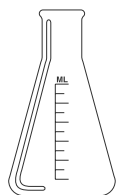


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Note from the Editors

In this issue of the Biopharmaceutical Report we are pleased to feature a short article on an important area of career development for statisticians that is rarely discussed in journals or textbooks. Building on a talk she gave at JSM in 2004, Dr. Chuang-Stein shares her personal experience and offers advice on the non-technical or 'soft' skills needed for statisticians to be maximally effective in biopharmaceutical companies. Although the intended audience is industry statisticians in the early-to-mid stage of their careers, we trust that statisticians and technical professionals in non-industry jobs will also recognize the value of acquiring the skills advocated by the author. We hope you enjoy the article and find it helpful to refer back to later for a refresher. ■

Cultivating Non-technical Skills of Pharmaceutical Statisticians

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Abstract

While graduate schools and many professional workshops provide training opportunities for technical skills, technical skills are only one part of the many skills a statistician needs to be successful in an industry highly committed to excellence and the multi-disciplinary team approach. In this paper, we will highlight some non-technical (soft) skills that would be useful to a pharmaceutical statistician. We will also share some observations on how one might go about cultivating such skills. The goal is to create awareness of these non-technical skills and their

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acquisition to help statisticians achieve their fullest potentials in the pharmaceutical industry.

Introduction

Frequently, we are asked by educators and graduate students who are interested in a career in the pharmaceutical industry the following question:

What does a pharmaceutical sponsor look for in a statistician?

A typical answer for a staff position includes the following qualifications:

- Sound statistical knowledge
- Knowledge about commonly-used statistical software such as SAS®
- Good oral and written communication skills
- Experience with the drug development process and interactions with regulatory agencies are highly desirable, but not mandatory

The above qualifications are frequently listed in job advertisements. Most of these qualifications can be verified with relative ease during the interview process. For example, sound statistical knowledge could be minimally checked by an individual's academic credentials, publications, and scenario playing during the interview process. Knowledge about SAS® could be checked by gentle probing. Oral communication could be evaluated by asking the candidate to give an oral presentation. Mail correspondences with a potential candidate could reveal to some extent the writing skills of a candidate at the non-technical level.

By comparison, non-technical skills such as "having a high standard of excellence," "proactive engagement," "ability to deliver on promise," "organized and focused," "positive attitude," "tenacity to reach the goal" etc., are much harder to judge. Equally hard to assess is an individual's potential to enhance the above as part of an ongoing professional development endeavor. Interestingly enough, non-technical skills are often the cornerstones for an individual's success not only in the technical dimension, but also in his or her overall effectiveness as a statistician.

There are many workshops for statisticians to learn new statistical methodology and discipline-specific knowledge. There are short courses offered by universities, individual researchers, organizations, and conferences. These venues are extremely effective, offering statisticians a means to continue their professional development at the technical level. By comparison, there are very few workshops designed to focus on a statistician's non-technical skills.

Several authors have discussed statisticians' contributions to biomedical research and how statisticians could further such contributions [1-4]. In this paper, we will look at the behavioral side of statisticians by focusing on non-technical skills. The development of such skills, in general, is not as well recognized and practiced. Part of the reason is the difficulty in identifying these skills and the challenge in measuring the impact of such skills. For example, how does one measure the impact resulting from an attitude change?

Instead of attempting to measure the importance of developing non-technical skills with definitions and metrics, we will highlight in this paper some non-technical skills that we believe are important for a pharmaceutical statistician to develop. We will also share some observations on how one might go about acquiring such skills. The goal is to create awareness of the need for cultivating such skills so that statisticians may achieve their fullest potentials in an industry highly committed to excellence and the multi-disciplinary team approach.

Non-technical Skills: Some Examples

Passion, Courage, and Tenacity

The CEO of a major pharmaceutical company once inspired his staff with three words --- passion, courage, and tenacity. These three words describe the forces that propel and enable individuals with a high desire for success to move towards their goals.

Positive Attitude

Many organizations purchase skills, but hire for attitude. It is often said that life is 10% of what happens to us and

90% of how we deal with life events. We can't control most of the things that occur to us, but we can certainly choose how to respond to the circumstances surrounding us. A positive attitude is contagious. It is not only good for our own mental health, but is also good for an organization's health.

Proper Social Etiquette

We learned to say "thank you" and "sorry" when we were young. We also learned the rule of not doing to others what we did not want others to do to us. We need to hold onto these basic manners. We also need to have the grace to accept professional feedback (positive and negative). Composure and warm regards for others will help portray us as socially well-balanced individuals.

A Habit of Excellence and High Standards

A desire for excellence and high standards is a good start. Ultimately, it needs to become a habit. Habits express our characters, and determine our effectiveness or the lack thereof.

