Princeton-Trenton Chapter) where there is a high concentration of potential Biopharm members. We are supporting the ASA Princeton-Trenton Chapter Symposium on "Career Development for Statisticians". A member of the Biopharm Section membership committee will speak at the Symposium to introduce the Biopharm Section and to discuss membership benefits.

As I've mentioned previously, the section thrives on the new ideas, enthusiasm, and manpower provided by volunteers. Volunteering, of course, is helpful for career growth since it allows one to demonstrate service to the statistical community. It is also an excellent opportunity to network and to work with colleagues outside of your own company or institution. Finally, it is both fun and fulfilling since the Biopharm Section members are nice people to work with. Those interested in volunteering and joining the section activities, please send an email to volunteer.asabiopharm@gmail.com.

For those of you going to JSM in Boston, I'd like to encourage you to attend the Biopharm Section mixer and meeting on Tuesday, August 5th from 5:30 to 7pm. I promise to keep the business part brief to allow as much interaction among section members as possible. See you there!

Matilde Sanchez-Kam
Chair, Biopharmaceutical Section 2014
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Meta-analysis in the Context of Due Diligence

Charles L. Liss, Director, Statistical Science, AstraZeneca

Introduction

Meta-analysis is the quantification and synthesis of data from multiple studies, using formal standards for rigor. It is a methodology for deriving estimates from multiple studies and calculating an associated confidence interval. Usually, an integrated analysis will have more statistical power to detect a treatment effect than the individual studies, and, therefore, meta-analysis is used for combining data from undersized studies or detecting modest treatment effects. As such, it lends itself naturally to the area of due diligence.

In this paper, “due diligence” refers to the process by which one company reviews the data collected by another entity (another pharmaceutical company, a non-profit research center, etc.) regarding a candidate drug in development in order to make a recommendation as to whether that candidate drug should be in-licensed or co-developed. A statistician is typically assigned to the due diligence team to review the data for integrity, quality and make an assessment of the probability of successful completion of a development program. This is a fairly common scenario in the pharmaceutical industry and clearly may have large implications for the financial health of the companies involved. This paper is not meant to be prescriptive, but to stimulate discussion in this important area of statistical practice.

Meta-analysis Process

An overview of the due diligence process from a statistical perspective would likely include many if not all of the following steps of a meta-analysis:

- Write protocol;
- Perform a systematic review of the available data;
- Extract data and calculate individual study statistics;
- Review studies for suitability for pooling;
- Calculate pooled summary statistics;
- Perform sensitivity analyses;
- Report and interpret results.

Many would argue that the amount of time allotted to conduct due diligence does not afford the ability to write a full protocol. However, the development of a protocol or an informal statistical analysis plan is highly recommended. The plan would require the due diligence team to consider the objective(s) of the data review and facilitate a common understanding of the patient population, the experimental treatment(s) being used, the comparator treatments, the primary and secondary outcomes in terms of efficacy, safety, healthcare resources, etc. and their linkage. Preparation of the plan should have as input at least an overview of the drug development plan conducted to date by the prospective partner. That is, there should be at least an overview of the therapeutic area, the claim sought, the prevalent therapies in the area, the patient population included, the outcomes measured and what studies are available in each phase of development (Phase I, IIa, IIb, III). Therefore, there will be a consensus within the internal group (we will refer to the company conducting the review as the “prospector”) of what the results of the meta-analysis are meant to address.

Sharing of the protocol or SAP with the company to be reviewed (hereafter referred to as the “partner”) should also facilitate the process of the review. First, the partner will know that the process is not simply a “fishing expedition” or an attempt to find a “gotcha” in the review process, but a serious scientific inquiry. Second, the partner will be aware of what data is being sought and prepare the information accordingly. And, finally, because the partner knows the data best, they should be able to provide input into the plan with regards to its feasibility as well as subtle

issues with respect to study design, analysis populations (e.g., intention-to-treat versus per protocol analyses), missing data, endpoint definitions, and derived variables, etc.

Unlike a typical meta-analysis, where a tremendous amount of work and care are required to obtain the relevant data via literature search and calculation of individual study statistics, this part of the process should largely be straightforward in the due diligence scenario. The partner should make all data available. However, some consideration of the studies to be included in a meta-analysis may still be necessary if different patient populations, different treatment doses or regimens had been examined in early development. The prospector may only be interested in those studies which are relevant to the development of the drug going forward. Or, there may only be interest in a subgroup of the patient population included in the earlier studies. Likewise, the partner's internal reports of the completed studies should already contain the individual study summary statistics.

