Biopharmaceutical Section

American Statistical Association

Biopharmaceutical Report

Volume 21, No. 1 **Winter 2014**

Chair: ***Matilde Sanchez-Kam*** **Editors:** *Yongming Qu, Ugochi Emeribe, Paul Gallo*

Note from the Editors

Last year, 2013, was designated the International Year of Statistics – a remarkable way to celebrate our profession. This year, we are celebrating the 175th anniversary of the American Statistical Association (ASA) which is one of the USA oldest associations. So, 2014 provides unique opportunities to showcase the contributions of Biopharmaceutical section, and we hope you will participate.

As always, this issue of *Biopharm Report* is very informational. It has an insightful article on "Challenges and Opportunities of Growing China CRO" which is written by **Helen Yin** (Tigermed MacroStat USA), **Minzhi Liu** (Tigermed MacroStat Asia), and **Ward Chartier** (TechZecs). The article focuses on global ways of working with small service companies which is increasingly the trend for Pharmaceutical companies.

Also, in this issue, **Birol Emir** from Pfizer and Columbia University wrote a book review on *Applied Predictive Modeling* which is co-authored by Max Kuhn and Kjell Johnson. The book discusses the entire process of predictive modeling including hands-on exercises and R-packages that can be used for prediction modeling. Feel free to check out the book.

Please read the transition letter from the outgoing Chair, **Amit Bhattacharyya** and the in-coming Chair, **Matilde Sanchez-Kam** to get top level information on the goals set for 2014. Also, there are summary reports on FDA-industry Statistics workshop and Non Clinical Biostatistician conference, and summary minutes from Executive Committee meeting.

Finally, we would like to thank the outgoing editor, **Jose Alvir**, for his service to Biopharmaceutical section and warmly welcome **Paul Gallo**, the in-coming Associate Editor.

We the editors are privileged to help disseminate information, and we will continue to do so in 2014. Best wishes in the New Year! ■

Contents

The Transition Letter 2013 → 2014

Dear Biopharm section colleagues,

It has been a pleasure and privilege to lead the section's activities during the year. As in many processes, I just learned the important things on the job as the year went by; and now the time has come to hand over the reins to the ever-enthusiastic Matilde to carry on the torch and ignite a few more sparks in 2014.

At the ASA level, the biopharm section was proud to be part of the International Year of Statistics (IYS), for which ASA successfully led a great show that spread into other statistics organizations globally. As a contributor to this effort, the Biopharm has sponsored conferences with the international themes. To celebrate the IYS, Janelle Charles and Stephine Keeton wrote an article in this report highlighting examples about how statistics has influenced the public policies in different regions of the world. Throughout the year, I had been enthusiastically reading the IYS Monthly Newsletter that ASA has been publishing—I hope many of you are reading the newsletter. If you haven't got a chance yet, please check these out at *www.statistics2013.org/participant-newsletter-archive*. The good news is that this effort will continue in 2014 with the new name "The World of Statistics"—I am sure our section will do its best to contribute to the effort next year.

I mentioned during my letter in September, the ASA Biopharm section FDA-Industry Workshop was successfully organized. Thanks to the co-chairs Bruce and Lilly; and the many volunteers on the steering committee and ASA office. The summary report in this newsletter will give you a glimpse of the event in 2013, along with the plan for the next years' workshop for which the 2014 co-chairs are already in full swing soliciting session proposals.

Looking back in 2013, I hope you have seen a significant increase in communication this year through use of the Biopharm community egroup discussions. I would like to see more of these in the future. It is important that the section members are informed of important announcements about conferences, webinars & courses, and issues relevant to the biopharmaceutical statistics community. The year also brought many new podcasts which are growing in popularity—appreciate the effort of Richard Zink and Rima Izem for leading these efforts. You have certainly seen the increase in number of webinars sponsored by the section—thanks to the two co-chairs Shailaja and Satrajit. The section had a renewed focus to enhance student engagement in statistics by providing funding to a few biopharmaceutical research related organization in order to bring in more students through travel funding and other activities. I would think that this focus will continue in the future years.

I like to thank all the executive committee members and the committee volunteers who served the section during 2013—your valuable time, effort and leadership made all the difference in making the section run smoothly. The section thrives on volunteers and we need even more for new ideas, enthusiasm, and manpower. Those interested in joining the section activities, should please send an email to *volunteer.asabiopharm@gmail.com*.

It would be perfect to close this by acknowledging the great support of the co-editors—Jose, Yongming and Ugochi—for keeping up to their promise of publishing four *Biopharm Report* (quarterly) throughout 2013—great job!!

