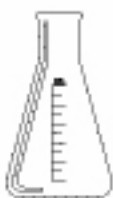


Biopharmaceutical Section



American Statistical Association

Biopharmaceutical Report

Volume 16, No. 3

Fall 2009

Chair: Anna Nevius

Editors: David Henry, Jose Alvir, Deborah Panebianco

Note from the Editors

Although randomized clinical trials are the most widely accepted method of estimating treatment effects in clinical trials, there is important information available in observational studies. In this issue's feature article, Michael Gaffney and Jack Mardekian discuss the challenges of removing selection biases in treatment effect estimation and describe propensity score methods used to address confounding.

Other section news include the section calendar, minutes of several section executive committee meetings, the section treasurer's report, and a request for volunteers to help organize the 2010 FDA/Industry Statistics Workshop.

We have several articles in the works for upcoming issues that we expect to interest you. The next article will discuss population pharmacokinetic and pharmacokinetic/pharmacodynamic modeling. As always, we are open to suggestions for additional articles. ■

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Propensity Scores in the Analysis of Observational Studies

Michael Gaffney, Ph.D., Jack Mardekian, Ph.D., Pfizer Inc

Introduction

The randomized trial, in which subjects are randomly assigned to one of the study treatment options, is the strongest study design in clinical research. The randomization forms the statistical basis to answer the essential question of whether the observed magnitude of the differences in response between treatment groups is due to chance. If the “p-value”, the probability that the observed difference is due to chance alone, is sufficiently small, then the randomization allows for the inference that one treatment is better than the other. In the absence of randomization, the p-value does not measure the probability that the observed difference is due to chance alone. The size of the difference and hence a small p-value could be due to any number of confounding factors. This potential bias due to confounding factors is present in all observational studies. An observational study is one in which treatment is not randomly assigned. A confounding factor is one that is associated with the outcome of interest and with the assignment of treatment. For example, if Treatment A and Treatment B are both drugs which reduce the risk of myocardial infarction, an unadjusted comparison of risk based on an observational dataset where Treatment A is prescribed proportionally more frequently to men will be biased. Thus, in the analysis of observational studies appropriate statistical methods must be employed to address the bias due to confounding factors.

Propensity Scores

One method developed to control bias in observational studies is propensity scores (1). A propensity score P is the probability of an individual being prescribed a specific treatment (say Treatment A) given a set of covariates. These covariates are all the measured factors which are associated with treatment and outcome and hence may bias the estimate of the treatment effect. The propensity score is estimated by a regression model where treatment is the dependent variable and the independent variables are variables associated with treatment selection, disease severity, patient health, patient characteristics and outcome. Coefficients obtained from the regression model are used to calculate a subject's propensity score given the subject-specific values of the covariates. Covariates which are determined after treatment selection should not be included in the propensity score model. Thus, covariates such as compliance and dose, which may be an effect of treatment, should not be included as they may create spurious treatment effects or may attenuate real effects. The analytical roles of pre and post-treatment covariates are different and post-treatment covariates can not logically be part of a propensity to prescribe a treatment (2-3).

The propensity score is used in the analysis of observational studies in three primary ways:

1. As a single covariate in a regression analysis. As will be illustrated in the example, the propensity score is a summary score of how known potential confounders are unequally distributed to the treatment groups.
2. As a stratification variable. Subjects in strata defined by propensity scores have approximately the same probability of treatment assignment and hence are comparable within strata.
3. As a matching variable. Subjects are matched (1 to 1 or 1 to n) on the probability of treatment assignment. The propensity score allows for a summary matching for all known confounders. The decision to prescribe different treatments to subject with the same propensity score can be viewed as a pseudo-random decision.

Two additional points should be stressed. Propensity scores give a method for dealing with known confounders in observational studies. Even after taking into account the known confounders there may be residual bias in the estimation of the treatment effect due to unknown confounders. Unknown confounding can be addressed by

either sensitivity analysis (4) or by the method of instrumental variables (5). Propensity Scores are also useful in the design of observational studies (6). These topics are not addressed in this paper.