One area of controversy may be the use of data from ongoing studies. Obviously, the prospector would like access to all available data, however, a partner may not wish to endanger the integrity of an ongoing trial (say, for example, a confirmatory double-blind Phase III trial) by unblinding the data for the prospector. Although the prospector's statistician may be unblinded employing a "firewall" between the prospector and the partner, it may be untenable to have personnel outside the partner's organization having more information than is available to the partner.

As noted above, the next step in the plan is to determine if it is possible to pool the available studies and, if so, how. It is important to understand the differences between the studies that will be combined with regard to study design, duration of treatment, duration of follow-up and patient population as well as the variability associated with the outcomes(s) of interest. Ideally, factors which are measured in each trial and pre-specified in the plan can be employed to explain a large amount of the variability between studies and incorporated into the meta-analytic model for analysis. A tabular summary of key factors that could have an impact on treatment effect could prove most useful. Such factors include: calendar time period over which the study was conducted, number of patients, treatment groups (including dosage and regimen), demographic characteristics (age, gender, ethnicity) and other key prognostic or predictive factors common in the disease area or endpoint of interest. This summary will also be useful in providing transparency as to the choice of studies when reporting on the analysis.

How to pool studies may be as simple as a cumulative meta-analysis approach by phase of development in which each phase is modeled to inform the next phase. Thus, one would put oneself in the position of retracing the development of the drug over time accumulating information along the way. Studies in Phase I regarding the pharmacokinetic properties of the drug could be modeled to make predictions on the effect of the product on the first studies in the patient population (Phase IIb). The primary interest is likely to be how the results in a small number of patients in Phase IIb may be modeled to predict outcomes in Phase III (i.e., the confirmatory trials used to obtain claims for approval and usage by regulatory agencies). It should be noted that other approaches such as hierarchical models may also be considered.

The meta-analytic methodology will largely be driven by the objectives of the plan. In the due diligence scenario, the primary interest will likely be in estimating the treatment difference between an experimental therapy and placebo and/or an experimental therapy and an active control. A Bayesian framework is commonly used in the context of estimation (rather than the common confirmatory frequentist approach). The cumulative meta-analysis approach lends itself naturally to the definition of a prior distribution for the outcome of interest, which then informed by the data at each development point, yields a posterior distribution on which probability statements may be made. Specifically, the posterior distribution will allow the statement of 95% credible intervals for the parameter of interest (i.e., a region in which we expect the estimate to lie with 95% probability) as well as make probability statements about where the estimate may lie in a range of values. These are likely to be the estimates of most interest in the interpretation of the data and making a recommendation about the probability of success of a development program going forward.

Of course, one of the primary considerations (and criticisms) of the Bayesian meta-analysis approach is the specification of the prior distributions. Prior distributions may be derived from data at each phase of development. However, in this context, the use of non-informative priors (in which one may only assume a normal distribution or a uniform distribution) may be helpful in comparing different assumptions as a sensitivity analysis.

Typically, the result of a due diligence effort from the statistician's perspective is a report of the results of the pooled analysis, interpretation and a recommendation. Key to any recommendation is the assumptions made in the analysis. One of the strengths of the Bayesian approach is a clear understanding of the underlying assumptions

included in the models. As noted earlier, a table with the studies included in the analysis, explicit presentation of the prior distributions employed in the meta-analysis model and the ability to make probability statements about the range over which the estimated value (say, the mean treatment difference with placebo) may vary all will add to the clarity and transparency of the recommendation. A simple yea/nay recommendation may be required, but the latter ability may also be important to quantifying a probability of success going forward in development.

Meta-analysis Methodology

This section provides more detail on the meta-analysis methodology discussed above. Some considerations in determining the meta-analysis approach for the problem in hand include whether only summary statistics (aggregate data or AD) or individual patient data (IPD) are available, how to deal with heterogeneity between studies, fixed versus random effects models and the use of meta-regression to take into account covariates either at the study or patient level which have an effect on the outcome of interest. Some limitations of the methodology are discussed at the end of this section.

In the context of due diligence, individual patient data for each study should be made available to the prospector's statistician. Meta-analysis of IPD is generally considered the "gold standard" because it allows modeling covariates such as age, concomitant conditions and therapies at the patient level rather than using summary statistics at the study level. It also allows for the analysis of subgroups of data which were not previously defined by the partner. However, time may not allow the prospector to run statistical models with thousands or tens of thousands of patients (which may be common in the study of vaccines or mortality, for example). Methods also exist to employ both AD and IPD in the same meta-analytic model.

