Volume 24, No. 2 • Spring 2017

BIOPHARMACEUTICAL REPORT

CONTENTS

IMPROVING OUR COMMUNICATION AND PRESENTATION SKILLS

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Why the Need

Scenario 1

Imagine yourself sitting in a conference room, listening to a fellow statistician give a talk. The speaker is proposing a new approach to a hard problem. The approach is innovative and has great potentials. Still, you spotted some weaknesses immediately. You raise your hand, waiting for a chance to speak. What are you going to say when the speaker calls upon you? Are you going to first praise the out-of-box thinking and acknowldge the ingenuity behind the proposal, or are you going straight into criticisms on the weaknesses? How long will it take before you use the word "but" in your comment?

Statisticians were trained to be scientists. As scientists, we pride ourselves to be truth-seekers and truth-keepers. We feel compelled to shine light on imperfect arguments and suboptimal evidence. We demand perfection of new approaches even though the current ones have their own limitations. We are eager to share our experience, expertise and insight.

What many of us fail to recognize is that there are many ways to share expertise and offer feedback. Have you observed how well-respected and much-liked statisticians express their opinions on a presentation? They often start by praising the salient points of the presentation before offering their suggestions. For the latter, instead of using a definitive tone, many of them choose to ask questions such as "Have you thought of trying A or B?" or "What do you think will happen if you do X, Y or Z?"

Scenario 2

Now imagine you've just heard an amazing presentation. You look around the room. Most in the audience have this awed expression on their faces. Many are on their feet and clapping their hands. You have this incredibly warm feeling washing over you. You are overwhelmed by a strong sense of affinity with the speaker.

Take a moment to reflect on the presentation. How did the speaker manage to arouse such a powerful feeling in you? Was it the message? Was it the delivery? Was it the vigor of the speaker? Was it the strong conviction projected by the speaker? Or, was it the combination of all of the above that created a perfect storm of a presentation?

You have given presentations before. Perhaps the topics you presented were not the kind that could have aroused the kind of deep feelings as the one you just heard. But, if you are to give a presentation on a topic similar to the one you just heard, could you do it in such a way to produce a similar response in your audience?

Some people were born with a gift in communication and public speaking. They are by far the minority. The rest of us have to cultivate these skills through active observations and dedicated practices. President Lincoln once said, "Give me six hours to chop down a tree and I will spend the first four sharpening the axes." The need for continuous improvement becomes stronger as we gain seniority at work because we are expected to be able to more effectively communicate with and present to decision-makers (Chuang-Stein et al., 2010). In many organizations, excellent communication and presentation skills are part of the requirements for promotions to a senior level.

Unlike taking a short course or working toward a professional degree, there is no clearly marked finish line for our journey to seek greater communication and presentation skills. While there are help aids and books on communication and presentation (e.g., Carnegie 1936, 1962; Barrett, 2006), I will share a few simple rules that have helped me personally on the long journey of self improvement. These rules are not exhaustive, but they are a good place to start.

Pointers for Effective Communications

Communicate in a way to arouse a positive response. We are humans before we are statisticians. As humans, we desire to be acknowledged and validated. Direct criticisms without any preamble tend to invoke the defensiveness in us. On the other hand, suggestions expressed in the form of a question after praise tend to make us more receptive to the comments and appreciative of the commentors. Yet, despite our positive reaction to this type of communication style, we don't necessarily emulate them consiciously ourselves. We should change this.

Remember that words matter. I once saw a youtube video *www.youtube.com/watch?v=Hzgzim5m7oU*. In the video, a blind man sat on a mat in front of a building. Next to him was a cardboard sign saying "I'M BLIND. PLEASE HELP ME." Occasionally a passerby dropped a coin on his mat. A woman in dark sun glasses walked by him and circled back. She took out a pen and wrote on the other side of the cardboard. The blind man felt her shoes as a way to get to know her. After the sign change, passerbys started dropping handfuls of coins on his mat, often in a respectable manner. At the end of the day, the woman returned and stood in front of the man. By the feel of the shoes, the man knew it was the same woman from the morning. He asked what she did to his sign. She said "I wrote the same, but different words." The words she used were "IT IS A BEAUTFIL DAY and I CAN'T SEE IT." The clip ends with the message "Change Your Words; Change Your World."