Propensity Score Used as a Covariate

The propensity score P for Treatment A is estimated by a regression model such as:

$$(1) \quad T = \beta_0 + \beta_1 V_1 + \beta_2 V_2 + \dots + \beta_k V_k$$

where T is 1 for subjects prescribed Treatment A and 0 otherwise and V_i $i = 1 \dots k$ are the known confounders. The above regression model is linear, but logistic regression is often used in estimating the propensity score. Both models will be used in the example. The data used as illustration in this paper were extracted from a healthcare claims data base of a large national managed-care organization from January 2002 to December 2005 (7). In this data base 83448 patients received one of two statins; Treatment A ($N=65960$) or Treatment B (17488). Patients were observed up to 3.5 years and the primary endpoint was the first inpatient admission due to a cardiovascular event, CVE (840 events, 1.27% in Treatment A and 340 events 1.97% in Treatment B).

Table 1 summarizes the univariate association of 6 confounders with treatment assignment and outcome. As shown in the table, age ≥ 60 years, a diagnosis of hypertension or diabetes, a previous CVE, males and the use of the anti-clotting drug Plavix make it less likely to be prescribed Treatment A. In addition, all these variables are associated with an increased risk of an event. Thus, any direct comparison of the CV event rate between Treatment A and Treatment B is biased against Treatment B due to these confounding variables.

Table 2 gives the propensity score coefficients obtained from both a linear and logistic regression model. The negative coefficients indicate that the presence of any of these risk factors decreases the probability of being prescribed Treatment A. Thus on the linear fit the probability of being prescribed Treatment A ranges from 0.821 (a subject with the absence of all risk factors) to 0.553 (a subject with the presence of all risk factors). All the

Table 1. Univariate odds ratios (OR) of Confounders with CV events and Treatment A Assignment

Variable	Treatment A Assignment		CV Event	
	OR	(95% CI)	OR	(95% CI)
Age ≥ 60	0.89	(0.85, 0.92)	2.35	(2.09, 2.64)
Hypertension	0.84	(0.81, 0.86)	2.30	(2.04, 2.60)
Diabetes	0.80	(0.77, 0.84)	1.71	(1.50, 1.92)
Previous CVE	0.39	(0.37, 0.41)	7.81	(6.90, 8.84)
Males	0.91	(0.88, 0.94)	1.87	(1.65, 2.12)
Plavix	0.43	(0.41, 0.46)	7.48	(6.61, 8.47)

Table 2. Propensity Score coefficients obtained from linear and logistic regression

Variable	Linear Regression		Logistic Regression	
	Coefficient	p	Coefficient	p
Constant	0.8211		1.5180	
Age ≥ 60	-0.0050	0.1173	-0.0315	0.1030
Hypertension	-0.0135	0.0001	-0.0846	0.0001
Diabetes	-0.0328	0.0001	-0.1924	0.0001
Previous CVE	-0.1375	0.0001	-0.6740	0.0001
Male	-0.0062	0.0296	-0.0386	0.0280
Plavix	-0.0732	0.0001	-0.1369	0.0001

imbalances between treatment groups seen in age, hypertension, diabetes, previous CVE, sex and Plavix use are contained in the propensity scores. Therefore, to adjust for imbalances in these covariates in the analysis of event rates only the propensity score needs to be included in the model. To demonstrate this, the primary outcome of CV events was analyzed by a traditional multivariate regression model using all the covariates which went into estimating the propensity score and by a regression model using only the propensity score as a covariate. Table 3 summarizes the results of these analyses. It can be seen from this table that both the linear and logistic model give the same adjusted estimate of risk difference whether one uses all the covariates individually in the model or uses just the propensity score. This is always the case because the part of the treatment effect orthogonal to the propensity score is identical to the part of the treatment effect orthogonal to all the confounders. Thus, whether one does the analysis in one step (all confounders) or two steps (propensity score) the treatment effect is identical. With respect to the logistic regression model the numerical results may not be identical due to the non-linear model and the maximum likelihood estimation procedure, but will be substantively the same.

The method of using the propensity to treatment score as a single covariate to address confounding can be related to another method of adjusting for confounding, the risk of event score. The risk of event score is the probability of having the event of interest given a specific set of the confounding variables, for example, the Framingham Heart Study cardiac risk score. Similar to the propensity score, the risk of event score is estimated by a regression model such as:

$$(2) \quad R = \beta_0 + \beta_1 V_1 + \beta_2 V_2 + \dots + \beta_k V_k$$

Table 3. Summary of analysis of event rates

	Linear Model		Logistic Model		
	β SE	95% CI	β SE	OR	95% CI
No covariates	-6.94(1.01)	(-8.92, - 4.96)	0.442(0.065)	0.643	(0.566, 0.730)
Model 1 (all covariates)	-1.42(1.00)	(-3.38, +0.54)	-0.120(0.067)	0.887	(0.778, 1.011)
Model 2 (propensity)	-1.42(1.00)	(-3.38, +0.54)	-0.120(0.067)	0.887	(0.778, 1.012)

β is the coefficient of the treatment effect. In the linear model it estimates the difference in the event rates ($\times 10^{-3}$) and estimates log of the odds ratio in the logistic model.