Heterogeneity refers to the differences between the studies to be pooled in the meta-analytic model. This variability may be the result of different study designs (parallel group versus cross-over, multiple treatment arms not replicated across studies), different patient populations in terms of the definition of the condition under study as well as demographic and other clinical characteristics as well as the duration of treatment and follow-up. Sources of variability may also be artefactual as has been shown in meta-analyses using different metrics for binary outcomes such as relative risk or absolute differences in rates. One way to consider heterogeneity is analogous to variability between centers within a multi-center clinical trial. Another is to explicitly include a term (commonly termed τ^2 , tau) also to be estimated in a random effects model for a continuous normally-distributed endpoint y_{ij} as below:

Let $y_{ij} \sim \text{Normal}(\mu_{ij}, \sigma^2)$ where

$$\mu_{ij} = \delta_{0i} + \gamma_{1i}x_{1ij}$$

and

$$\gamma_{1i} \sim \text{Normal}(\delta_1, \tau^2).$$

In this construct, δ_{0i} represents the control effect in study i . The treatment difference in study i is represented by γ_{1i} and δ_1 is the pooled treatment difference of interest. Tests for whether τ^2 is significantly different from zero (analogous to whether there is a significant interaction between treatment and center) are available. However, these tests suffer the same lack of power when there are a small number of studies to be pooled. A common recommendation is to include a measure of the extent of heterogeneity such as Higgin's I^2 , which measures the consistency of findings as the proportion of total variation in the point estimate.

In building a meta-analytic model there is a choice of considering the study-by-treatment interaction to be fixed or random. With a small number of studies indicating similar estimates for the outcome of interest, a fixed model will likely be very similar to the random effects model. However, in an analysis with a large number of studies, a random effects model may provide a more generalizable result.

Application of Bayesian meta-analysis involves the calculation of posterior distributions by using Markov Chain Monte Carlo (MCMC) methods usually based upon Gibbs sampling. Fortunately, meta-analysis methods exist for both the AD and IPD approach as well as many different kinds of outcomes (binary, ordinal, continuous, survival data, etc.).

One of the benefits of the cumulative meta-analysis approach is that different factors' effects on the overall estimate of treatment effect may be explored in a very intuitive and straightforward way. Funnel and forest plots of the cumulative estimate may be ordered by publication date, sample size, control group event rate, the difference between treatment and control or other covariates to inform further analyses. However, one drawback of the cumulative meta-analysis approach is the possibility of inflated alpha levels due to multiple looks at the data. Although controversial among Bayesian and frequentist statisticians, controlling type I error may be a concern if calculation of probability values is one of the meta-analysis objectives. In the context of a due diligence analysis, sequential methods to control the overall type I error could be planned since the number of trials and the number of interim looks should be known a priori.

Limitations

This paper has discussed a common scenario in statistical practice related to the due diligence process. To maintain this focus, other issues regarding meta-analysis have not been discussed, but bear acknowledgement. Meta-analytic models for AD have not been addressed in any detail. Likewise, discussion of meta-analysis of safety endpoints has also been eschewed. There has been much discussion in the literature of employing meta-analysis of rare events which may only be observable over a combination of studies. Please see the selected bibliography for discussion and these and other related issues.

This paper has also not discussed the computational aspects of the analyses approaches discussed herein. Fortunately, there are programming languages (SAS[®], R, SPSS[®] and Stata[®]) as well as dedicated programs (WinBUGs[®], Comprehensive Meta-Analysis[®], Metawin[®] and Revman[®]) for most practical applications.

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Statistics and Its Role in Global Public Health – A Snapshot View

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Disclaimer: The views expressed in this article are those of the authors and do not necessarily represent the views of their respective affiliations.

Introduction

This article was written by members of the Biopharmaceutical Section of the American Statistical Association as one activity to commemorate the 175th anniversary of ASA. In keeping with the objectives, the purpose of this article is to increase awareness of the contributions of statisticians and statistical methods in the pharmaceutical industry and their impact on global public health.