I am so happy to pass on the mantle to Matilde Sanchez with whom I have developed good friendship through working together for the section in the last couple of years—another indirect benefit for volunteering for the section I believe.

Over to you, Matilde! My best wishes to you and best of luck …….

I wish all the Biopharmaceutical section members a successful 2014.

Amit Bhattacharyya
(Outgoing) Chair, Biopharmaceutical Section (2013)
Email: *Amit.Bhattacharyya@gsk.com*

Looking Ahead to 2014

My year as Chair-elect was spent learning the ropes from a great mentor, Amit Bhattacharyya. I would like to thank Amit for being Chair during 2013 and for his many years of dedicated service to the Section. He did an excellent job and the Section once again had a great and exciting year.

I would like to welcome new incoming members of the Executive Committee for 2014, namely Dionne Price (FDA) as Chair-Elect, Gary Aras (Amgen) as Program Chair-Elect, Heather Thomas (Watson) as Treasurer and Alan Hartford (Agensys) as Council of Section Representative. In addition, I've appointed Edmund Luo (Bausch and Lomb) as Secretary, Amarjot Kaur (Merck) and Erik Pulkstenis (MedImmune) as Executive Committee Members, Paul Gallo (Novartis) as Associate Editor for the Biopharm Report and Cristiana Mayer (J&J) as the Industry Co-Chair (together with the FDA Co-Chair Shiowjen Lee) for the ASA Biopharm FDA Industry Workshop.

Some of the initiatives I plan to champion are to a) retain and increase our membership; b) foster collaboration across different professional statistical organizations (DIA, QSPI) with international statisticians, and across different ASA section/chapters with synergistic activities; c) strengthen the collaboration and link between the Biopharm Section, ASA journal, and Statistics in Biopharmaceutical Research; and d) form Scientific Working Groups. I will provide more details on the above initiatives in the next issue of *Biopharm Report*.

Also, I would like to develop ideas as to how we could best utilize our positive financial situation to best serve our members and the statistics profession. If you have any ideas or suggestions that you would like the Executive Committee to consider, please send them to me. I would encourage everyone to please check out our new website *http://community.amstat.org/BioP/home* for current news and contact information.

For 2014, we look forward to another outstanding year for the Biopharm Section and to the celebration of the ASA's 175th anniversary.

Matilde Sanchez-Kam
Chair, Biopharmaceutical Section 2014
Email: *msanchez@arenapharm.com*

Challenges and Opportunities of a Growing China CRO

Helen Yin, MS, Company Director, Tigermed MacroStat USA;
Minzhi Liu, PhD, Managing Director, Tigermed MacroStat Asia;
and Ward Chartier, PE, Principal, TechZecs

Introduction

MacroStat, founded in Shanghai in 2005, is a Contract Research Organization (CRO) providing statistical and data management services to both international and Chinese pharmaceutical companies. Tigermed, a Chinese full service CRO, acquired MacroStat in 2010. MacroStat has continued as a distinctive legal entity, and now has nearly 100 staff, over 60% of who are statisticians and biostatistical programmers.

This article will describe the present and emerging situation for CROs in China, the challenges experienced by MacroStat and other CROs, the actions MacroStat has undertaken and is pursuing to overcome these challenges, and what the future holds for CROs operating in China.

The China Environment

The latest 5-year plan in China, promulgated by the National People's Congress in March 2011, particularly mentions targets for healthcare reform. As the population in China ages, an increasing proportion of the healthcare resources will be deployed towards geriatric needs. Recent estimates state that in 2013, about 9% of China's population is $\geq$ 65 years. This will increase to about 20% by 2035, and will begin to level off in 2050 at about 24%.

The rapid industrialization of China correlates with the rise of new health issues that might be due to increased urbanization with more people living in close proximity, pollution, lifestyle changes, and widely reported instances of adulteration of food, personal care products, and other consumer products. The associated health issues increase the demand for healthcare resources. Finally, the rising middle class in China is demanding healthcare that is at par with the well developed healthcare infrastructure in other countries.

These pressures are driving increased demand in China for hygiene products, pharmaceuticals, and medical treatments presently available in other countries. The 2011 five-year plan strives to address this demand in several ways. These include expanding the availability of improved healthcare into rural China, and substantially growing the domestic pharmaceutical development and manufacturing industry. From 2011 through to 2015, the Central Government will provide about RMB 12 billion (approximately USD 2 billion) in new investment for biotechnology in China.