Table 4. Risk of Event Score coefficients obtained from linear and logistic regression and treatment effect with risk score alone in the model.

Variable	Linear Model		Logistic Model		
	Coefficient	p	Coefficient	p	
Age	0.0090	0.0001	0.5871	0.0001	
Hypertension	0.0059	0.0001	0.4997	0.0001	
Diabetes	0.0060	0.0001	0.3629	0.0001	
CVE	0.0385	0.0001	1.1188	0.0001	
Male	0.0058	0.0001	0.4799	0.0001	
Plavix	0.0327	0.0001	0.9916	0.0001	

	β	SE	95% CI	β	SE	OR	95% CI
Model 3 (risk score)	-1.42(1.00)	(-3.38, +0.54)	-0.120(0.067)	0.887	(0.778, 1.011)		

where now R is 1 for subjects who experience an event and 0 otherwise and V_i $i = 1 \dots k$ are the known confounders. Table 4 gives the risk of event score coefficients obtained from both a linear and logistic regression model as well as the adjusted treatment effect when only the risk score is used as a covariate in the model. It can be seen from Tables 3 and 4 that the adjusted treatment effect is identical for all three models. Therefore, obtaining the propensity score to treatment and adjusting the treatment effect by this propensity to treatment score is the same as obtaining the risk score to the outcome event and adjusting the treatment effect by this risk of event score. This is so because the part of the treatment effect which is orthogonal to the least-squares prediction of the event rate by all confounders is the same as the part of the treatment effect which is orthogonal to the least-squares prediction of treatment assignment by all confounders.

Propensity Score Used as a Stratification Variable

Propensity scores permit the sub-classification on multiple confounders at once. Since the subjects within a specific stratum have similar propensity scores they are comparable with respect to the confounding variables. Thus, an analysis with propensity scores as a stratification variable is a method to control for confounding. Usually quartiles or quintiles of the propensity scores are used to define the strata. Table 5 gives the odds ratio (95% C.I.) for a CV event using quintiles as a classification variable in a logistic regression model. This odds ratio is somewhat stronger than the result shown in Table 3 when propensity score is used as a covariate. The within strata results can be used as a diagnostic tool to explore reasons for this difference in results. The mean propensity scores and CV event rates are almost identical between treatment groups for quintiles 2 through 5 (Table 5). The odds ratio is close to 1 when quintiles 2 through 5 are analyzed. Within the first quintile (subjects with the set of confounders least likely to be prescribed Treatment A and most likely to be prescribed treatment B), there is a higher CV event rate in Treatment B. Logistic regression analysis within the first quintile yields an odds ratio of 0.690 (0.586, 0.813). However, there is also residual confounding within the first quintile as shown in the different mean propensity scores in treatment groups. Adding the individual propensity score to the logistic regression analysis of quintile 1 yields an adjusted odds ratio of 0.849 (0.719, 1.004). Thus, the use of the propensity score to classify subjects indicates no treatment effect in the 4 highest quintiles and a 15% reduction in CV events in Treatment A in the first quintile. One could then look at the distribution of the 6 confounders within the quintiles in order to understand what these results imply with respect to the individual confounders. This was done and showed that all patients with a previous CV

Table 5. Mean propensity score, event rate by quintiles and logistic regression results

Q	%N	Treatment A		Treatment B		
		P	CVE	%N	P	CVE
1	17.6	0.720	0.035	27.3	0.695	0.050
2	20.8	0.797	0.013	20.9	0.796	0.014
3	18.3	0.807	0.011	16.7	0.807	0.012
4	22.4	0.815	0.005	17.6	0.815	0.005
5	20.8	0.820	0.003	17.5	0.820	0.002
Quintile	OR (95% C.I.)					
1-5	0.796 (0.700, 0.905)					
2-4	0.992 (0.802, 1.227)					
1	0.690 (0.586, 0.813)					
1 (propensity score)	0.849 (0.719, 1.004)					

event were in the first quintile. Thus, while the use of the propensity score as a covariate indicated an OR of 0.887, the use of the propensity score as a stratification variable showed effect modification indicating a benefit in subjects with a previous CV event.