Pharmaceutical product development spans various scientific fields including biology, chemistry, and statistics. Statisticians play important roles in study design, data collection, and analyses throughout a product's lifecycle: early development phases (I and II) when proof of concept is being established, pre-market (phase III) when studies provide data to confirm efficacy and safety of the product for regulatory approval, and post-market (phase IV) when the continued safety and effectiveness is investigated. Numerous statistical methods have been developed and applied in the pharmaceutical industry, for example, survival analyses in products to treat cancers, group sequential methods for trials designed with interim monitoring for safety or futility, and data imputation methods for trials with a high percentage of missing data, to name a few. Certainly, the complexity of the statistical method depends on various factors including the prevalence of the disease under investigation. Many standard statistical techniques are based on large sample assumptions and applicable for studying diseases that are very prevalent, that is, affecting a large percentage of the population. However, such methods may not have desirable properties in small sample settings that arise when studying less prevalent or rare diseases.

Rare diseases are an important public health issue and a challenge to medical care. In general, a rare disease, also referred to as an orphan disease, is any disease that affects a small percentage of the population. There is no universal definition of rare diseases except that they are rare. Some countries have developed definitions based on their particular ecosystem. In recent years, much progress has been made globally, such as specific legislation to encourage discovery and development of orphan drugs, patients' advocacy organizations to provide vast information on rare diseases and improve patients' access to healthcare, special research programs to strengthen basic and applied research on intractable and rare diseases, and so on. The approval of products for rare disease indications generally relies on small clinical trials, which raise distinct and difficult statistical issues. These issues include the need to maximize efficiency, the inappropriateness of asymptotic methods for small samples and, in some cases, the use of historical controls and the need for thorough understanding of the natural history of a disease [1].

The evaluation of safety of pharmaceutical products also presents unique statistical challenges, particularly when the outcome investigated is rare. Safety evaluations span a broad range of severities, such as investigating the risks of allergic reactions that have no lasting effects on patients, to life-threatening effects such as cardiovascular complications. When analyzed separately, a single study may not be large enough or may be too limited in scope to provide adequate conclusions about the risks with respect to the safety outcome being assessed. In recent years there has been increased use of meta-analysis in assessing pharmaceutical product safety, for example, suicidality for anti-depressants, and major cardiovascular disease for diabetes products. Meta-analysis is an analysis technique whereby data from multiple studies, primarily randomized clinical trials, are combined to estimate the overall risk (and the uncertainty around the risk) associated with the product under investigation compared to appropriately selected controls. An advantage of this technique is an increase in sample size, thereby yielding more precise estimates. However, there are several issues which need to be carefully considered. One critical issue is bias reduction. There are various sources of bias that may be introduced in meta-analysis, for example, in retrospective meta-analyses the study selection criteria may be influenced by the knowledge of the study results. Selecting studies

with mostly “positive” results can bias the risk estimates obtained from the analysis. Another issue is determining weights that represent the relative information from each study that is integrated. This issue is related to the choice of statistical model, fixed- versus random-effects, used for estimating the risk. Yet another challenge that arises in meta-analyses for safety is the re-use of studies originally designed for efficacy for investigating safety. Several publications have been written and research continues to evolve about the use of meta-analyses for safety.

The examples that follow illustrate a few applications of statistical methods and their impact in the pharmaceutical industry. These examples are by no means a representative sample of all the statistical contributions made globally, or in the regions illustrated, in this field. The first example discusses an application of meta-analysis in evaluating product safety. The second example illustrates a statistical method applied for efficacy and safety of a product studied to treat a rare disease.

United States: An Example of Meta-analysis Applied to Cardiovascular Safety

One area in the pharmaceutical industry where meta-analyses have been used is investigating the risk of serious cardiovascular outcomes associated with the use of products to treat diabetes, in particular for treatment of type 2 diabetes. Diabetes is a worldwide chronic disease characterized by high blood glucose levels that results from defects in the body’s ability to produce or use insulin. According to the American Diabetes Association, currently 25.8 million people in the United States have diabetes and in 2007 diabetes resulted in approximately 230,000 deaths. Statistical methods to ensure the safety of drugs that are used to treat patients with such debilitating diseases is of extreme importance for the global public health.

In 2007, a meta-analysis of 42 clinical studies suggested increased cardiovascular risk associated with the use of rosiglitazone (a thiazolidinedione product used to lower blood glucose in patients with type 2 diabetes) compared to placebo or other antidiabetic regimens [2]. This meta-analysis was based on a fixed-effect Peto method odds ratio for estimating the overall cardiovascular risk across all studies and the corresponding 95% confidence interval. The rosiglitazone label was revised to include findings of this meta-analysis in a boxed warning. In 2010, results of further meta-analyses that included additional clinical studies as well as other data sources which continued to suggest elevated cardiovascular risks with use of rosiglitazone contributed to the U.S. Food and Drug Administration (FDA) decision to significantly restrict the distribution of the product [3]. In November 2013, the FDA announced it was requiring the removal of certain restrictions on prescribing and using rosiglitazone to reflect new information regarding the cardiovascular risk of the medicine [4].

