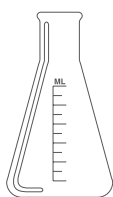


## Biopharmaceutical Section



American Statistical Association

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**Chair:** Katherine Monti

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## Note from the Editors

We thank Anirban Basu (MS Biostatistics, University of North Carolina - Chapel Hill, PhD Public Policy, University of Chicago) and David O. Meltzer (MD and PhD Economics, University of Chicago) for contributing the featured manuscript in this issue. They agreed to write the manuscript, knowing the very tight deadlines for the Fall issue. The entire writing, review and editing process took less than six weeks. Drs. Basu and Meltzer introduce us to the value of information analysis, a systematic tool to quantify the value of research. This tool could help statisticians become more proactive partners in determining priorities in research given the limited availability of resources.

Dr. Basu is an Assistant Professor of Medicine at the University of Chicago and a faculty research fellow at the National Bureau of Economic Research. He will join the Department of Health Services in the School of Public Health and the Department of Pharmacy at the University of Washington, Seattle as an Associate Professor in January of 2011. His research interests lie in revealing heterogeneity in clinical and economic outcomes in order to establish the value of individualized care. Dr. Basu is an Associate Editor for both *Health Economics* and the *Journal of Health Economics*. He has been very active in the leadership of the Health Policy Statistics Section of the American Statistical Association. This short introduction cannot do justice to his numerous awards and professional activities.

Dr. David Meltzer is an associate professor in the Department of Medicine and an associated faculty member in the Harris School and the Department of Economics. His research in health economics and public policy focuses on the theoretical foundations of medical cost-effectiveness analysis and the determinants of the cost and quality of care, especially in teaching hospitals. As with Dr. Basu, one cannot do justice to Dr. Meltzer's numerous awards and professional activities in a short paragraph. ■

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## Quantitative Methods for Valuing Comparative Effectiveness Information

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### Introduction

Resources available to fund research are limited. Whether in national funding organizations, such as the National Institute of Health, in pharmaceutical companies or in not-for profit private foundations, decision makers face the challenge of prioritizing research based on their budget. The newly popular area of *comparative effectiveness* research (CER) provides an important example of the need for research prioritization. CER conducts head-to-head comparisons to determine which drugs, devices, and procedures are most effective and carry the lowest risk. The 2009 American Recovery and Reinvestment Act dedicates \$1.1 billion to this end, which may enhance the resources available for public funding agencies including the National Institute of Health and the Agency for Healthcare Research and Quality, to support CER. Although many factors enter the decision making criteria that guide prioritization of CER within these organizations, probably the most important is the effect of such research on patient welfare. One way to assess such value is using value of information analysis (VOI).<sup>1,2</sup> VOI is a systematic tool to quantify the value of research. It estimates the probability that research will generate new information that will change decisions compared to decisions that would be made in the absence of such research (for example, with current information). It then multiplies this probability by a quantitative measure of value that would result due to the change of this decision. Research that cannot change decisions or cannot change decisions of any importance (value) is deemed to have a value of zero. Therefore, VOI analyses use an expected value criteria to quantify value of research. In this article, we explore the concepts of VOI and discuss various avenues via which such analyses could be useful tools for decision making on research prioritization.

### Theoretical Underpinnings of Value of Information Analysis

Concepts on the value of research can be closely tied with those of the value of a diagnostics test. Consider a diagnostic test that can reveal with certainty whether a patient has a disease or not. Let the prevalence of disease in

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the population be  $p$ . If it is revealed that the patient has the disease, he receives treatment and obtains incremental benefits worth  $B$  compared to no treatment. If the test indicates that the patient does not have the disease, he does not receive treatment and receives zero benefits (the baseline of comparison in this stylized example). The expected value of using the diagnostic test is given by  $p \cdot B$ . Without the diagnostic test, however, a physician has to make a guess about whether the patient has the disease. If a patient with the disease does not get treatment he misses out of the benefits. If a healthy patient receives treatment, he may experience the harms of treatment worth  $-H$ . The incremental expected value of treating everyone compared to treating no one will be  $p \cdot B + (1-p) \cdot (-H)$ . Without loss of generality, let  $p \cdot B + (1-p) \cdot (-H) > 0$  and therefore everyone gets treatment according to the expected value comparison. The value of the diagnostic test, therefore, will be the difference between the expected population value with the diagnostic test and the expected population value without it:

$$p \cdot B - [p \cdot B + (1-p) \cdot (-H)] = (1-p) \cdot (H) > 0 \quad (1)$$

Equation (1) shows that in this stylized example the value of a diagnostic test lies in identifying patients who do not have a disease and therefore should not have received the treatment. Conversely, the value of a diagnostic test can also arise from identifying patients with the disease so that they can get the treatment. The value of a diagnostic test represents the most basic application of value of information analysis.

In a parallel comparison, one can think of CER to be a form of diagnostic test that, with perfect information, can reveal which of the competing treatment/technology should be used in a certain population. Let there be two treatments T1 and T0. The parallels with diagnostic examples lie in comparing T1 being the better (worse) treatment to a patient having (not having) the disease. Let the outcomes of T0 be normalized to zero. If T1 is better than T0, let the incremental benefits of T1 over T0 be  $B$  (i.e.  $B > 0$ ). If, in contrast, T0 is better than T1, then let incremental loss of T1 over T0 be  $-H$ . Let  $p$  denote the anticipated (prior) probability that a perfect CER reveals T1 to be better, in which case the population obtains incremental benefits  $B$  due to receiving T1 instead of T0. Instead, if it reveals that T0 is better then the population receives T0 and obtains a normalized value of zero. Thus the expected population value of using CER information is  $p \cdot B$ . In contrast, without CER information the treatment decision is made for the population based on expected value comparison. The incremental expected value of giving everyone T1 versus T0, without knowing with certainty if T1 is better than T0, is  $p \cdot B + (1-p) \cdot (-H)$ . Without loss of generality, let  $p \cdot B + (1-p) \cdot (-H) > 0$  and therefore everyone gets T1 according to the expected value comparison. The value of CER, therefore, will be the difference between the expected population value with CER information and the expected population value without it:

$$p \cdot B - [p \cdot B + (1-p) \cdot (-H)] = (1-p) \cdot (H) > 0 \quad (2)$$

Identical to Equation (1), Equation (2) shows that the value of CER lies in identifying the better treatment and choosing that treatment to provide to the population.

Value of information analysis is rooted in statistical decision theory,<sup>3</sup> and in theories of the economics of information.<sup>4</sup> Value of information methods for valuing medical research have been discussed in the literature since the 1980s.<sup>5,6,1,2</sup> Next we discuss some of the methodological approaches to value of information analysis.

## Maximal Value of Research (MVR)

Maximal value of research presents an upper bound to the value of research in a disease area and closely mimics the cost-of-illness or burden of illness approaches.<sup>2</sup> Such a value estimate applies to all possible research in that disease area including developing of new therapies that may eliminate the disease in the population. The primary advantage of such a metric is that it is easy to calculate as data requirements are minimal and a small upper bound can eliminate other nuanced analyses that are described below. However, the disadvantage of MVR is that the upper bounds may be quite large and therefore not provide any guidance on research prioritization. It is important to note that economists have used such a technique to estimate the value of medical research. For example, Murphy and Topel quantified advances in life expectancies in the United States made over the last fifty years and concluded that they were about as important to increasing welfare over this period as increases in per capita income.<sup>7</sup> Cutler and colleagues used these methods to establish the value of medical spending in the United States over four decades and

found that, on average, the increases in medical spending since 1960 have provided reasonable value.<sup>8</sup> As Meltzer point out, estimates of average value may be important to ascertain the value of the overall medical research enterprise, but does not inform whether a specific research proposal should be funded at the margin.<sup>9</sup> To answer such questions one must engage in other methods that require additional information.

## Expected Value of Perfect Information (EVPI)

The expected value of perfect information (EVPI) quantifies the value of precise determination of outcomes that dictate choice among alternative treatments. Outcomes can be based solely on benefits or on net monetary benefits<sup>10</sup> where uncertainty in costs of treatments are also accounted for. In any case, one must use a threshold estimate to convert effectiveness unit into monetary units so that they can be compared to costs or benefits of other interventions. Such threshold value represent the maximum willingness to pay by the decision maker for an extra unit of benefit and has theoretical underpinning in microeconomic theory.<sup>11,12,13</sup> In practice, EVPI is usually established over a range of these threshold values.