Propensity Score Used as a Matching Variable

The propensity score gives a method to match subjects on multiple covariates using one scalar score. Subjects with identical propensity scores have the same probability of being prescribed Treatment A based on the known confounders and hence the actual prescription of treatment can be viewed as a random choice and emulates a randomized clinical trial.

In this example, due to the dichotomous nature of all confounders, there are only $2^4 = 64$ possible propensity scores. Therefore matching on identical propensity scores can be achieved. When one matches and carries out the stratified-matched analysis the OR is 0.923. This analysis has the strength that it compares subjects on Treatment A to subjects on Treatment B with the identical set of confounders. However, the treatment effect obtained from the stratified-matched model of 64 strata is the same treatment effect from a fully saturated model of all 6 confounders and all possible interactions. Thus, this example relates nicely the concept of matching to parameterization of a model. Just as a model including all possible interactions (e.g., 5-way and 6-way interactions) may be viewed as over-parameterized, so too can matching on all 6 confounders be viewed as over-matching. Thus, the matching may be too strict to obtain the best estimate of the treatment effect.

Discussion

The properties of the use of propensity scores as a covariate in the analysis of the outcome variables do not seem to be fully understood. Some analyses have used both the propensity score and a subset of the confounders used to determine the propensity score in the analytical model (8). The finding that the results of these models are in agreement is unremarkable. In the linear model, the inclusion of the propensity score and any subset of the confounders will yield the identical treatment effect due to orthogonality. When the models are not linear the estimates may slightly differ numerically due to the maximum likelihood estimation and the non-linear model but not substantively. Thus, the question of whether the results from a propensity score model or traditional regression with all the confounders are similar (9-10) is answered analytically by realizing the information space is the same in both models with respect to the adjusted treatment effect.

With respect to the use of the propensity score as a classification variable, this example shows the diagnostic strength of this method for assessing effect modification and the identification of treatment benefit in subsets based on the original confounders. The use of both stratification by propensity score and the propensity score as a covariate in the model to address residual confounding strengthened and clarified the findings in this example. This combination of techniques often enhances the analysis. (11-12).

Finally, the example in this paper demonstrates the direct link between the concepts of matching and parameterization, more specifically over-matching with over-parameterization. In this example precise matching could be made on all individual propensity scores (all 64 combinations of confounding factors). However, this may not lead to the best estimate of treatment effect because it is equivalent to estimating a treatment effect in a fully saturated model of all 6 confounding effects and all possible interactions. From both perspectives, over-parameterization and over matching, the data are not used in the most efficient way to estimate the parametric effects of interest.

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Biopharmaceutical Section Calendar

December 15, 2009

Webinar: Bayesian Clinical Trials

Scott Berry (Berry Consultants)

Noon – 2 pm (Eastern Time)

<http://www.amstat.org/sections/sbiop/webinarseries.html>

March 21–24, 2010

ENAR 2010 Spring Meeting

Hilton New Orleans Riverside

New Orleans, LA

<http://www.enar.org/meetings.cfm>

July 31–Aug 5, 2009

Joint Statistical Meetings

Vancouver, British Columbia, Canada

<http://www.amstat.org/meetings/jsm/2010/index.cfm>

Sept. 20–22, 2009**FDA Industry Workshop**

Grand Hyatt

Washington, DC

<http://www.amstat.org/meetings/fdaworkshop><http://fdaindustry09.blogspot.com> ■

Summary of Minutes of the Biopharmaceutical Executive Committee Meeting San Antonio, March 16, 2009 Rick Caplan (Secretary)

—Anna Nevius made the following appointments:

- Veronica Taylor and Tom Keefe to the Executive Committee.
- Dave Henry, Deb Panebianco and Jose Alvir as editors for the Biopharmaceutical Report.
- Tammy Massie and Carmen Mak to Chair the 2009 FDA/Industry Workshop
- Neal Thomas to chair the Fellows Committee
- Keith Soper, Greg Campbell, Stacy Lindborg as members of the Fellows Committee

—Katherine Monti appointed Ivan Chan to co-chair the 2010 FDA/Industry Workshop with Qian Graves.

—Steve Gulyas presented the Treasurer's final 2008 report and the 2009 report to date. The year 2008 started with \$314K and ended with \$350K. Duplicate charges from JSM were resolved. The reports were accepted by the EC.

—The Executive Committee discussed the proposal from Creative Street Media Group. The EC approved \$7000 for Creative Street Media to develop a web clip prototype.