Although there have been attempts to develop drugs in China for sale world-wide, the pharmaceutical industry in China produce generic versions of drugs developed outside China. Given the earlier mentioned pressures from the populace, there is a remarkable movement to produce under license, various drugs recently developed in other countries. Consequently, the China Food and Drug Administration (CFDA) wants to ensure the safety of the Chinese people, and as such requiring careful qualification of these drugs before their widespread availability in the country.

These various initiatives and imperatives require more involvement of CROs. To an extent, the CFDA is requiring that the full range of pharmaceutical development, including the support services that CROs provide, be conducted within China. Various sources estimate that the growth of the CRO industry in China will approximately double from about USD 2 billion in 2013 to about USD 4 billion

by 2018. These potential revenues and growth rate that will likely continue past 2018 are attracting global CROs to establish in China and are encouraging local entrepreneurs to launch new CROs.

Challenges for CROs in China

With this significant business opportunity comes substantial challenges, some of which are relatively unique to China compared to the international landscape. The CFDA has published and continues to update its regulations. Some of the restrictions are quite different from what international pharmaceutical companies typically experience in other locations. Understanding the distinctions of healthcare regulation in China encourages global pharmaceutical companies to seek individuals cognizant of the CFDA requirements as guides to successfully navigate through the requirements in order to deliver tested and approved products.

Establishing and Retaining a CRO Team in China

Global and domestic CROs have undertaken a variety of strategies and tactics to be successful in providing services in China. Global CROs have either launched their own operations in China with émigré Chinese managers in charge, or they have acquired existing CROs founded by Chinese nationals. Local CROs have hired returnees with international experience, or have tapped into professionals previously working for prestigious Chinese pharmaceutical companies.

World-wide, customers universally demand competence, on-time delivery, quality, and service from their suppliers. Pharmaceutical companies contracting with CROs are no different. Research has shown that service providers, like CROs, that routinely and consistently deliver high total value to customers can charge a premium for their services.

Having competent and professional employees is essential. The situation in China for all CROs is that there is a shortage of candidates who are able to perform at the level required by global customers. As Chinese pharmaceutical companies inevitably rise to the level of meeting global requirements, there will be even greater demand for top-notch biostatisticians and Biostatistical Programmers among CRO operations in China.

While graduates from Chinese universities have a sound technical background, they are generally not at par with their counterparts from developed countries in terms of readiness to apply their technical skills in the business environment. CROs will most often need employees with at least a Masters degree, and those with a PhD degree are preferred.

CROs in China have three sources for recruiting employees. First, companies can attract/ hire from other companies, people who, through years of experience and possibly overseas education, have the required technical competence. Second, companies can search for Chinese émigrés in other countries and encourage them to return to China where they can make a larger professional impact. Third, China CROs can recruit from universities mostly in China, and over months and years, train these employees to achieve global standards.

These three initiatives all have limitations. In the first instance, if hiring employees from a China company, employees might have developed working habits contrary to what the CROs need in order to successfully support global customers. It is difficult to change these habits, but is often necessary.

The Chinese workforce has attributes that distinguishes it from global workforce. Overall, work ethics is strong and productivity is high. Managers in China can rely on their employees to come to work every day. The typical daily attendance rate is about 99%. Employees with analytical skills like statisticians and programmers socialize little during the workday and remain focused on their work. Output is high, as a result. It is fairly easy for managers to schedule overtime on short notice, on weekends, or even during holidays. However, managers must comply with the overtime limits set by the Labor Bureau, and pay the legally required overtime rates. In addition, Chinese employees have a great desire to demonstrate their capabilities and pursue opportunities to develop themselves. These attributes have helped many Chinese companies remain competitive, even though labor costs are rising quickly.

Whilst it is attractive to recruit new graduates, they require considerable training before they can competently work with minimal supervision on projects for global customers. Once trained and capable, these employees become attractive targets for recruiters helping to staff competing CROs. This leads to the typical 15% annual professional employee turnover rate in coastal China, and about 25% among CROs. So, there is great pressure on all employers to retain their employees. Every company has a different culture and will deploy a range of retention tactics unique to its circumstances. MacroStat has done the same, and enjoys an employee turnover rate well below the usual rate. Customers deeply appreciate the consistency that a stable workforce provides.