The basic premise for EVPI can be readily illustrated. Let  $Y_1$  and  $Y_0$  denote the potential monetized outcomes for treatments T1 and T0, respectively. As suggested above,  $Y_k$  ( $k=0,1$ ) can be effectiveness outcomes such as life expectancies or quality-adjusted life years monetized using threshold willingness to pay or the net monetary benefits that is the monetized effectiveness minus costs. Let the marginal distributions of  $Y_k$  be given as  $F_k(Y_k)$ . Let  $\mu_k = E(Y_k)$  be the expected value of these potential outcomes. Decisions about the best treatment can be based on comparing the expected outcomes and choosing the one that produces the maximum expected value. However, since current evidence is most likely based on a finite sample from the marginal distributions of  $Y_k$ , the decision maker possesses information (an estimate) on only a sample analog of these expectations,  $\bar{Y}_k$ . Consequently, the decision maker also faces uncertainty around  $\bar{Y}_k$  represented by the joint distribution  $G(\bar{Y}_1, \bar{Y}_0)$ . Let an estimate for  $\bar{Y}_k$  based on current information be  $\hat{y}_k$ . Although the current decision may be based on comparing estimated mean per patient benefit:  $Max\{\hat{y}_1, \hat{y}_0\}$ , there is a chance that this decision is different from the fully informed decision, which is assumed to be  $Max\{\mu_1, \mu_0\}$ . The value of future research, using an infinite sample, that can produce perfect information on  $\mu_k$  and completely eliminate uncertainty can then be written as the difference between the expected per patient outcome realized based on decisions made with such perfect information minus the expected outcome realized based on current decision:

$$EVPI = \iint Max\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0) - Max\{E(\bar{Y}_1), E(\bar{Y}_0)\} \quad (3)$$

Equation (3) can also be written as the following (derivation shown in the Appendix):

$$EVPI = I(\hat{y}_1 > \hat{y}_0) \cdot Pr(\bar{Y}_1 \leq \bar{Y}_0) \cdot \iint \{Max\{\bar{y}_1, \bar{y}_0\} - \bar{y}_1\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \\ + I(\hat{y}_1 \leq \hat{y}_0) \cdot Pr(\bar{Y}_1 > \bar{Y}_0) \cdot \iint \{Max\{\bar{y}_1, \bar{y}_0\} - \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0), \quad (4)$$

where  $I()$  is an indicator function. The first row of equation (4) tells us that if the current decision is to use T1, then the value of future perfect research depends on the probability that T0 is the best treatment and the average incremental value obtained by changing the decision from T1 to T0. The second row establishes a similar expression if the current decision is to use T0. Since both parts of equation (4) are weakly positive,  $EVPI \geq 0$ .

A population version of  $EVPI^{14}$  can be computed based on the time horizon and the scale over which the per-patient EVPI accrues:

$$Pop. EVPI = \sum_{t=0}^{\infty} \beta^t \cdot N_t \cdot M_t \cdot (1 - h_t) \cdot EVPI, \text{ where} \quad (5)$$

$t$  = time periods (usually annual)

$\beta$  = discount rate

$N_t$  = population size facing the decision to choose between treatments in each period

$M_t$  = time period specific implementation rate; ranges from 0 to 1 and represent the fraction of the population whose treatment decisions are influenced by evidence.<sup>14,15,16</sup>

$h_t$  = time period hazard of comparator treatments becoming outdated; once any of the comparators becomes outdated there is no value of improved decision making on them.

Comparing population EVPI across multiple research proposals would generate a ranking of these proposals in terms of their expected value in the population. This in turn can serve as a valuable input in prioritizing allocation of research dollars given limited resources.

## Expected Value of Individualized Care (EVIC)

EVIC establishes the value of research that can help individualize treatment choices across patients.<sup>17</sup> Compared to EVPI, EVIC primarily comprises of value of research that identifies variability of treatment effects over individual level values of heterogeneous parameters such as preferences, demographics, genetics and other characteristics. EVIC therefore attempts to establish the value of both exploratory research that studies treatment effect heterogeneity and factors that help predict that heterogeneity and also confirmatory research that establishes treatments effects within a subgroup  $s$  defined by the relevant factors identified from exploratory analyses. Often these subgroups are defined by combinations of levels of these individual level characteristics. EVIC can be expressed as an extension of EVPI:

$$\begin{aligned} \text{EVIC} &= \sum_s \left[ \iint \text{Max} \{ \bar{y}_1^s, \bar{y}_0^s \} dG^s(\bar{Y}_1^s, \bar{Y}_0^s) - \text{Max} \{ E(\bar{Y}_1), E(\bar{Y}_0) \} \right] \\ &= \sum_s \left[ \left( \iint \text{Max} \{ \bar{y}_1^s, \bar{y}_0^s \} dG^s(\bar{Y}_1^s, \bar{Y}_0^s) - \text{Max} \{ E(\bar{Y}_1^s), E(\bar{Y}_0^s) \} \right) + \left( \text{Max} \{ E(\bar{Y}_1^s), E(\bar{Y}_0^s) \} - \text{Max} \{ E(\bar{Y}_1), E(\bar{Y}_0) \} \right) \right] \end{aligned} \quad (6)$$

where  $s$  indexes the subgroups. The part within the second set of parentheses indicates the value of identifying  $s$  over which treatment effects are heterogeneous. It also represents the value of collecting covariate information for making sub-group (or individual) specific treatment choices.<sup>17,18</sup> The part within the first set of parentheses represents the EVPI for each subgroup and indicates the value of confirmatory trials that precisely establishes the value of treatment effects within each subgroup.

In practice, however, the value of individualization must be established in comparison to the baseline levels of selective treatment allocation that is already prevalent in the population. Therefore,

$$\text{EVIC} = \sum_s \iint \text{Max} \{ \bar{y}_1^s, \bar{y}_0^s \} dG^s(\bar{Y}_1^s, \bar{Y}_0^s) - \sum_{s'} \text{Max} \{ E(\bar{Y}_1^{s'}), E(\bar{Y}_0^{s'}) \} \quad (7)$$

where  $s'$  is the subgroup classification that is already in use to allocate treatments. If  $s'$  is close to the ideal  $s$  in a population, value of individualization will be greatly reduced.

Finally, a population level EVIC can be computed based on the subgroup specific degree of implementation and hazard of technology extinction:

$$\text{Pop. EVIC} = \sum_{t=0}^{\infty} \beta^t \cdot (1 - h_t) \sum_s M_t^s \cdot N_t^s \cdot \left[ \iint \text{Max} \{ \bar{y}_1^s, \bar{y}_0^s \} dG^s(\bar{Y}_1^s, \bar{Y}_0^s) - \text{Max} \{ E(\bar{Y}_1), E(\bar{Y}_0) \} \right] \quad (8)$$

## Expected Value of Sample Information

EVPI establishes a necessary condition for doing research as it informs about the expected value of perfect information. If EVPI is low, then it is quite likely that any practical implementation of research would likely generate even lower value. Such research proposals can therefore be assigned lower weights in terms of value. However, a large EVPI is not sufficient to recommend funding of a research proposal. A practical research design would have limits to its size due to budget and therefore cannot fully eliminate uncertainty. Moreover, the cost of such research usually increases with size of the study. Expected Value of Sample Information (EVSI) is a related VOI method

that can be used to establish the value of future research that only partially eliminates current levels of uncertainty. In other words, it can be used to establish optimal sample sizes for future research that would maximize value accounting for cost of doing such research.<sup>19,20,21</sup>

EVSI naturally follows a Bayesian approach for the propagation of uncertainty over time as new evidence is generated. For example, if future research is conducted on a sample size of  $n$ , then the posterior mean of outcomes, denoted by  $(\bar{Y}_1^{(n)}, \bar{Y}_0^{(n)})$ , will be a weighted average of the current (prior) means and the sample means of outcomes from the future study of size  $n$ . Decision making on treatment choice will be based on estimates of these posterior means:  $Max\{\hat{y}_1^{(n)}, \hat{y}_0^{(n)}\}$ . However, due to sampling error of a future study of size  $n$ , posterior outcome means will follow a distribution  $G^{(n)}(\bar{Y}_1^{(n)}, \bar{Y}_0^{(n)})$ . EVSI is simply equivalent to the EVPI calculation as in (3) but using the expected posterior distribution of the mean outcomes instead of the prior distribution:

$$EVSI^{(n)} = \iint \left( Max\{\bar{y}_1^{(n)}, \bar{y}_0^{(n)}\} \right) dG^{(n)}(\bar{Y}_1^{(n)}, \bar{Y}_0^{(n)}) - Max\{E(\bar{Y}_1, \bar{Y}_0)\} \tag{9}$$

Cost( $n$ ) represents the costs of carrying out a study of size  $n$ . The part within the parentheses in (9) represents EVSI based on realization of outcomes for any one future trial of size  $n$ .