The preceding example demonstrates a scenario where meta-analyses of a marketed product to treat diabetes contributed to regulatory decisions in the United States. Currently, FDA Guidance recommends that any company seeking marketing approval for such products in the United States should ensure that phase II and phase III clinical trials are appropriately designed so that meta-analyses can be performed. The goal of these meta-analyses is to illustrate that the cardiovascular risks are below a specified threshold prior to submission of the product application [5]. The need for advances in the science of meta-analysis methods has also received Congressional recognition in the United States and is included among the research goals in the 2012 Prescription Drug User Fee Act (PDUFA) V legislation. Among the PDUFA V commitments, FDA will publish a guidance to “promote a better understanding and more consistency among Agency, industry, and other stakeholders regarding meta-analyses and their role in regulatory decision-making”. Certainly, statisticians will make significant contributions to the execution of PDUFA V commitments related to meta-analyses.

India: An Example of Non-Parametric Statistical Methods Applied to a Rare Disease

Public awareness of rare diseases is increasing around the world. People with rare diseases, advocacy groups, health-care professionals, and representatives of regulatory agencies are working to develop and describe approaches that can be taken in the design and analysis of small clinical trials to obtain reliable and valid results. One example of a rare disease is chronic myeloid leukemia (CML), which is the most common form of adult leukemia in India. The annual incidence ranges from 0.8–2.2/100,000 population in males and 0.6–1.6/100,000 population in females in India [6].

In a multinational phase III study, including patients in India, non-parametric statistical methods were used to evaluate the safety and efficacy of a product in development to treat this condition in patients with newly diagnosed chronic phase CML [7]. In non-parametric methods, few or no assumptions are made about the parameter of interest of the population distribution from which the sample is drawn. Non-parametric methods are often considered when the sample sizes are small, as is often the case with clinical trials studying rare diseases. For this clinical trial, a two-sided Clopper-Pearson 95% confidence interval was used to compare the rate of confirmed response between the treatment groups compared in the trial. Until a few years ago this disorder could not be treated. However, as a result of the new innovations in medicine and statistical methods, CML has been transformed to a chronic condition from a fatal disorder. Hence, every year, September 22 is marked as World Chronic Myeloid Leukemia Day.

As a consequence of the impact of rare diseases around the world and the magnified importance of adequate study planning in small clinical trials, legislations have been passed and many organizations have been formed to address the important concepts and statistical design methods for small clinical trials. In India, the Foundation for Research on Rare Diseases and Disorders is a registered non-profit, non-governmental organization which aims to provide disease-specific information for as many rare diseases as possible. The foundation also works to connect patient support groups across the country, develop a comprehensive online rare diseases and disorders registry, and develop a rare diseases and disorders biospecimen repository. Ultimately, their aim is to make these resources available for rare affected patients, health care professionals, epidemiologists, basic and clinical researchers and policy makers.

Summary

The examples presented in this article are only but a few cases to show the importance of statistics in enhancing global public health. Numerous statistical methods, in addition to those mentioned in this article, are continually being developed to meet emerging challenges in pharmaceutical product development.

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Update on Exciting Endeavors

On behalf of Pabak Mukhopadhyay (Novartis) and the ASA Biopharmaceutical Executive Committee, I would like to inform you of 2 exciting and ongoing endeavors - the ASA 175th Anniversary and the World of Statistics

ASA Celebrates Its 175th anniversary—“Celebrate Our Past – Energize Our Future”

www.amstat.org/asa175/celebrateourpast.cfm

ASA held its first annual meeting in November, 1839 declaring “*The objects of the society shall be to collect, preserve, and diffuse statistical information in the different department of human knowledge.*” As ASA grew, so did its publications, newsletters, meetings and membership spanning the globe. As ASA celebrates its past and looks to the future, the ASA 175th Anniversary Steering Committee proudly presents three key focus points for the future of ASA:

- **StatSharp** embraces statistical education outreach activities
- **StatGrowth** reflects the desire to see the ASA grow in number and in its reach to emerging areas of statistical practice
- **StatImpact** communicates the positive impact of statistics on our world more effectively and broadens that impact further.