There are two other retention measures that are somewhat unique to China. First, the social aspect of work is an important motivator. The annual dinner, which takes place near the Chinese New Year holiday, is an unwritten requirement. Employees expect a big event, and a great deal of planning goes into staging the dinner. The annual dinner does much to cement relationships within teams, and among all employees at all levels. Second, employees in China extend loyalty more to their close co-workers and superiors than they do to the company. Well-trained and effective leaders and managers develop enduring bonds with their subordinates. It is common that if a manager or a particularly valued and influential employee leaves a company, others will soon follow. Identifying, developing, and training particularly respected and capable employees, and then promoting them, does much to retain the broader workforce.

Part of the culture at MacroStat is that we present ourselves as a quality-driven global company. In order to convince employees that they must consistently deliver results that meet or exceed global technical standards, it helps greatly to hire people who already have an international orientation. Employees who speak good technical English, and are flexible about accepting cultural differences are essential. Additionally, hiring managers must screen to ensure that candidates are fundamentally ethical. Thereafter, managers must monitor interactions between employees, clients, competitors, and vendors to ensure that these are all conducted ethically. Employees with these attributes can better provide distant clients with the assurance that they will receive the required support, completed to professional standards.

Quality

CROs rely on adhering to precise and detailed Standard Operating Procedures, Working Procedures, Good Clinical Practices, Good Laboratory Practices; and on staff experience and knowledge in order to assure quality. Depending on the clients and the countries targeted for product approval, there can be important differences within these documented requirements and procedures. CRO managers need to strictly follow the guidelines and require the same from their subordinates.

Universities generally do not train their students to become competent in these standards. Newly hired graduates will require a time of intense hands-on training to learn these requirements. By so doing, they will also acquire experience and knowledge about clinical trials. In addition to training their employees, managers must also rigorously inspect and audit employees' work to ensure full compliance with regulations.

CROs develop their own approaches at a detailed level to assure quality. Some combination of a company-wide quality system, training, retraining in order to fulfill new or changing requirements, quality control tools, processes designed to minimize mistakes, quality assurance and internal audit system, robust corrective action plans, and tight integration with customer audit systems, will go a long way to assure, every day, that CROs deliver high quality work to clients.

It takes a great deal of time to instill a durable quality assurance culture into a company and individual employees. Oftentimes, what a new employee thinks is good enough quality is insufficient ie, the global standards are much higher than assumptions. It requires great personal discipline among managers and leaders to constantly and consistently drive the message of exemplary quality among all employees. Once done, clients can easily perceive that there is a pervading spirit of quality in a CRO resulting in new business or repeat business.

The problem of "good enough" is more pervasive in the culture of China than in some other countries. If the attitude of "good enough" creeps into a CRO, it must be expunged because it is extremely

dangerous. “Good enough” work can lead to users of “good enough” pharmaceutical products becoming injured or dying.

In the 1920s, the philosopher and Ambassador Hu Shi wrote a short story, Mr. Chabuduo, or Mr. Almost Good Enough. In the story, Mr. Chabuduo conducts his life in a series of “good enough” misadventures and dies as a result. Hu wrote the story to make a sharp statement about the shortcomings he saw in Chinese society, warning that the trend needed to be changed. Likewise, leaders of CROs in China need to be aware that “good enough” attitude can infiltrate their companies, and as such, should take stringent measures to prevent it.

Service

Routinely delivering skillful customer focused service is in its infancy in China, but gains have been rapid. Chinese enterprises are shifting away from near monopolistic environments and are engaging in vibrant competition. Whilst single service providers in China are similar to other countries in how they deliver services, independent Chinese companies are making comprehensive and rapid improvements in their ability to provide customer service at levels similar to other countries. Expanding business and technical language skills in English and Japanese makes a difference. Some companies provide language training for selected employees. Aggressive companies have employees who are willing to participate in international teleconferences outside of normal office hours to increase interaction with clients.

Different countries have different levels of time sensitivity. For example, in a particular culture, the common phrase “as soon as possible” actually means “do it whenever you want.” It is essential for employees of global CROs to meet or exceed their clients’ time sensitivity and expectations for speedy responses. Chinese employees are typically very prompt, and meet time commitments.

The Internet has many resources to aid understanding what behaviors professionals in different countries expect. Often, a client located in one country will have employees representing distinct cultures, all with different expectations and modes of working. CROs in China can help to build their professional reputations by educating their employees about how to work effectively with people from different cultures.

On-time delivery is a critical component of customer satisfaction. Clients expect perfect products to be available when they need them. Perfect but late is unacceptable. Likewise, poor quality but delivered on time is also unacceptable. Top notch CROs build their businesses on a foundation of delivering total value, the balanced combination of quality, on-time delivery, and service, every day to their clients.