A population version of EVSI can be computed as follows:

$$Pop. EVSI = \left( \sum_{t=T(n)}^{\infty} \beta^t \cdot N_t \cdot M_t \cdot (1 - h_t) \cdot EVSI^{(n)} \right) - Cost(n),$$

Population EVSI differs from population versions of EVPI and EVIC in two ways. First, it accounts for the expected costs of conducting a study of size  $n$ . Second, accumulation of benefits in the population only occurs after the completion of the study. Duration of a study,  $T(n)$ , will likely depend on the size of the study.

In practice, EVSI calculations can be accomplished using Monte Carlo simulations where sample distribution of outcomes from a future study of a specific size  $n$  can be drawn from the current (prior) distribution of outcomes and then combined with that prior distribution in order to compute the posterior means. For example, let the current evidence on  $\bar{Y}_1$  be generated from a sample of size  $n_0$  and its current (prior) distribution be given as  $Normal(\hat{y}_1, \hat{s}_1)$ , where  $\hat{s}_1$  is the standard error of  $\bar{Y}_1$ . Data on  $Y_1$  from a future study can be simulated by the following algorithm. For each iteration  $j$  indicating one such study,

1. Draw a deviate for  $\bar{Y}_1 = \bar{y}_1^{(j)}$  from  $Normal(\hat{y}_1, \hat{s}_1)$ . This deviate represents the population mean from which a future study data will be drawn.

2. Draw a dataset of size  $n$  on  $Y_1$  from  $Normal(\bar{y}_1^{(j)}, \hat{s}_1 \cdot \sqrt{n_0})$ . The mean and standard error of the mean from this dataset is denoted by  $m^{(n,j)}$  and  $s^{(n,j)}$ .

3. The posterior distribution of  $\bar{Y}_1$  based on the dataset in (2) can then be written as  $Normal(\bar{y}_1^{(n,j)}, s_1^{(n,j)})$ , where  $\bar{y}_1^{(n,j)} = (w_1 + w_2)^{-1} \cdot (w_1 \cdot \bar{y}_1^{(j)} + w_2 \cdot m^{(n,j)})$  and  $s_1^{(n,j)} = (w_1 + w_2)^{-0.5}$ ,  $w_1 = \hat{s}_1^{-2}$  and  $w_2 = n \cdot (\hat{s}_1^{(n,j)})^{-2}$ .

4. Follow 1-3 to draw posterior means for  $Y_1$  and  $Y_0$ . Calculate  $EVSI^{(n,j)}$ , which represents EVSI based on realization of outcomes for any one future trial of size  $n$  (part within the parentheses in (9)).

5. Repeat steps 1 to 4 several ( $j = 1, 2, \dots, J$ ) times and average  $EVSI^{(n,j)}$  over all these iterations to obtain  $EVSI^{(n)}$  and Pop.  $EVSI^{(n)}$ .

Note that in this stylized example, a normal-normal conjugate prior and data-likelihood sets up for a easy closed form solution for the posterior. For non conjugate priors, one much include an additional step between 2 and 3 that may use Markov-chain Monte Carlo (MCMC) techniques to calculate the posterior.

Although EVSI methods have been primarily used to determine optimal sample size for future studies, it is quite apparent that such methods can be used to determine many other features of the study design such as length of follow-up, cross-over protocols and adaptive assignment protocol. Like EVPI and EVIC, a population version of EVSI can also be computed.

## Empirical Examples

*EVPI and EVSI:* The calculations of EVPI and EVSI are illustrated using an empirical example where the goal is to compute the expected value of resolving residual uncertainty about the right choice of antipsychotic agents for patients with schizophrenia. This is a complex problem involving both differences in many dimensions of effectiveness and differences in costs among the alternative treatments. This question has recently been the subject of the large NIH-funded randomized CATIE trial examining the comparative effectiveness of typical and atypical antipsychotic agents in schizophrenia.<sup>22</sup> The results of the CATIE trial have been controversial, with some persons viewing them as strong evidence that atypical antipsychotics do not offer treatment benefits, while others pointing out a variety of limitations of the study, including that the primary outcome was continuation on a medication, and that effects on quality of life were estimated with considerable imprecision. Meltzer, et al. (2009) have reexamined the results of the CATIE trial from a value of information perspective.<sup>23</sup> They first use data on the incidence, prevalence and mortality associated with schizophrenia in the United States and find that about 3.9 million prevalent cases and about 50,000 annual incident cases with schizophrenia in the United States would potentially benefit from better choices of antipsychotic agents. They then, assuming the commonly held estimate that a quality-adjusted life year is worth \$100,000, calculate what the value would be of finding evidence of varying levels of difference in efficacy between the agents studied. To do this, they use the mean and 95% confidence interval for the incremental effects reported in the CATIE study of atypical antipsychotics (ziprasidone used as the prototype) compared to first generation antipsychotics (perphenazine) on quality of life of 0.011 (-0.005, 0.02750) and monthly costs of \$861 (-1829,4742), to calculate the net expected dollar value of health benefits minus costs of determining the best option among the drugs studied in CATIE using a net benefit framework that determines which therapy offers the greatest benefits net of costs. Discounting future benefits and costs at 3%, for the annual incident cases indefinitely into the future, this is \$6.6 billion per year over their lifetime, or \$4.5 billion / 0.03 = \$220 billion. For the prevalent cases over their remaining lifetime, this is \$207 billion after discounting at 3%. Thus the expected value of comparative effectiveness data to determine the true comparative effectiveness of atypical antipsychotics is \$220 billion + \$207 billion = \$427 billion. Assuming that this information would only continue to be valuable for the next 20 years, comparative effectiveness studies that could definitively answer this question as to the preferred single therapy for schizophrenia would still be worth \$308 billion.

Having determined that the potential value of perfect information concerning the comparative costs and effectiveness of first and second generation antipsychotics is large, EVSI methods were used to identify the optimal sample size for future studies that try to more precisely address the same questions that CATIE sought to address.<sup>23</sup> They found that the expected value of information on net health benefits of treatments is maximized for a future trial of size between 20,000 and 22,500 per arm. Such research is expected to produce a value close to \$308 billion. Optimal sample sizes were not sensitive to the threshold value for a QALY.

*EVIC:* Prostate cancer treatment is controversial because there can be great variability in whether a cancer will progress and because the treatments (typically surgery, radiation, or watchful waiting) can have significant side effects, and because patient's preferences over these outcomes can vary. Basu and Meltzer incorporate these factors into a complex decision analytic model of the value of prostate cancer treatment in terms of both health care costs and gains in quality-adjusted life expectancy.<sup>17</sup> To develop a single unified metric, they convert these gains into dollars. Heterogeneity in this metric is driven by the distribution of individual quality of life weights on different prostate cancer-related health states and represents the s-dimension of EVIC calculations. Interestingly, when compared to watchful waiting, they find that the expected value of determining the best single treatment that would be applied across all men is only about \$29 per 65 year old prostate cancer patient, while the benefit of finding the best therapy for each man given his or her preferences and individual clinical attributes is about 100 times higher at \$2,958 per 65 year old patient. Viewed at a population level in the U.S., this is worth over \$70 million annually and \$2.3 billion in discounted value (at 3%) for this stream of benefits each year occurring into the indefinite future. That the benefits of individualized therapy are so large compared to the benefits of finding a single best therapy may seem surprising at first, but is less surprising when one understands that heterogeneity in patient preferences and other clinical attributes among men with localized prostate cancer is such that the three major treatments are each chosen by approximately the same number of men. Thus selecting a single treatment would inherently lead to some mismatching of treatments to patients. This is where the idea that comparative effectiveness research can help

*In principle, research is worth performing whenever its expected value net of costs is positive. In practice, research funds may be limited so that it may not be possible to fund all research projects with positive expected value.*

to identifying subgroups of patients most likely to gain from specific treatments shows its great potential for value. Historically, such subgroups have often been identified using clinical attributes or diagnostic tests, but it is likely that in the future these will also be complemented increasingly by genetic testing, producing even larger potential gains from comparative effectiveness research.