A Willingness to Learn

We are in a dynamic environment. New science is being discovered every day, requiring new and more efficient statistical methodology. To keep our technical edge, statisticians need to learn on the fly. The learning is not limited to statistical issues. It should include the disciplines we are supporting as well as major issues that affect our industry.

Discipline and Focus

Organizations look for individuals who have the drive and the will to get the job done. Brainstorming and thinking out of the box are the first step to laying out a plan. Putting together a well-thought out plan and taking it to completion require unwavering discipline and focus.

Respect and Trust

Respect and trust are often the deciding factors for a team's success. The ability to find a common platform to build respect and trust will be crucial. We also need to remember that respect and trust are things we need to earn ourselves.

Leadership Skills

Leadership is not for the few; it is for all. Leadership does not necessarily equate to power. It is the ability to identify an issue, analyze it, propose a solution, obtain the necessary endorsement, and execute the solution, either alone or with a group. For many, the prospect of taking initiative, being the one responsible, and possibly facing an undesirable outcome, is intimidating. The important thing is to realize the freedom leadership skills can offer and to consciously take action to acquire such skills.

Good Mindset about Changes

The only certainty about our industry is change—change in drug discovery, drug development, medicine delivery, regulations, and policies. There are also organizational changes brought on by mergers and acquisitions. Rather than worrying about how external changes might affect us, it is better to have the right mindset and prepare ourselves continuously in anticipation of change.

Proactive Engagement and Critical Thinking

Statistics is not a discipline that exists by itself and for itself. Pharmaceutical statisticians offer their expertise to

colleagues in other disciplines. Under this working model, it is important that pharmaceutical statisticians proactively engage themselves and demonstrate their value by offering their critical thinking.

Willingness to Modify Our Behaviors

Many statisticians are introverts. Our personality contributes to our career selection. However, our disposition does not give us the excuse not to perform as a fully effective and engaging team member. While we do not necessarily need to change our personality, we need to be willing to modify our behaviors to help create an uplifting work environment.

Acquiring Non-technical Skills: Action Plan

Acquiring non-technical skills is similar to acquiring technical skills. It takes time, effort, and dedication. Mentorship helps, but the learning needs to be self-motivated, coming from an individual's desire to acquire these skills. This author has personally found the following pointers useful.

Setting Goals

Goals help us focus our efforts and if properly balanced, they guide us like the North Star. It is important to have short-term and long-term goals. It is equally important to regularly check the relevance of the goals and check our progress against them. Goals are not fixed. They should be modified for good reasons. Long-term goals help us ride out the short-term interruptions brought on by external changes.

Gaining Maturity with Time

As our years of service progress, we need to ensure that our maturity progresses at least at the same pace. Maturity gives us a sense of independence. It also contributes to our goal realignment. For example, many people have not considered joining management at the beginning of their careers. However, as one matures, the desire to influence through the management route might become appealing. One can accelerate the maturity process, but patience is an important element on the road to maturity.

Being Generous with Volunteering

Volunteer to take on tasks that are outside of our normal responsibilities. One can never predict how the experience gained might help us later in our careers. Moderation is an important consideration when volunteering. Nothing loses our credibility faster than over-commitment and under-delivery. Besides, one is likely to suffer burnout from over-commitment.

Seizing the Opportunities

Opportunities come to a prepared mind. This applies to all opportunities, but even more so to the development of leadership skills. For individuals not gifted with natural leadership disposition, it is scary to take the first step and accept even a small leadership role. Start with small roles to build up confidence. Since a reward for a job well done is a chance to do more, small opportunities often lead to bigger opportunities. However, these chain of events start with one's ability and willingness to seize the first opportunity.

Avoiding Playing the Victim

Some people feel that development can only take place if there is monetary and time commitment from management. Undoubtedly, money and protected time greatly facilitate the development, but we should not let the lack of them prevent us from engaging in development activities on our own. After all, we are the primary beneficiaries of our development effort. One common characteristic of successful people is their ability to take responsibility for themselves and refuse to play the victim.

Forming Alliances with Peers and Management

If we support our peers, they will support us in return. As for management, it is helpful to form an alliance with our supervisors so that they are aware of our development plans and could be in a position to support us. Nonetheless, we need to be aware that project support often takes priority over individual development activities and we need to be flexible in fitting development activities around project needs. Therefore, it is important that we work with our management to help create a win-win situation for both parties.