—Membership survey (*Ram Suresh/Iksung Cho*): It will be web-based, and it will incorporate comments from the Executive Committee. They are in the process of obtaining ASA Board and Legal approvals. They are reviewing 2 university bids to conduct the survey.

—ENAR Mixer: The EC will defer the decision on whether or not to sponsor the 2010 ENAR Mixer until the JSM meeting.

—Plenary speakers: This initiative is on hold. There is already a process for choosing plenary speakers at JSM. The FDA/Industry Workshop is the only venue where we could select a plenary speaker, but it doesn't fit the program, at least for 2009.

—Jim Colaianne requested that the Biopharmaceutical Section support the Non-Clinical Biostatistics Conference will be held at Harvard, October 21–23. The theme will be "Statistical Methodologies: Key to Discovery and Development." The meeting is aimed primarily at the pharmaceutical industry. Europe currently has meetings every two years. The intention is for a meeting to be held in the US on the years that there are not meetings in Europe.

—The Executive Committee approved the motion (11 for, 0 against, 5 abstain), after a roll-call vote, to allocate \$7500 this calendar year as one-time support to this non-clinical Biostatistics conference, providing that the conference organizers follow other provisions of our guidelines, such as filing a report on expenses to the Executive Committee after the meeting. The following were considerations in approving this motion:

- This is a start-up of a unique meeting.
- The meeting will serve part of the Biopharmaceutical Section membership that is currently under-served and has been for a long time.
- For perspective, we currently accept that we are losing approximately \$2500 per webinar on an audience which is already being served by the section.

—2009 Web-based training (Mani Y. Lakshminarayanan/Venkat S. Sethuraman): There have been 3 webinars so far this year. Vendor fees were discussed. The recommendation was made to negotiate a price for the entire year, which will help plan for next year.

—2009 FDA-Industry Workshop (Carmen Mak, Tammy Massie): The site will be the Capitol Hilton in Washington DC. The change of venue is adding to the cost. The program will be finalized by the end of the month. There will be 27 sessions with 8 half-day courses.

—Corporate Sponsors Committee (Russ Helms): \$5000 has been contributed or promised so far in 2009. \$10K to \$12K is expected by the end of the year, which is less than contributed in 2008. ■

Summary of Minutes Ad Hoc Biopharmaceutical Section Executive Committee

Teleconference, June 10, 2009

Rick Caplan (Secretary)

The Interactive Outreach initiative, specifically the interactive web site, was discussed. There were two proposals. Both were approved with a roll call vote.

1) Creative Street Media Group will come to JSM in August 2009 and shoot at least 3 video clip interviews which can be used for the web site or for other purposes (eg, burned DVDs for instructional use by members); at a cost not to exceed \$25000. This was approved with a vote of 9 to 8.

2) Creative Street Media Group will further develop the existing prototype web site, apart from the section of the web site that will contain the video clips; at a cost not to exceed \$15000. They will obtain broader BIOP Section input. This was approved with a vote of 15 to 0. (The voting was curtailed after a clear majority was reached.) ■

Summary of Minutes of the Biopharmaceutical Executive Committee Meeting Washington DC, August 3, 2009

Rick Caplan (Secretary)

—Member survey (Ram Suresh/Ed Luo): The survey uses Survey Monkey. The survey is designed to be anonymous. The EC reviewed and approved money to support the survey.

—BIOP sponsorship of meetings (Kannan Natarajan): The EC agreed to a case-by-case sponsorship of meetings.

—Election update: 2010 slate of candidates (Kannan Natarajan): Most positions are open. Contact Kannan to nominate someone.

—2009 Program Chair Report (Matilde Sanchez/Dionne Price): For 2009 JSM, the BIOP Section sponsored 2 invited sessions, 19 contributed sessions, and 3 continuing education courses.

—2009 web-based training for members (Mani Lakshminarayanan/Venkat Sethuraman): There has been a successful monthly seminar series in 2009. We changed vendors, which saved money and has allowed more control over costs.

—Biopharmaceutical Report (David Henry/Jose Alvir/Deborah Panebianco): The editors hope to have a third issue published later this year.

—Council of Sections Report (Margaret Minkwitz): The ASA Board will streamline its interactions with committees. They are creating the ability to have member action alerts for issues that affects ASA. They agreed to a voluntary accreditation process, which will include a requirement for experience; and they are setting this up.

—Web Clip Statistical Outreach Proposal (Jeremy Jokinen/Steve Gulyas): Creative Street Media (Dan Gollnick, Susan Gee, Thomas Douglass) presented information and answered questions about the proposal. They organized interviews at ASA headquarters to be conducted during the JSM meeting.