## Conclusions

Value of information analysis provides a theoretically grounded set of tools to develop quantitative estimates of the expected value of research that can be used to inform research priorities. Although VOI may have substantial data requirements, approaches to bound VOI estimates using more limited data increase their potential for practical application. Specific VOI approaches, such as the expected value of sample information (EVSI), are especially well suited to informing study design. The expected value of individualized care (EVIC) may be especially important in cases in which heterogeneity in treatment effects is a critical concern.

In principle, research is worth performing whenever its expected value net of costs is positive. In practice, research funds may be limited so that it may not be possible to fund all research projects with posi-

tive expected value. In such cases, VOI calculations can be used to select the set of research projects most likely to produce the greatest population benefits. To inform such comparative assessments of research value, it is important that VOI methods be comparable in terms of relevant factors such as discount rates, value of health assumptions, and appropriate identification of the affected population (e.g., for U.S., U.K., etc). Such comparable estimates of VOI could be used to rank projects much in the way league tables are sometimes used to rank the cost-effectiveness of medical interventions. VOI estimates may also be useful to investigators who are seeking funding as a way to quantify “significance” or “impact” in their research proposals.<sup>24</sup>

Although VOI theory has well established roots, the field continues to develop both methodologically and in terms of applications. As it does so, it will be important to broaden the pool of persons trained to advance and apply VOI methods. At the same time, policy makers will need to learn how to best incorporate VOI into the process of research prioritization. Given the complex and inherently uncertain nature of research, it is crucial that VOI not be applied in isolation of the other concerns that have always driven research prioritization, such as scientific innovation, methodological rigor, the past accomplishments of key personnel, and the resources available within the research environment. Some of these elements may explicitly or implicitly influence VOI calculations, but nevertheless will continue to deserve independent attention by informed individuals whose judgment must ultimately continue to be the cornerstone of research prioritization. If VOI delivers its promise, those judgments should be expected to be better informed and to be more likely to result in decisions that will enhance population health.

## Appendix:

Derivations of Eq (4) from (3):

$$\begin{aligned}
 \text{EVPI} &= \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0) - \text{Max}\{E(\bar{Y}_1), E(\bar{Y}_0)\} \\
 &= \\
 &I(\hat{y}_1 > \hat{y}_0) \cdot \left( \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0) - E(\bar{Y}_1) \right) \\
 &+ I(\hat{y}_1 \leq \hat{y}_0) \cdot \left( \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0) - E(\bar{Y}_0) \right) \\
 &= \\
 &I(\hat{y}_1 > \hat{y}_0) \cdot \left\{ \Pr(\bar{Y}_1 > \bar{Y}_0) \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0) + \Pr(\bar{Y}_1 \leq \bar{Y}_0) \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \right\} - E(\bar{Y}_1) \\
 &+ I(\hat{y}_1 \leq \hat{y}_0) \cdot \left\{ \Pr(\bar{Y}_1 > \bar{Y}_0) \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0) + \Pr(\bar{Y}_1 \leq \bar{Y}_0) \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \right\} - E(\bar{Y}_0) \\
 &= \\
 &I(\hat{y}_1 > \hat{y}_0) \cdot \left( \left\{ \Pr(\bar{Y}_1 > \bar{Y}_0) \cdot E(\bar{Y}_1 | \bar{Y}_1 > \bar{Y}_0) + \Pr(\bar{Y}_1 \leq \bar{Y}_0) \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \right\} \right. \\
 &\quad \left. - \left\{ \Pr(\bar{Y}_1 > \bar{Y}_0) E(\bar{Y}_1 | \bar{Y}_1 > \bar{Y}_0) + \Pr(\bar{Y}_1 \leq \bar{Y}_0) E(\bar{Y}_1 | \bar{Y}_1 \leq \bar{Y}_0) \right\} \right) \\
 &+ I(\hat{y}_1 \leq \hat{y}_0) \cdot \left( \left\{ \Pr(\bar{Y}_1 > \bar{Y}_0) \iint \text{Max}\{\bar{y}_1, \bar{y}_0\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0) + \Pr(\bar{Y}_1 \leq \bar{Y}_0) \cdot E(\bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \right\} \right. \\
 &\quad \left. - \left\{ \Pr(\bar{Y}_1 > \bar{Y}_0) E(\bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0) + \Pr(\bar{Y}_1 \leq \bar{Y}_0) E(\bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \right\} \right) \\
 &= I(\hat{y}_1 > \hat{y}_0) \cdot \Pr(\bar{Y}_1 \leq \bar{Y}_0) \cdot \iint \left\{ \text{Max}\{\bar{y}_1, \bar{y}_0\} - \bar{y}_1 \right\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0) \\
 &+ I(\hat{y}_1 \leq \hat{y}_0) \cdot \Pr(\bar{Y}_1 > \bar{Y}_0) \cdot \iint \left\{ \text{Max}\{\bar{y}_1, \bar{y}_0\} - \bar{y}_0 \right\} dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0),
 \end{aligned}$$

where the last equality follows from that fact  $E(\bar{Y}_1 | \bar{Y}_1 \leq \bar{Y}_0) = \iint y_1 dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 \leq \bar{Y}_0)$  and  $E(\bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0) = \iint y_0 dG(\bar{Y}_1, \bar{Y}_0 | \bar{Y}_1 > \bar{Y}_0)$ .

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## Letter From the Chair

### Katherine Monti (Rho, Inc.)

The Biopharmaceutical Association thrives only because of the volunteers who donate their time and energy. Elsewhere (*Amstat News*), I have thanked many who have been contributing over this last year. While each and every volunteer deserves to be recognized early and often, rather than relist the names, I would like to use my space here to identify ways that you can join the volunteer pool. Many who are interested just are not quite sure how to go about it, and I would like to bridge that gap.

How can you help the section? Let me count (some of) the ways:

- **Offer to help, either on a specific committee or on an as needed basis.**

—Incoming Chair Steve Wilson ([stephen.wilson@fda.hhs.gov](mailto:stephen.wilson@fda.hhs.gov)) is in charge of appointments made in 2010 and starting in 2011; incoming Chair-elect Steve Gulyas ([sgul@lundbeck.com](mailto:sgul@lundbeck.com)) assumes that role for appointments made during 2011. You can send an email to either or both of them.

—If you want to know what committees are available, check the Section's website ASA website: [www.amstat.org/sections/sbiop/](http://www.amstat.org/sections/sbiop/)

- **Share your intellectual contributions**

—Offer to submit an article to this publication, *The Biopharmaceutical Report*, by contacting the editors, Jose Alvir ([jose.alvir@pfizer.com](mailto:jose.alvir@pfizer.com)), Debbie Panebianco ([deborah\\_panebianco@merck.com](mailto:deborah_panebianco@merck.com)), and Amit Bhattacharyya ([amit.bhattacharyya@gsk.com](mailto:amit.bhattacharyya@gsk.com)).

—Submit an application for a short course to be presented at JSM and sponsored by the Biopharm Section. Submit proposal ideas to Carmen Mak ([carmen.mak@spcorp.com](mailto:carmen.mak@spcorp.com)), 2011 Program Chair. It is too late for JSM 2011, but you can start working on a course to submit in September 2011 for JSM 2012; see [www.amstat.org/education/cecoursesatjism.cfm](http://www.amstat.org/education/cecoursesatjism.cfm).

—Offer to present a somewhat shorter course to be presented as Section webinar. Contact Mani Lakshminarayanan ([mani\\_lakshminarayanan@merck.com](mailto:mani_lakshminarayanan@merck.com)) or Venkat Sethuraman ([venkat.sethuraman@novartis.com](mailto:venkat.sethuraman@novartis.com)) to discuss joining the prestigious list of contributors to date.

—Submit to the Poster competition. There is real money involved here, and so far, little competition. (You are all statisticians so you know that “little competition” directly implies “a high probability of winning an award.”) Contact Yongming Qu ([qu\\_yongming@lilly.com](mailto:qu_yongming@lilly.com)) to submit a poster for consideration.

—Organize a session for JSM (see Carmen Mak above).