Maintaining our Intellectual Independence

Many pharmaceutical statisticians work as consultants. There will be occasions when we might be pressured to take a position with which we may not agree. We need to learn how to speak up on such occasions in a professional manner without appearing arrogant or defensive. This is one case where observing a highly effective senior statistician in action will be very beneficial for a less experienced statistician. The ability to stay true to the principles of statistics in a professional manner will win us respect in the long run, even if not in the short term.

Keeping the Right Balance

It is important to have the appropriate perspective and keep the right balance. Professional development is a long-term project. We need to pace ourselves throughout our career, always keeping our eyes on our goals.

Finding a Mentor

Find a mentor or a role model in the organization. When we are paired with a senior member, we can learn how experienced people handle sensitive situations. A mentor's enlightenment can sometimes save much time spent searching in the dark.

Building Relationship and Bridges

The pharmaceutical industry is a small industry. With mergers and acquisitions, the industry is getting smaller all the time. In such an environment, it is important that we keep our professional courtesy at all times. Meeting goals at the cost of fouled professional relationships is not a true success, just like leaders who deliver at the expense of ruined lives are not true leaders. Building bridges and networking will reap us much benefit throughout our professional lives.

Giving Ourselves Pep Talks Regularly

It has been said, the power to effect changes for the better is within us, not in the favorableness of circumstances. The same statement is true with the cultivation of our non-technical skills. While circumstances might delay or accelerate the acquisition of such skills, the driving force needs to come

from within. We need to believe in ourselves and reaffirm our activities through regular pep talks to ourselves!

Striving for the Best within Our Reach

We can't all be captains. Some of us have to be the crew. We have different roles, based on our ability, training, and personal goals. No matter what our roles are, we should strive to be the best we could be under the circumstances we are in. We should respect each opportunity and give it our best shot. We might be constrained, but the sincerity and respect we give to each task will be felt and appreciated by our collaborators.

Concluding Remarks

Cultivating non-technical skills is as important as cultivating technical skills. Both are an integral part of a statistician's continuing professional development. Many authors have discussed on-the-job training for pharmaceutical statisticians in recent years [5-12]. Statistical organizations have also emphasized the importance of continuing professional development for all statisticians. The Royal Statistical Society has gone to the extent of quantifying the amount of professional development activities expected of its members on a yearly basis [13].

There is an old Chinese saying that "it takes 10 years to grow a tree and it takes 100 years to grow an individual." While we can't necessarily expect to have 100 years at our disposal, we can expect to have at least 30 years to develop our careers. This, plus the 20 or more years we spent in various learning institutions, mean that we will have devoted more than 50 years of our life to activities related to our career and our profession. This is a long-term process. Passion, courage, and tenacity are enabling forces in the passage.

Developing individual statisticians contributes to the development of the statistics profession. A profession is made up of individuals. Each profession relies on every one of its members to collectively help sharpen the image of that profession. While leaders of the statistics profession can provide a vision for the statistics profession, the real driving force to advance our profession lies with individual statisticians. Good technical skills win us respect from our colleagues. However, good technical skills combined with good non-technical skills win us not only respect, but also trust. It is the latter that will allow us to perform ultimately at the strategic level, further expanding the influence of statisticians beyond that offered by a technical role!

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Short-courses on Bayesian Clinical Trials at JSM 2005

Kannan Natarajan, Bristol-Myers Squibb and Ming-Hui Chen, University of Connecticut

As part of the ASA Continuing Education program, the Biopharmaceutical Section and the Section on Bayesian Statistical Science proudly co-sponsor two great courses, CE_02C—Bayesian Clinical Trial Design—Approaches and Implementation (August 6) and CE_08C—Adaptive Bayesian Clinical Trials (August 7), on the use of Bayesian methods in clinical trials offered by eminent statisticians in this area with many examples provided from actual clinical trials. These two courses are offered as a pair targeted to students or professionals with a good knowledge of statistics and some familiarity with the practice of clinical trial design, to provide a comprehensive knowledge of the fundamental principles of Bayesian methods, its applications and further advances and possibilities of designing efficient clinical drug development programs. A discount of \$50 off the total registration fee is provided to attendees who register for both



short-courses. If you decide to register for both courses, please check CE_02080C on the registration form to sign up for both courses. You could, however, also register for either of these courses individually.

The first course CE_02C—Bayesian Clinical Trial Design—Approaches and Implementation on Saturday, August 6, is offered by Profs. Peter Mueller and Jack Lee, of the University of Texas M.D. Anderson Cancer Center. This one-day short course will consist of eight lectures, each lasting approximately 45 minutes, covering aspects of Bayesian inference related to the design and analysis of clinical trials. This introductory course will start with a review of the Bayesian paradigm and how it applies to decision making in general and to clinical trials in particular. The lectures are planned as a mix of review of basic theory and concepts and a discussion of practical trial designs. A discussion on Bayesian clinical trial design for early phase trials, including inference about the maximum tolerable dose, dose finding and adaptive allocation will be made. The course will review designs based on tracking posterior probabilities of clinically meaningful events, designs based on inference loss, and designs based on a formal decision theoretic formulation of the trial goals. Time permitting, sequential algorithms, reviewing practical implementations of backward induction and a setup of drug discovery as a sequential process, will be discussed. Examples will be drawn from actual trials at M.D. Anderson Cancer Center.