—Student paper competition (Christie Clark): Sixteen papers were submitted. The winning paper was submitted by Violeta Hennessey, for her paper entitled “A Bayesian Approach to Dose-Response Assessment and Synergy and Its Application to In Vitro Dose-Response Studies”.

—Corporate Sponsors Committee (Russ Helms): The BIOP EC agreed to continue the corporate sponsorship program as is, but in the future will consider modifying or ending the program.

—Poster Competition (Steve Gulyas): The 3 winning posters were submitted by Kelly Zou, Arminda Siqueira and William Coar. The poster titles and names of co-authors are as follows:

“Beta-mapping and beta-regression for changes of ordinal-rating measures on Likert scales”
Kelly Zou, Martin Carlsson

“Clinical trials, drug discovery, making decisions in bioequivalence studies: A statistical contribution”
Arminda Siqueira, Daniela Braga, Paula Chellini

“Estimation of treatment retention: The peak-trough ratio”
William Coar, Darrin Despain, Brian Wiens ■

BIOP Treasurer’s Report

ENAR 2009 – San Antonio, TX

Submitted by Steve Gulyas

BEGINNING BALANCE	1/1/2008		\$314,089.53
<i>REVENUE</i>			
Member Dues		\$11,364.67	
Registration Fees		\$44,050.00	
Interest		\$11,090.76	
Net Share (FDA/Industry)		\$8,031.79	
Net Share (JSM CEs)		\$12,587.49	
Contributions		\$16,050.00	
SUBTOTAL			\$103,174.71
<i>EXPENSES</i>			
Phone		(\$41,294.41)	
Internet		(\$550.00)	
Honorarium		(\$2,000.00)	
Credit Card Fees		(\$541.64)	
AV Equipment Rental		(\$1,202.58)	
Contributions to Other Orgs		(\$4,000.00)	
Food		(\$11,000.96)	
Awards/Plaques		(\$3,400.00)	
Software Support		(\$3,288.00)	
SUBTOTAL			(\$67,277.59)
CURRENT BALANCE	12/31/2008		\$349,986.65

Request for Volunteers for 2010 FDA/Industry Workshop

Dear Biopharm Section Members,

The 2010 FDA/Industry Statistics Workshop will be held from September 20-22, 2010 at the Grant Hyatt, Washington DC.

To ensure an interesting and productive workshop we are looking for volunteers to join the organizing committee as well as topics to be presented in a variety of formats including: Plenary/Concurrent Sessions, Roundtable Luncheon Discussions and Short Courses.

Please consider submitting proposals, topics, speakers or session chairs for deliberation. Please use the following format for submitting your proposals.

1. Up to 3 Keyword(s) to describe the proposed session
2. Name(s) of proposed session Chair/Organizer
3. <5 sentence description of the proposed session
4. Type of session proposed (course, plenary/concurrent or roundtable discussion)
5. Name(s) of proposed Speakers

Proposals should be emailed to Meeting Co-Chairs: Ivan Chan and Qian Grave at **FDA_Industry_WKSP2010@yahoo.com** by **January 8, 2009**.

An organizing committee meeting will be held in late January 2010 to finalize the session proposals. Details on the organizing committee meeting will be provided at a later date.

Our goal, with your input and assistance, is to make the 2010 FDA/Industry Workshop a tremendous success!

If you have any constructive suggestions for improving the FDA/Industry Workshop experience, we welcome your feedback and suggestions.

Sincerely,

The 2010 FDA/Industry Statistics Workshop Co-chairs:

Ivan and Qian

Ivan S.F. Chan (Merck)

Qian Grave (FDA)

FDA_Industry_WKSP2010@yahoo.com ■

Let's Hear from You!

If you have any comments or contributions, please contact the Editors: David Henry, phone 609-818-4142, email david.henry@bms.com; Jose Alvir, email Jose.Alvir@pfizer.com; Deborah Panebianco, email deborah_panebianco@merck.com.

We are looking for volunteers to write articles that will be of interest to our members. Some authorless topics that have been suggested include animal studies and veterinary medicine, bioequivalence in biologics and personalized medicine. If you have been working in an area and would like to suggest a topic or volunteer to write, please send us an email. Non-technical articles related to our work are welcome. One example might be an article about outsourcing statistical programming to Asia. Perhaps someone could write an article about how to effectively work when the statistical programming is outsourced. How is it different from using a regular CRO? How will our function change?

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