—Participate in or attend the FDA/Industry Workshop. Brenda Crowe ([crowe\\_brenda@lilly.com](mailto:crowe_brenda@lilly.com)) and Joan Buenconsejo ([joan.buenconsejo@fda.hhs.gov](mailto:joan.buenconsejo@fda.hhs.gov)) are the 2011 co-chairs.

- **Nominate a candidate to be a fellow of the ASA**

—Submit a name to the Fellow Committee; contact Neal Thomas ([neal.thomas@pfizer.com](mailto:neal.thomas@pfizer.com)), Greg Cambell ([greg.cambell@fda.hhs.gov](mailto:greg.cambell@fda.hhs.gov)), Stacy Lindborg ([lindborg\\_stacy@lilly.com](mailto:lindborg_stacy@lilly.com)), or Demissie Alemayehu ([demissie.alemayehu@pfizer.com](mailto:demissie.alemayehu@pfizer.com)). The section usually does not actually prepare nomination packets, but the Committee will help in various ways.

- **Encourage statistics students to participate**

- Encourage them learn about and join the Section.

- Encourage them to submit to the Student Paper Award competition.

- Have them contact John Johnson ([jjohnson@cato.com](mailto:jjohnson@cato.com)) if they would they like to help out at JSM. We always need help with the Contributed Awards ballots at JSM.

- **Help nurture future statisticians**

- Got kids? No matter. Either way, participate in Career Nights in schools. ASA can provide information; Rick Peterson is the Section Liaison ([rick@amstat.org](mailto:rick@amstat.org)).

- Got a chapter? Some chapters have Career Nights (or Days). Go help out.

- Got internet? Look at our website at [www.biostatpharma.com](http://www.biostatpharma.com) (but it may not work on Firefox). The site is off to a great start, but it needs fleshing out. Submit ideas to Steve Gulyas ([sgul@lundbeck.com](mailto:sgul@lundbeck.com)).

By now you have gotten the idea: there are oodles of way to help out the Biopharmaceutical Section, so it is easy to find something that matches your talents and time. Don't be shy!

Finally, I thank all of you who have worked for the section or are working for it now with a special thanks to Anna Nevius, the 2009 Chair, who helped me this year in so many ways. Your efforts are genuinely appreciated more than a few words can convey. But mostly, thank you for the opportunity to serve as Section Chair this year.

Happy Holidays and best wishes for 2011.

Katherine Monti, 2010 Chair  
[katherine\\_monti@rhoworld.com](mailto:katherine_monti@rhoworld.com). ■

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## Report of October 2009 Survey of ASA Biopharmaceutical Section Members

Edmund Luo<sup>1</sup>, Ram Suresh<sup>2</sup>, Thomas Lin<sup>3</sup>, Iksung Cho<sup>4</sup>

<sup>1</sup>Forest Laboratories, Inc. <sup>2</sup>Merck & Co., Inc. <sup>3</sup>Allergan, Inc., <sup>4</sup>MedImmune, LLC.

### Abstract

In October 2009, a survey was conducted by the Biopharmaceutical section to section members. The 36-question survey was designed to collect information on demography, statistical society involvement, professional experiences, compensation and education, professional meetings and continuing education activities, and career development, as well as to solicit feedback and suggestions from the members on the services provided by the Biopharmaceutical section. The survey was sent to 2422 members with email address on file. Of the 2371 members with correct email address, 636 (26.8%) responded, and 592 completed all 36 questions.

The results showed that most members are in the United States (92.0%); male (67.9%); White (70.0%) or Asian (26.1%); 35-64 years old (77.6%). In terms of working experiences, 67.9%, 52.5%, 28.0%, and 16.7% have worked or are working for pharmaceutical or biotech companies, academia, contract research organizations (CROs), and government, respectively. On average, our members have 8.7 years of experiences in pharmaceutical or biotech companies, 4.3 years in academia, 1.8 years in CROs, and 1.8 years in government.

## Introduction

To better serve its members, the Biopharmaceutical Section needs to know who they are, what they do, and what kinds of services and supports they need from the section. The Membership Committee and the member service team of the New Initiatives Committee in 2008 both identified the need to conduct a new survey to update the information collected in the 1996 survey and to obtain more insights into the section's profile, and since then have been working together on the member survey. The survey was designed and finalized by the Survey Committee (Edmund Luo, Ram Suresh, Thomas Lin, and Iksung Cho) in 1Q2009 after incorporating the comments from Biopharmaceutical Executive Committee and ASA Survey Review Committee. The survey was originally planned to be open from October 12, 2009 to October 31, 2009. On October 25, 2009, response rate was about 17%, and a reminder was sent by the hosting website via email to those who hadn't responded, with the deadline extended to November 15, 2009. To boost the response rate, all mandatory questions were changed to optional questions during the survey according to the suggestions received from our members.

## Method

After realizing that outsourcing the implementation, conduct and analysis of the survey was beyond the allotted budget, the team proposed a do-it-yourself approach, which was subsequently endorsed by the Biopharmaceutical Executive Committee in June 2009. In September 2009, the 36-question survey was implemented at *surveymonkey.com* by Edmund Luo, and members' email addresses were provided by the section chair. The survey invitation and the messages from section chair and chair elect were sent to all members via email from an ASA email account. Each member received a unique hyper link to the online survey hosted by *surveymonkey.com*. *Surveymonkey.com* managed the survey and sent pre-set reminder to those who didn't respond. At the survey close, *surveymoneky.com* provided summary statistics for each question, and the survey results were downloaded for future analysis. To keep the survey anonymous, no name, affiliation, postal address, or email address was collected.

## Results

On October 12, 2009, the survey invitation was sent to the 2422 email addresses, of which 51 were outdated. When the survey was closed on November 15, 2009, 636 members (26.8%) responded to the survey, and 592 completed all 36 questions.

*To better serve its members, the Biopharmaceutical Section needs to know who they are, what they do, and what kinds of services and supports they need from the section.*

**Demographics**

The Biopharmaceutical Section membership is primarily located in the US (92.0%) with PA, NJ, CA, NC, MA, MD, CT as the most popular states; 3.0% of the members live in Europe, and 2.0% live in Canada. Most members (67.9%) are male. The vast majority (77.6%) of members are between 35 and 64 years old (Figure 1). As shown in Figure 2, most members are White (70.0%) or Asian (26.1%). About 1.3% of members are Black and 3.6% are Hispanic.

**Statistical Society**

Our members have been a professional statistician for 17.4 years on the average with 25% of them being 7 years or less and 25% being 26 years or more. They have been ASA members for an average of 16.5 years and Biopharmaceutical Section members for an average of 9.7 years. About 25.1% of the members belong only to the Biopharmaceutical Section, and 29.7% and 29.5% of the members belong to one additional and two additional sections, respectively.