Several initiatives are underway in honor of ASA's 175th anniversary celebration:

- Effective teaching of statistics at the K-12 level is important to the future of our profession and to improving the statistical literacy of the general public. ASA members Chris Franklin and Tim Jacobbe are leading a group that will prepare a document called *The Statistical Education of Teachers (SET)*. The *SET* corresponds to *The Mathematical Education of Teachers*, published by the Conference Board for the Mathematical Sciences, and will provide guidance to teacher education programs about proper preparation of individuals who will teach statistics.
- Collaboration with the Committee on Member Retention and Recruitment to find mission-appropriate ways to increase membership, and working with the Council of Chapters Governing Board to support chapters in their local outreach endeavors to quantitative professionals who have yet to engage with chapters or the ASA; the goal is to reach 20,000 members.
- The theme for JSM 2014 is "Statistics: Global Impact - Past, Present, and Future." There will be **StatImpact**-themed sessions.
- A special issue dedicated to the impact of statistics is under consideration by *The American Statistician*, with papers to be collected in 2014 for publication in 2015. The journal *Statistics in Biopharmaceutical Research* will publish invited papers related to the theme of the anniversary celebration throughout 2014.
- A major public relations campaign will be launched in 2014 to encourage young people to consider statistics as a career.

World of Statistics

<http://www.worldofstatistics.org>

The World of Statistics (WoS), the successor to the International Year of Statistics, is the go-to place for the field of statistics. WoS global membership consists of 2,350 organizations located in 129 countries sharing the following common goals:

- Increasing public awareness of the power and impact of statistics on all aspects of society
- Nurturing statistics as a profession, especially among young people
- Promoting creativity and development in the sciences of probability and statistics.

The WoS website promotes these goals by providing regular blogs on applications of statistics that are bettering our lives, information about the many interesting and rewarding careers in statistics, and up-to-date information on statistically related events and activities worldwide. WoS keeps statisticians informed and connected to the many individuals and organizations sharing commons goals.

As 2014 rolls out we will continue to provide updates as well as share opportunities for how the Biopharmaceutical Section can participate in the 175th Anniversary activities as well as the World of Statistics. In the meantime, we encourage you to check out the websites and learn more. ■

Erik Pulkstenis
VP Clinical Biostatistics & Data Management
MedImmune

Biopharmaceutical Section Initiating Mentoring Program

The Biopharmaceutical Section is pleased to introduce a mentoring program for the enhanced benefit of its members!

Networking can be challenging but is beneficial. Meeting others in our profession can help us quickly learn the ropes, improve our careers, and contribute to the statistical profession. Finding a mentor has its challenges, and, with that in mind the Biopharmaceutical Section is initiating the mentoring program based on the mentoring blueprint created by the Committee on Applied Statisticians.

The goal of this initiative is to help members further enrich and enhance their professional experience through achieving personal and professional goals. This may commonly occur through sharing of knowledge and experience between a professional practitioner and someone entering the profession of statistics. A constructive mentorship relationship can take many forms and may occur at any stage of one's career with benefits for both the mentor and mentee. We will provide hands-on resources for mentors and mentees to facilitate their interactions. Information related to the mentoring activities and additional resources for mentors and mentees will also be made available via the Biopharm website in the future (<http://community.amstat.org/BioP/aboutus/mentoringprogram>).

Currently we are looking for mentors and mentees for this program. Are you interested in becoming a mentor to a statistician and helping initiate this program? Are you a potential mentee, or can you nominate a statistician who may be looking for a mentorship program? If so, please e-mail contact info to (biopharmmentoring@gmail.com) with the subject: "Biopharm Section Mentoring Program". It would be helpful if you also send a resume to help us match mentors and mentees by June 15. Please contact Amarjot Kaur (Amarjot_kaur@merck.com) or Jennifer Gauvin (jennifer.ls.gauvin@gsk.com) if you need any additional information or clarification related to this program. ■

Calling All Volunteers!

Want to get involved in Biopharm Section activities, but not sure how? The Section is always looking for volunteers, so drop us an e-mail at volunteer.asabiopharm@gmail.com.

Let's Hear from You!

If you have any comments or contributions, please contact the Editors: Ugochi Emeribe, email ugochi.emeribe@astrazeneca.com; Paul Gallo, email paul.gallo@novartis.com; or Yongming Qu, email qu_yongming@lilly.com. We are looking for volunteers to write articles or suggest topics that will be of interest to our members. The topics can be technical, but non-technical articles related to biopharmaceuticals are welcome. Please send us an email.

The *Biopharmaceutical Report* is a publication of the Biopharmaceutical Section of the American Statistical Association.