CRO managers and leaders can engage in a variety of tactics to deliver and implant the culture of customer service into employees’ thinking. These include training newly hired and existing employees, requiring managers to enforce policies, developing simple slogans that create a mental picture of the desired behavior, expecting company leaders to set the example for other employees to follow, getting feedback from clients on how to improve services, analyzing examples of failed or insufficient customer service at lessons learned workshops. Chinese employees are usually highly motivated to learn, and will readily apply their training to their daily work.

Superior customer service often results in wins for clients and repeat business for CROs.

Compliance

The guidance for China CROs is to fully comply with all laws, policies, and regulations, and to be constantly aware of changes to laws and regulations. It is always risky and potentially very expensive to disregard compliance.

The regulatory landscape of China is changing as the CFDA seeks to grow the biotechnological innovation capability of the country and to qualify international drugs and treatments for use in China. China CROs and their leaders must stay abreast of changes not only of laws, rules, and regulations in China, but also the changes in other countries.

For CROs that will import raw ingredients and equipment, China Customs regulations are complex, and are rigorously enforced. Penalties and other sanctions can be very disruptive. It is both wise and essential to vigorously check any activity that will involve China Customs in order to be 100% compliant.

At the operational level, clients often impose their own policies on CROs. Sometimes different clients have policies that can create potential conflicts within CROs that have several clients. It requires sound leadership in CROs to deftly navigate these conflicts so that CRO employees do not inadvertently commit errors. The cost of preventing problems is always less than the cost of fixing problems that occur. CROs that attain global and quality awareness through the measures described above will avoid many, if not all of these challenging situations.

Managing Growth

MacroStat and other CROs in China are experiencing rapid and sustained growth. Regardless of industry or geographic location, significant growth always stresses an organization and its employees, and exposes weaknesses of every kind in a company's processes.

Managing rapid growth requires experienced leaders who have a thorough understanding of how to integrate several different disciplines—operations, finance, quality, human resources, etc.—into a cohesive team all pulling at maximum strength in the same direction. MacroStat has put considerable effort into carefully managing this situation, thus ensuring that clients remain fully satisfied.

Future Trends

In order to meet the needs of global clients, CROs need a flexible combination of geographical sites and virtual out-reach using modern telecommuting tools. If they are not already, China CROs need to be multi-national, at least in the virtual sense. While there will still be a need for small, local CROs serving selected niches, the movement is towards medium to large CROs with offices strategically located around the globe in order to better serve clients. MacroStat and its parent Tigermed are presently in a global expansion and acquisition mode.

As pharmaceutical companies continue to reshape their businesses, CROs need to add to their suite of capabilities so they can offer more services to clients. These could include some primary R&D activities, assisting with clinical trials, software development for standardization, and other activities. MacroStat has begun to contribute more expertise in clinical trial designs.

Employees in China have a strong desire to work for big name companies and enjoy the status that confers. For that reason, major multinationals seem to have less trouble recruiting the talent they seek. As the role of CROs increases, there is opportunity for companies like MacroStat and Tigermed to attain increasing levels of name recognition. This helps to attract leading candidates for employment, and the attention of clients' procurement agents seeking CRO partners large enough and capable enough to serve clients' broad spectrum of needs.

Retaining employees in a hot labor market like China demands a creative approach to delivering a highly desirable professional working experience in addition to the usual satisfiers of salary and benefits. Employees want to work for a successful company and outstanding leaders. Executives who, in a way, see their employees as a special category of customers deserving of the right kinds of attention and care, will achieve superior retention rates, as MacroStat has.

It is inevitable that clients will seek greater levels of partnership with CROs. The pharmaceutical industry is moving past using CROs as quick-turn around sources of less expensive labor, and moving more towards using the scope of professional talents available in CROs and planned partnerships. In its short life, MacroStat has established solid partnerships with some clients that show every sign of enduring.

Conclusion

Highly successful CROs will be the ones that successfully differentiate themselves from the growing list of CROs and independent consultants who have experience working at leading pharmaceutical companies. The situation is made more challenging by the unique requirements of operating in China and fulfilling the requirements set by the CFDA. Having employees who are equally competent in managing in China and in other countries is a powerful combination that benefits clients.

Various marketing initiatives can help CROs achieve name recognition. The best way MacroStat has found to enhance its name is by consistently delivering high quality work, on time, using high quality people with superb customer service. Clients desire CROs that consistently deliver with these attributes, and employees want to work for companies with sterling reputations. Attaining this recognition is time consuming, but necessary. Furthermore, improving MacroStat's reputation in the market requires tenacity and persistence from well-trained leaders and managers.