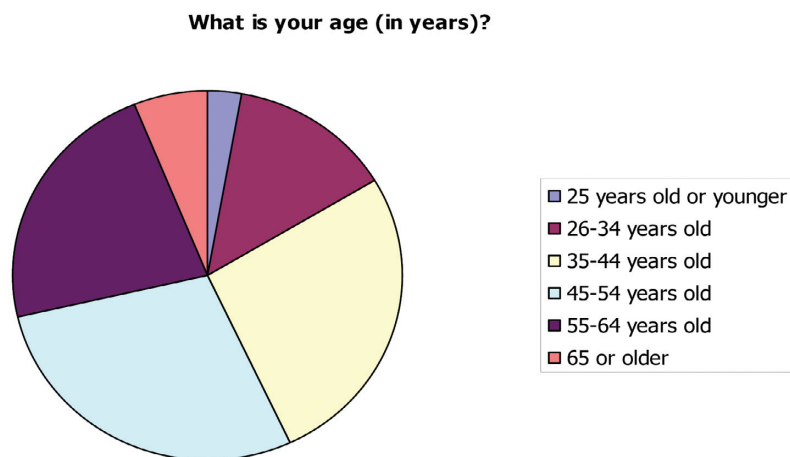


Figure 1: Age

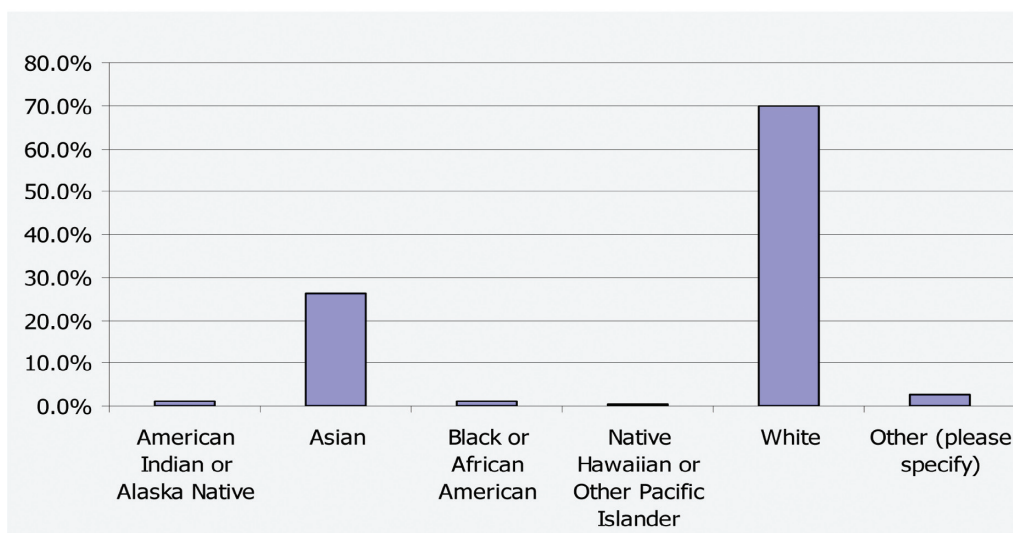


Figure 2: Race

### Professional Experiences

As shown in Figure 3, 78.3% work primarily on human drugs, 32.4% on biologics, blood and vaccines, and 26.5% on medical devices. Figure 4 shows that 54.1% of the members work primarily on late development, 49.8% on statistical methodology, 33.8% on early development, 19.4% on outcomes research, and 17.2% on pre-clinical.

Of the 611 members who responded to the working experiences question, 67.9%, 52.5%, 28.0%, and 16.7% have worked or are working for pharmaceutical (including device) or biotech companies, academia, contract research organizations (CROs), and government, respectively. On average, members have 8.7 years of experiences in pharmaceutical (including device) or biotech companies, 4.3 years in academia, 1.8 years in CROs, and 1.8 years in government.

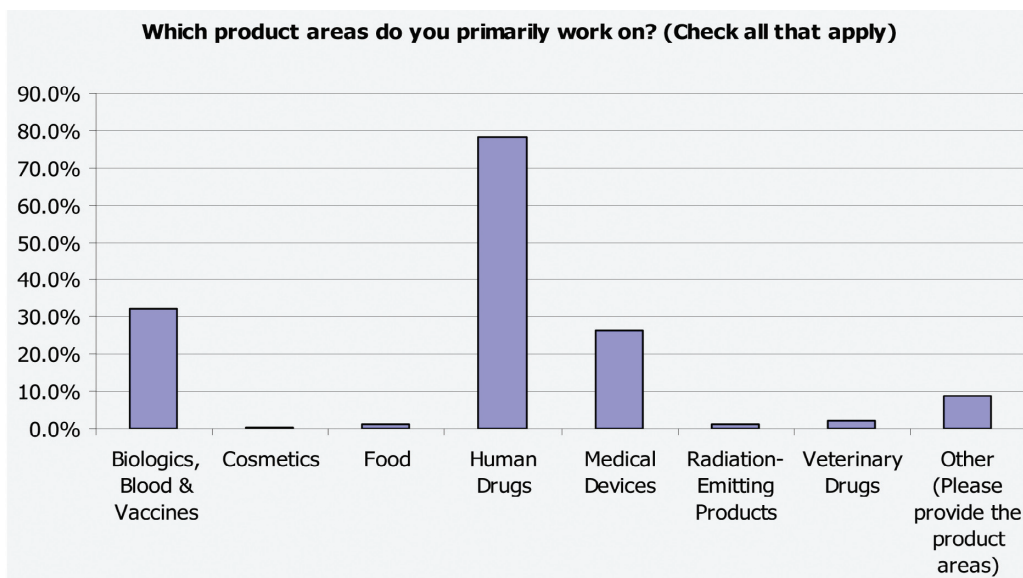


Figure 3: Primary Product Areas

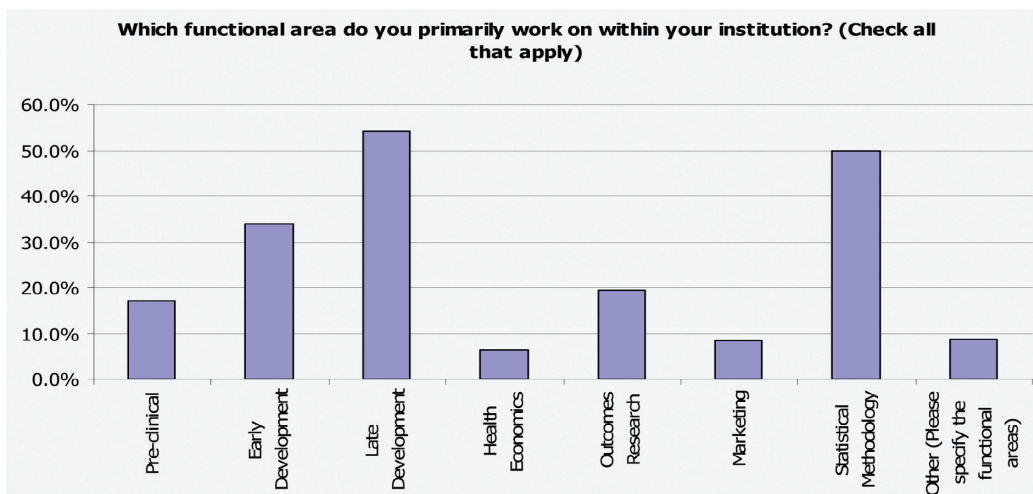


Figure 4: Primary Functional Areas

The major problems faced by our members are high workload, data quality related issues, and too much time spent on non-statistical tasks. For medical publications, 13.0% of the members are always given adequate credit as a co-author for the statistical work, 43.0% are usually given credit, and 20.8% are sometimes given credit.

**Compensation**

As shown in Figure 5, the majority of members (56.9%) earn an annual salary (including usual bonuses) between \$90,001 and \$180,000 with almost uniform distribution in the categories of \$90,001 to 105,000, \$105,001 to \$120,000, \$120,001 to \$135,000, \$135,001 to \$150,000, and \$150,001 to \$180,000, 20.1% have annual salary below \$90,000, and 23.0% above \$180,000.

**Education**

The majority (95.0%) of the members hold an advanced degree in statistics or related field: 59.6% with doctorate degree and 35.4% with master’s as the highest degree. Some of the members (8.7%) hold a doctorate (including MD and JD) degree in non-statistics related field, and 19.2% have a master’s as the highest degree in non-statistics related field. A small proportion (9.1%) of the members is full- or part-time students working on an advanced statistical degree.

**Professional Meetings and Continued Education**

The survey asked the members the statistical meetings they attended in the past 5 years regarding frequency and quality. The most popular meetings are JSM, FDA/Industry Statistics Workshop, ENAR, and DIA meetings, attended

**What is your annual salary including usual bonuses (in U.S. dollars)?**

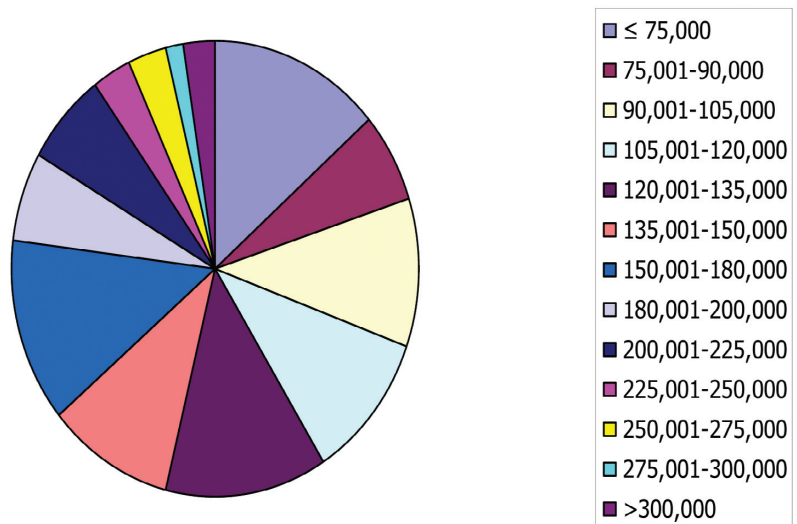


Figure 5: Compensation

by 68.3%, 45.1%, 29.2%, and 26.1% of the members at least once, respectively. The highest quality was awarded to the FDA/Industry Statistics Workshop, where 93.9% of attendees rated “excellent” or “good” vs. 90.2% for ENAR, 82.1% for JSM, and 71.8% for DIA meetings. Our members also participated in internal company sponsored meetings, where 38.1% of members attended at least one, and 31.6% at least two such meetings in the past 5 years.