The second course CE_08C—Adaptive Bayesian Clinical Trials on Sunday, August 7, is offered by Scott M. Berry, Berry Consultants, LLC, and Prof. Donald A. Berry of the University of Texas M.D. Anderson Cancer Center. The course will describe recent Bayesian innovations in the design and analysis of clinical trials. The goals are (i) more efficient clinical trials and clinical development programs, and (ii) treating patients more effectively, both those in and those outside of trials. Innovative trial designs have been effected at the University of Texas M. D. Anderson Cancer Center, in national oncology studies and in pharmaceutical and medical device industry-sponsored trials. The course will provide some background on Bayesian designs for clinical trials and give several case studies of the Bayesian adaptive approach used in actual designs and analyses presented to the FDA. These examples include the possibility of early stopping, seamless phases II and III trials with sequential sampling, using early endpoints to guide sample size and early stopping, and dose finding. The cost savings of such approaches are usually substantial.

The use of Bayesian methods in clinical trials is a topic of great interest in academia, industry and regulatory agencies, and since seats are limited, the Biopharmaceutical section and the Section on Bayesian Statistical Science strongly urge you to register early for these courses. ■

2005 FDA/Industry Workshop, September 14-16, Washington, DC

Ken Koury, Schering-Plough

This three-day workshop is the 9th in a series of annual meetings that have been sponsored by the ASA Biopharmaceutical Section in cooperation with the FDA Statistical Association. It will be held September 14-16 at the luxurious Marriott Wardman Park Hotel in Washington D.C. Tutorials are scheduled on the first day, September 14, followed by two days of sessions on the science and statistics associated with the development of new medical products (pharmaceuticals, biologics and devices). The workshop has been very popular since its inception because it is designed specifically to bring together statisticians from industry, academia, and the FDA, and it provides a unique opportunity for open dialogue on issues of mutual interest.

The theme of this year's workshop is Statistics, Safety, and the Critical Path—Keys to Successful Development of Medical Products. The tutorials include classes on FDA Guidance Documents, Multiplicity Issues, Nonparametrics, and Micro-Array Analysis. A series of plenary and parallel sessions will discuss a wide variety of important, timely issues, including, for example: statistics and the FDA Critical Path initiative, evaluation of the safety of new and marketed products, the role of statisticians on data monitoring committees, Bayesian trial designs with case studies, pharmacogenetics, adaptive designs, clinical trial simulation and modeling, CDISC, bridging studies, and non-randomized trials. Also, the statistical and regulatory issues associated with secondary endpoints, non-inferiority studies, combination products, patient questionnaires, vaccines, devices, pre-clinical safety evaluation, analysis of the QT interval, and diagnostic studies will be discussed. Based on the very positive feedback from last year's attendees, luncheon roundtables will be included again this year on Thursday, September 15.

The Marriott Wardman Park Hotel is a premier meeting site located in a convenient, historic setting in Washington D.C. Covering 16 rolling acres of gardens and woodland, the hotel is perched on a small bluff overlooking Rock Creek Park. There is an on-site Metro stop, and it is within walking distance of the National Zoo and within eight miles from Reagan National Airport. A block of sleeping rooms has been arranged for workshop attendees. To receive the special workshop rates, attendees must book their reservations by Thursday, August 25th.

Please visit www.amstat.org/meetings/fdaworkshop for the preliminary program, a list of workshop organizers, and the registration form. The organizing committee looks forward to seeing you in September! ■



Let's Hear from You!

If you have any comments or contributions, contact **Editor:** Demissie Alemayehu, Sr. Director/Team Leader, Biostatistics & Reporting, 205-9-13, Pfizer, Inc., New York, New York 10017; Phone 212-573-2084; email: alemad@pfizer.com, **Associate Editor:** David Giltinan, Staff Scientist, Biostatistics, Genentech Inc., 1 DNA Way, South San Francisco, CA 94080; Phone 650-225-2296; email: giltinan@gene.com; or **Past Editor:** Kevin W. Anderson, Biostatistical Consultant, 3400 Iroquois Way, Ambler, PA, 19002; Phone 215-646-4453; email: kwanderson@rcn.com.

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