MacroStat is dedicated to working with clients with large company capability amplified by responsive small company service. Resolutely delivering high quality work on-time to clients' standards, accompanied by cordial service, satisfies clients and encourages repeat business. This approach is difficult to achieve, but it is a major cornerstone of MacroStat's company culture. ■

Book Review: *Applied Predictive Modeling*

Kuhn and Johnson, New York, NY; Springer, 2013, xiii + 600 pp., $89.95 (H) ISBN 978-1-4614-6848-6

Birol Emir, Pfizer Inc and Columbia University

In modeling, there are few terminology addressing the similar analysis techniques; Data mining, pattern recognition and machine learning. Now add predictive modeling to this mix. As the authors suggested the "predictive modeling" wholly integrates the process from the question to be addressed, data context and collection, data exploration and pre-processing, applying the tool and techniques for uncovering patterns with the ultimate goal of future prediction of an outcome. This is the major contribution of this book to the area. Secondly, the book incorporated an excellent R package, CARET (Kuhn 2008, Kuhn 2010). This package provides an interface that handles a wide range of more than 140 models. As authors mentioned in the text, a hands on approach is necessary and the availability of the package and the authors' book web site (URL: *http://appliedpredictivemodeling.com*) help immensely to achieve that. Most chapters end up with a computing section. This is another great feature for a hands on approach. A third reason why this book represent a significant contribution to the area is authors' clear, concise description of techniques in an intuitive way that concentrates on the strengths and the weakness of the methods. Appendix A, for example, presents a summary of characteristics of the models discussed in the book that clearly conveys the strengths and the pitfalls of the models in general terms. The case studies also help illustrate in detail comparisons of the methods. Finally the exercises at the end of most chapters are great hands on experience for the readers.

In *Applied Predictive Modeling* Kuhn and Johnson divided the text into four parts. The first part, General Strategies lays foundation by introducing a short voyage into what one may achieve at the completion of the book. After that it delves into the data exploration and pre-processing concepts that are mostly ignored in machine learning and data mining books. I strongly think this is an appraisable effort of the authors to bring "statistical thinking" to data collection, exploration and pre-processing in predictive modeling. Part II and III introduces the regression and classification models, respectively. Both traditional and modern techniques are covered. A lot of materials including simulations, innovative graphics, examples from varying areas and expert opinions from a vast literature help explain the intuition of these techniques. The book ends with Part IV with other important considerations. These included feature selection and factors that may affect model performance.

I taught a graduate (book can also be adapted easily to upper level undergrads) level class of different backgrounds (computer science, financial mathematics and statistics) using this book. I conducted an informal survey about the book at the end of the semester; content, usefulness for preparing the student for his/her future, chapter exercises etc. The book scored very highly in almost every aspects. A few students suggested that some review of basic statistics should have been included in the book although a lot of references and pointers were provided. Additionally I conducted predictive modeling analyses on "big data" at a large pharmaceutical company using the techniques and the ideas suggested by the book.

I strongly believe that *Applied Predictive Modeling* is an excellent addition to the literature and lays a strong intuitive foundation of traditional and modern statistical methods using a hands-on approach to predictive modeling.

References

Kuhn M. (2008). "Building Predictive Models in R Using the caret Package. *Journal of Statistical Software*, 28(5).

Kuhn M. (2010). "The caret Package Homepage." *http://caret.r-forge.r-project.org*. ■

Summary Minutes from ASA Biopharmaceutical Section Executive Committee Meeting

Ed Luo for Dionne Price

Meeting was held on 11th October 2013 at the ASA Headquarters in Alexandria, VA.

Matilde Sanchez informed the Executive Committee (EC) of the following appointments:

Secretary (Ad hoc – 1 yr)	Ed Luo
Associate Editor, Biopharm Report	Paul Gallo
Ad hoc EC Members	Erik Pulkstenis, Amarjot Kaur
Webmaster Chair	Yue Shentu
Co-chairs, BIOP Section FDA-Industry Statistics Workshop	Cristiana Mayer, Shiowjen Lee

Heather Thomas reported that the balance as of 30 September 2013 was $351,530.88, representing a loss of $4,181.21 since beginning of 2013. This is in line with the section's continuing effort to reduce the reserve and spend on member's value-added services. The balance did not include the revenue/expenses from the 2013 BIOP Section FDA-Industry Statistics Workshop. Revenue was generated from the membership dues and webinar registrations. Expenses included awards, honorarium, and contributions to other organizations.