The survey asked for the number of statistical short courses or workshops attended in the last 5 years. The average is 3.1 and the median is 2. In responding to whether the employers provided financial support to attend external statistical conferences and short courses in the past two years, 461 (77.3%) replied Yes while 135 (22.7%) replied No.

The most popular journals are *Amstat News*, *American Statistician*, and *Statistics in Medicine*, read regularly by 88.1%, 55.3%, and 50.7% of the members, respectively. Members regularly read *Biopharmaceutical Report* (40.8%), *Biometrics* (37.8%), and *JASA* (36.6%). In addition, 68 of the 598 members who answered the question listed journals other than those listed in the question.

To search for a paper or a book and to obtain a copy for their statistical work, the most popular tools are Google and employer’s library service, used by 76.1% and 60.7% of members, respectively, vs. JSTOR (28.6%) and Current Index of Statistics (25.6%).

### **Career Development**

In responding to the importance in enhancing and updating statistical skills, our members identified statistical books (93.1%), statistical journals (88.2%), software packages and manuals (87.2%), statistical short courses (82.3%), and statistical meetings (81.1%) as either “very important” or “somewhat important” vs. Biopharmaceutical webinars (62.7%). Our members also identified technical skills, inter-personal skills, presentation skills, and high visibility project work as the most important factors for career advancement.

### **Feedback on Biopharm Section**

In responding to the satisfaction with the Biopharmaceutical Section, 26.9% of the members chose “very satisfied,” 43.4% “somewhat satisfied,” 21.0% “neither satisfied nor dissatisfied,” 3.1% “somewhat dissatisfied,” and 0.3% “very dissatisfied.” The most important services provided by the Biopharmaceutical Section are sponsoring workshops and webinars on Biopharmaceutical topics, sponsoring relevant sessions at annual and spring meetings, and issuing section newsletter.

In responding whether to volunteer for the biostatistical outreach to promote statistics in high schools and colleges, 152 (26.4%) said Yes, and were willing to spend 4.2 hours per month on average.

In the past one year, 51.9% of the members attended at least one session of Biopharmaceutical webinar. On average, our members attended 1.6 sessions in the past one year, and were quite satisfied with the quality: 20.2% rated “excellent,” 50.3% “very good,” and 27.6% “good;” only 1.9% rated “poor”.

For the *Biopharmaceutical Report* and the Biopharmaceutical Section newsletter, 7.3% of the members rated “excellent,” 28.5% “very good,” 36.1% “good,” and 1.2% “poor,” and 26.9% indicated that they never read it.

In responding to the frequency of hearing from Biopharmaceutical Section about section news, 3.4% of the members desire weekly, 37.7% monthly, 41.5% quarterly, and 13.9% indicated to receive *Biopharmaceutical Report* only; 3.4% of our members are not willing to receive any news. For desired channels to receive information from the Biopharmaceutical Section, 79.1% of our members preferred updates via email, 48.4% *Biopharmaceutical Report*, and 25.9% updates via website. In the *Biopharmaceutical Report*, technical articles were valued by 78.7% of our members vs. industry news by 67.0% and section news 58.1%. ■

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## Biopharmaceutical Section Calendar

- December 6–10, 2010**     **66th Annual Deming Conference on Applied Statistics**  
Atlantic City, NJ  
<http://www.demingconference.com>
- March 20–23, 2011**     **ENAR Biometric Society Meeting**  
Hyatt Regency Miami  
Miami, FL  
<https://www.enar.org/meetings.cfm>
- May 23–25, 2011**     **Midwest Biopharmaceutical Statistics Workshop**  
Ball State University  
Muncie, IN
- July 30–Aug 4, 2011**     **Joint Statistical Meetings**  
Miami Beach, FL  
<http://www.amstat.org/meetings/jsm/2011>
- Sept. 19–21, 2011**     **FDA Industry Workshop**  
Marriott Wardman Park  
Washington, DC  
<http://www.amstat.org/meetings/fdaworkshop> ■

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## Summary of Minutes of the August 02, 2010 Meeting of the Biopharmaceutical Section Executive Committee at JSM held in Vancouver

Submitted by Rick Caplan

Minutes from the March meeting were approved. The EC agreed that a more timely summary of the minutes should be published in the Biopharm Report. This will be attempted by approving the summary of the minutes of this meeting by email, instead of waiting until the next EC meeting.

- Steve Gulyas presented the Treasurer's Report, which was approved and later presented by Steve Gulyas at the Business meeting.
- Ram Suresh and Ed Luo presented the draft report of the member survey. It will be published in the *Biopharm Report*.

- Neil Thomas presented the Fellows Committee report. The Section nominated two members, Jim Colainne and Brian Wiens; and both were accepted as ASA Fellows.
- Dionne Price reported that the Biopharm Section sponsored 35 topic-contributed sessions, 25 contributed sessions, 2 short courses and 14 roundtables at this year's JSM meeting. Jeff Maca is gathering ideas for 2011.
- Mani Lakshminarayanan and Venkat Sethuraman reported on web-based training. There are fewer attendees this year in the preclinical webinars, but this was expected.
- Ivan Chan and Qian Graves reported on the 2010 FDA/Industry Workshop. There will be 37 sessions, and they will try to introduce a Speaker Management system similar to the one used at JSM.
- Mani Lakshminarayanan, Alex Dmitrienko and David Breiter gave the Council of Sections report. The COS is seeking volunteers to help with initiatives:
  - Membership growth
  - Impact of the profession
  - Visibility and public awareness
  - Education
- A statistical literacy bill will be introduced in Congress. There will be an effort to have members urge their representatives to co-sponsor and support the bill.
- Christie Clark and Yongming Qu reported on the Student Paper and the Poster competitions, respectively, at the BIOP EC meeting and also at the Business meetings. The 1st and 2nd place winners of the Student Paper Competition were 1) Sihai Dave Zhao (Harvard) and 2) Yoonjin Cho (N.C. State). The 1st, 2nd and 3rd place winners of the poster competition were 1) Alice Dragomir, Jean-François Angers, Jean-Eric Tarride, Richard Joober, Sylvie Perreault 2) Kelly Zou 3) Michael T. Gaffney, Martin O. Carlsson, Kelly H. Zou.
- Steve Gulyas reported on progress on the Statistical Outreach Website. The “build” phase has been completed, and the site has been launched. Suggestions for further development are welcome. The site address is [www.biostatpharma.com](http://www.biostatpharma.com). ■

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## Summary of Minutes of the Biopharmaceutical Section Executive Committee

Submitted by Rick Caplan

This was the annual “transition” meeting, at which Executive Committee (EC) members whose terms end transition responsibilities to new EC members.

- Katherine Monti chaired the meeting. She welcomed incoming officers:
  - Steve Wilson (Chair)
  - Matilde Sanchez (Treasurer)

—Carmen Mak (Program Chair)

—Stephine Keeton (Section Representative)

- Steve Gulyas, Treasurer, reported that the account balance is \$332,708.13. He reviewed his list of questions about revenue and expenses.
- Steve also submitted a proposed 2011 budget. The overall goal remains to modestly reduce the cash on hand for the section to remain within non-profit guidelines and by continuing to support member services. Under revenues, there is no change in dues and no expected change in JSM course or FDA-Industry Workshop profits. Under expenses, \$50K was allocated to the Biopharm Web Clip Statistical Outreach site. The budgeted expenses for webinars in 2011 is \$50K, though actual expenses may be less than this because there may not be a full schedule of webinars. The webinar series was designed to benefit members, while losing money by defraying members' registration fees.
- Ivan Chan & Qian Graves reported that the 2010 FDA/Industry Workshop had a record high registration of 757. Surveys were very positive. Brenda Crowe and Joan Buenconsejo reported that planning is well underway for the 2011 Workshop.
- Neal Thomas expressed disappointment that the Fellows Committee has not received any nominations from the Section this year. Send him suggestions.
- Anna Nevius gave the current slate of candidates who will run in 2011 to serve in 2012:
  - Secretary: Christopher Miller and Dionne Price
  - Council of Sections: B. Christine Clark and Jim MacDougall
  - Program Chair Elect: Ivan Chan and Estelle Russek-Cohen
  - Chair Elect: Amit Bhattacharyya and Ram Suresh
- Steve Wilson reported the following appointments thus far for 2011:
  - Webmaster: Ed & Anna Nevius
  - Best Contributed Paper: John Johnson
- Dionne Price and Jeff Maca, the 2010 Program Chairs, reported a successful JSM. Jeff Maca and Carmen Mak, the 2011 Program Chairs, reported that 5 Invited Session proposals were accepted. The areas for the Invited Sessions are multiplicity, adaptive design, biomarkers, missing data, making better medical decisions based on visualizing risk/benefit. Two short courses were submitted for approval.
- The Member Survey Report, given by Ram Suresh and Ed Luo, was reviewed. It will be published in the *Biopharm Report*.
- Devan Mehrotra, Publications Chair, reported that all items are on track for the *Amstat News*.
- Russ Helms, Corporate Sponsors Committee Chair, reported receiving donations of \$12,250 thus far this year.
- There is a stable base of contributors, but requirements for requesting funding from companies has become more cumbersome.
- Heather Thomas is finishing data entry of ballots for the Contributed Paper Award.

- The Web Clip Statistical Outreach site is live. For the site to reach its full potential, we need a coordinator/champion to generate or inspire others to generate content. The EC authorized spending \$25000 in 2011 for phase III development of the site.
- The following were discussed and approved:
  - Minutes of the 02-August-2010 BIOP EC meeting
  - Treasurer's Report
  - 2011 Budget ■

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## The Second International Symposium on Biopharmaceutical Statistics

“Bridging Drug Development from Research to Marketing”

March 1–3, 2011

Palace Hotel, Berlin, Germany

The Second International Symposium on Biopharmaceutical Statistics will be held in the Palace Hotel in Berlin, Germany, from March 1 to March 3, with short course on February 27th and 28th, 2011. The conference is jointly organized by the European Medicines Agency (EMA), the International Society for Biopharmaceutical Statistics (ISBS) and the German Region of the International Biometric Society (IBS-DR). It is sponsored by the European Federation of Statisticians in the Pharmaceutical Industry (EFSPI).

**Who should attend:** Statisticians and related professionals who are involved in quantitative biopharmaceutical research, development and regulations.

**Detailed Information, Program Outline, Short Courses, Registration form and Hotel booking info:**

[www.isBioStat.org](http://www.isBioStat.org).

For further information, please contact: Richardus Vonk, Bayer Schering Pharma AG ([richardus.vonk@bayerhealthcare.com](mailto:richardus.vonk@bayerhealthcare.com)), or Amit Bhattacharyya, GlaxoSmithKline USA ([amit.bhattacharyya@gsk.com](mailto:amit.bhattacharyya@gsk.com)). ■

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## The 2011 FDA/Industry Statistics Workshop

September 19–21, 2011

Washington Marriott Wardman Park, Washington D.C.

The 2011 FDA/Industry Statistics Workshop will be held September 19-21, 2011 at the Washington Marriott Wardman Park, Washington D.C. This year we have a great improvement—online submission of session proposals (for plenary/concurrent sessions, short courses and roundtable luncheon discussions). Proposals will be accepted

via the online web form beginning **November 15, 2010** and will be accepted through **December 15, 2010** for plenary/concurrent sessions and short courses, while roundtable luncheon discussion proposals will be accepted through **February 28, 2011**.

Please submit proposals for **plenary/concurrent sessions, short courses and roundtable luncheon discussions** at [www.amstat.org/meetings/fdaworkshop/sessionproposals](http://www.amstat.org/meetings/fdaworkshop/sessionproposals).

An organizing committee meeting (open to all) will be held in late January 2011 to vote on proposals and to start to make decisions on organizers. Typically, at least 1 organizer from FDA and 1 from industry/academia are requested for each session. It is not necessary or desirable to have all the organizers arranged at the time of submitting a session proposal. Details on the organizing committee meeting will be provided at a later date.

Our goal, with your input and assistance, is to make the 2011 FDA/Industry Workshop a tremendous success! We look forward to receiving your proposals when online submission opens November 15, 2010. ■

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## The 9th International Conference on Health Policy Statistics

October 5-7, 2011

The Ritz-Carlton Cleveland, Cleveland, OH

The International Conference on Health Policy Statistics (ICHPS), organized by the Health Policy Statistics Section of the American Statistical Association plays a vital role in the dissemination process of health policy (and health services) statistics. ICHPS provides a unique forum for discussing research needs and solutions to the methodological challenges in the design of studies and analysis of data for health policy research. ICHPS's aim is to create interfaces between methodologists and sophisticated health service researchers, health economists, and policy analysts so they can exchange and build on ideas that they will disseminate to the broader health policy community.

<http://www.amstat.org/meetings/ichps/2011> ■

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## Upcoming Conferences

These upcoming conferences are either of recurring general interest to our membership or have been brought to our attention.

### FDA/DIA Statistics Forum 2011

April 10–13, 2011

North Bethesda, MD

<http://www.diahome.org/DIAHome/Education/FindEducationalOffering.aspx?productID=24168&eventType=Meeting>

### Society for Clinical Trials Annual Meeting

May 15–18, 2011

Vancouver, British Columbia, Canada

<http://www.sctweb.org/meeting.cfm>

## **DIA 2011 Convergence of Science, Medicine and Health**

June 19–23, 2011

Chicago, IL

<http://www.diahome.org/diahome/FlagshipMeetings/home.aspx?meetingid=23753>

## **ICSA 2011 Applied Statistics Symposium**

June 26–29, 2011

New York City

<http://www.icsa.org/2011>

## **International Conference on Robust Statistics (ICORS 2011)**

June 27–July 1, 2011

Valladolid, Spain

<http://www.icors11.uva.es/>

## **Seventh International Conference on Multiple Comparison Procedures**

August 29–September 1, 2011

Washington, DC

<http://www.mcp-conference.org/2011/index.php> ■

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# **Biopharmaceutical Section Poster Awards at 2011 Joint Statistical Meeting**

If you plan to attend the 2011 JSM and plan to present a poster, you may consider participating in the Poster Competition sponsored by the ASA Biopharmaceutical Section. All authors who present posters sponsored by the Biopharmaceutical Section are qualified to compete for this award. The entry criteria for the Poster Awards are:

- Topics in statistics which are applicable to biopharmaceutical research. Suitable topics include but are not limited to methodological issues in preclinical or clinical trials, epidemiology studies of drug safety (device or biological), genetic studies predicting drug (or biological) response, laboratory and toxicological data analyses, methods for high-dimensional data from high-throughput screening, and non-linear pharmacokinetic modeling.
- All JSM attendees (not restricted to members of the Biopharmaceutical Section) can participate in the competition.
- Posters will be evaluated based on the following criteria
  - Innovation
  - General applicability in pharmaceutical research
  - Appropriate example(s)
  - Effectiveness of presentation (well written, well organized, etc)

- Authors who compete for the Poster Awards cannot also compete for the Students Paper Awards.

Three awards with cash prizes of \$1000, \$600 and \$400 will be given for 1st, 2nd and 3rd place, respectively.

The process is as follows:

1. Submit an abstract through the Biopharmaceutical Section by the JSM abstract submission deadline.
2. Submit your poster to Yongming Qu, Chair for the Poster Awards through email ([quyo@lilly.com](mailto:quyo@lilly.com)) by May 1, 2011.
3. Each poster will be reviewed by two reviewers and an average score will be assigned;
4. Posters with the highest scores will be the winners.
5. Ribbons will be put on the corner of the posters to indicate the winners during the poster presentation at JSM.
6. Winners will be announced with certificates at the Biopharmaceutical Section Mixer at the 2011 JSM. ■

## Let's Hear from You!

If you have any comments or contributions, please contact the Editors: Jose Alvir, email [Jose.Alvir@pfizer.com](mailto:Jose.Alvir@pfizer.com); Deborah Panebianco, email [deborah\\_panebianco@merck.com](mailto:deborah_panebianco@merck.com); or Amit Bhattacharyya, email [Amit.Bhattacharyya@gsk.com](mailto:Amit.Bhattacharyya@gsk.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 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.