Venkat Sethuraman suggested utilizing social media to attract younger generations, and Yue Shentu, the incoming webmaster, will work with Venkat to identify talents for the social media team.

Matilde Sanchez proposed a strategic plan to foster collaboration by creating a unified statistical community across different professional statistical organizations and by highlighting the contributions of Biopharm members in the scientific process. **Brian Wiens** had a proposal for international outreach. **Amit Bhattacharyya** noticed significant overlap between sections, and proposed a liaison committee in 2014 to reach out and work with other sections and chapters. Amit, Matilde, and Brian will have further discussion at the 2014 ENAR meeting.

Steve Gulyas informed EC that as part of the IYS update, an article to summarize the impact of BIOP in global public health will appear in *Biopharm Report*. **Anna Nevius** is working on biostatpharma.com website, and there will more activities in 2014.

Venkat Sethuraman reported that there are 6-7 articles at *Amstat News* year to-date. Ed Luo and Yue Shentu are working on migrating the section's website to microsites, which will go live on November 1, 2013. The front page of the new website (*http://community.amstat.org/BioP/home*) has been created as the landing page.

Ugochi Emeribe confirmed that four issues of *Biopharm Report* will published each year. **Satrajit Roychoudhury** reported that there are 3 webinars on track for 2013. Venkat's proposal of no increase on webinar registration fee in 2014 is generally supported by the EC.

Olga Marchenko and **Qi Jiang** proposed to create a safety data analysis working group (SDA WG), and discussed the opportunity for potential membership, deliverables and forum. This will serve as a pilot for creating an upcoming committee to draft guidelines for forming working groups. The EC unanimously approved the creation of the Working Group.

Olga Marchenko presented membership retention and recruitment ideas, and complimented the new section website. EC brainstormed retention ideas, and discussed the possibility to charge additional fees for listening to audio recordings of webinars.

Nat Schenker, ASA President-Elect, gave a presentation on the ASA initiatives for 2014. **Ron Wasserstein**, executive director of ASA, discussed briefly the plan to celebrate ASA's 175th anniversary in 2014.

Ivan Chan reported that Biopharm section had 31 invited session proposals for JSM 2014. Four slots were allocated for invited sessions, and 2 additional proposals won the competition for invited sessions. Four short courses were proposed. A joint collaboration with International Chinese Statistics Association (ICSA) on Student Award competition was proposed to increase awareness of the Biopharm section student paper awards submission.

Bruce Binkowitz reported that there were 774 attendants in 2013 FDA-Industry Statistics Workshop. The workshop was a success, and 97% of the participants were very satisfactory as evidenced in the survey results. The mixer was well attended. There is a very good reception for a proposed special issue of Statistics in Biopharmaceutical Research (SBR), and there are enough articles for the issue to be published in March 2014.

Cristiana Mayer announced that the 2014 FDA-Industry Statistics Workshop will take place September 22-24, 2014 at Marriott Wardman Park in Washington D.C. The organizing committee meeting will be held on Tuesday, 11th February 2014 at Shady Grove University. The Steering Committee plans to keep the mixer for networking purpose.

Jose Pinheiro, the incoming editor of SBR, discussed his plan to increase the collaboration between Biopharm and SBR, and proposed to have SBR as the journal for special issue for FDA-Industry Statistics Workshop. ■

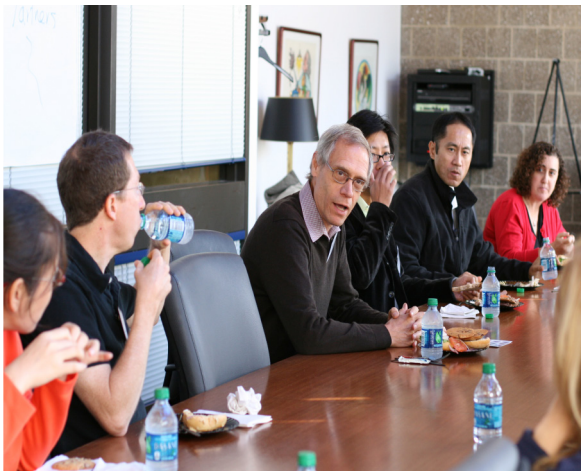
Summary Report on FDA-Industry Statistics Workshop

Bruce Binkowitz, Lilly Yue, Cristiana Mayer, and Shiowjen lee

The 2013 ASA Biopharmaceutical Section FDA-Industry Statistics Workshop was held on September 16-18. New additions to the workshop were well-received, including a mixer and keynote addresses in the opening plenary session. The workshop was attended by 775 registrants, about half of whom also attended a short course. Following the Workshop theme of the International Year of Statistics, attendees came from 15 different countries from beyond the United States. You could say the Workshop was an "international" success!

The 2014 ASA Biopharmaceutical Section FDA-Industry Statistics Workshop will be held September 22–24, 2014, at the Washington Marriott Wardman Park in Washington DC. As the online submission system has just been closed, we are excited to have received in total 100 proposals including those for 81 parallel sessions, 17 short courses, and 2 town hall sessions! The organizing committee meeting will be held in Rockville, Maryland on February 11, 2014, to vote on and finalize the workshop program. ■

Report on the 2013 Nonclinical Biostatistics (NCB2013) Conference



Mark Burgert (GSK) leads a lunchtime discussion involving students and industry mentors exploring career possibilities in nonclincal statistics.

Marie Davidian with conference co-chairs and Paul Lupinacci (left) and Paul McAllister (right).

The 2013 Non-Clinical Biostatistics Conference was held October 15-17, 2013 at the Connelly Center on the campus of Villanova University in Villanova, Pennsylvania. This was the third conference dedicated entirely to nonclinical and preclinical biopharmaceutical topics held in the U.S.

Planning for the conference started in June 2012 with the formation of a core organizing committee consisting of two co-chairs, Paul McAllister (GlaxoSmithKline) and Paul Lupinacci (Villanova), along with members Stan Altan (Janssen), James J Chen (FDA), Jim Colaianne (Johnson & Johnson), Jeff Hofer (Lilly), Fred Immermann(Pfizer), Tony Lonardo (Imclone), Jason Manro (Lilly), Alan Richter (Imclone), Keith Soper (Merck), Gary Sullivan (Lilly), Lin Tsai-Lien (FDA), Yi Tsong (FDA), and Kim Vukovinsky (Pfizer).

The conference theme was **Nonclinical Statistics – Improving Pharmaceutical Discovery, Development & Manufacturing**, and opened with participants having a choice between two half-day short courses:

- Strategies for Accelerating Formulation Development (Ron Snee, Snee Associates)
- Applied Bayesian Statistics for Nonclinical Areas: From Theory to Examples with Programming. (Bruno Boulanger, Arlenda).

Keynote speaker, Dr. Stan Young (NISS) began the conference by speaking on "A Tale of Two Matrix Factorizations." Marie Davidian, 2013 ASA President, gave the evening plenary address on the topic of "Business Analytics and Big Data: Are Statisticians Prepared?". Douglas Norton, chairman of the Mathematics & Statistics Department, delivered the formal welcoming address on behalf of Villanova University.

A total of 26 talks were delivered over the three-day period. The topics covered a broad spectrum of areas including Discovery, Biomarkers, Diagnostics, Safety, Pharmacology, and Manufacturing. In addition to the speakers mentioned above, there were 9 Invited presentations and 12 contributed talks. All of the presentations were high quality and directly relevant to pharmaceutical issues.

The conference organizing committee placed special emphasis on encouraging student attendance and participation at the conference. A conference announcement was sent to about 75 department chairs or graduate coordinators across the US. A prize of $200 was presented to each of the three student contributors (one contributed paper and two posters). A total of nine students attended the conference and the student registration fee of $100 was refunded to all nine students. The organizers intend to mount a more targeted

effort to attract student participation based on the lessons learned from organizing the NCB2013 conference. It is likely that starting earlier with student mailings and providing travel grants and awards as incentives will attract a broader participation in future conferences.

The 115 participants represented a broad international spectrum from industry, academia, and health care institutions. Forty-six percent of the registrants were Biopharmaceutical Section members. In addition to the participation of Biopharmaceutical Section, conference sponsors were Genentech and Johnson & Johnson. Administrative and facility support were provided by the Department of Mathematics and Statistics of Villanova University.

The conference provided opportunities for career development, professional networking, and discussions on current scientific and regulatory issues important to the nonclinical/preclinical pharmaceutical statistics community. Attention was drawn to the importance of nonclinical statistics to the drug development and commercialization process, and in that sense created greater visibility and recognition for the field of Statistics.

The organizing committee gratefully acknowledges the Biopharmaceutical Section of the American Statistical Association for its generous support of this third biennial nonclinical statistics conference without which the conference would not have been possible. ■

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: Yongming Qu, email *qu_yongming@lilly.com*; Ugochi Emeribe, email *ugochi.emeribe@astrazeneca.com*; or Paul Gallo, email *paul.gallo@novartis.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.