"Providing excessive details to people who only want the big picture will bore them. Communicating vaguely without substantial details will frustrate people who operate the best through verifiable data. Understanding other's styles is essential to achieving the objective of communication and influencing."

Understand others' communication styles. People have different styles in processing information and making decisions. Some speak with precision, requiring numerical details while others speak more conceptually. Some focus on what's right and are energized by argument and negotiation while others communciate warmth and tolerance, avoiding arguments and conflicts. Providing excessive details to people who only want the big picture will bore them. Communicating

vaguely without substantial details will frustrate people who operate the best through verifiable data. Understanding other's styles is essential to achieving the objective of communication and influencing.

Don't let our accent deter us. For many of us, English is not our native language. While we need to try hard to improve our proficiency in English, it is important to not let the language barrier impede our need to communicate. There is an increasing acceptance of foreign accent as long as the accent is not so thick to hinder comprehension. At times, some form of an accent may actually result in a listener's paying more attention to the speaker. A guiding principle is to speak clearly with a good pace.

Communicate often and proactively. Anticipating problems in advance and providing regular updates to others in a collaborative project will go a long way towards creating trust. We should avoid the approach of "I will let you know when I have results." Always follow the mantra—when in doubt, communicate.

Practice a difficult conversation with a confidant. There are times when we need to engage in a difficult conversation. This may include asking for a promotion, resolving a dispute with a colleague, or delivering a poor performance rating to a staff member. Difficult conversations should ideally be conducted face-to-face, or at least verbally. It will be very useful to practice the conversation with a trusted friend to strike an appropriate balance between the message itself and the delivery. The engagement needs to be done with as much understanding and dignity as possible.

Speak up. There were many times in my career when I sat in a conference room with good ideas but failed to speak up. I rememer berating myself afterwards for missing a perfect opportunity to build consensus around a promising idea. So, practice to speak up. We can also challenge the experts, as long as we do it in a repectable manner.

Think twice before hitting the "send" button. I have seen e-mail messages that should never have been sent in the first place. When the emotion runs high after a trigger event, it is easy to say or write things that we are likely to regret later. Once the words are out, we can't take them back. So, always think and read twice before releasing a message. If a follow-up to the trigger event is necessary, it will be better to have a verbal dialogue after a cooling period.

Pointers for A Good Presentation

No matter how many presentations I have given before, I always remind myself of the followings each time I have a chance to present.

- The first three minutes of a presentation is key. An excellent opener not only sets a good stage for the presesntation, it also helps ease the tension in the speaker. If necessary, write it out what we plan to say during the first three minutes.
- Prepare the contents to match the audience and the time allocated to the presentation. Nothing is more irritating than a speaker who goes on and on, totally disrespecting the schedule set for the presentation.
- Delivery is as critical as the contents. Put fresh energy into the delivery even if we have given the same presentation numerous times before. The audience deserves our best. Give ourselves a pep talk before each presentation.
- Use different tones and pauses to emphasize a particular point. Repetition of a core message is good. Humor is also good, as long as it is not done at others' expense.
- We need to argue strongly why the topic we are presenting is important. How else could we expect the audience to get excited about the topic and devote time listening to our presentation?
- A non-English-speaking presenter might be tempted to talk fast in an attempt to cover up an accent. This is not an effective strategy. A better way is to speak at a good pace and avoid using words that are particularly hard for the speaker to pronouce.
- Maintain eye contact with all our audience. While it is comforting to look at friends for confirmation, it is critical to remember that we are giving the presentation to all in the audience.

- Don't be distracted by the head-shaking of a few individuals. However, if many in the audience wear a puzzled look, it is time for us to pause and try a different approach to explain.
- Take time to prepare the talk until we are entirely comfortable with the contents and how we plan to deliver them. Except for a few experts with deep knowledge and experience, most of us are not good enough to just wing it. Besides, the audience are pretty good at spotting talks that are ill-prepared.
- Make our visual aids (e.g., slides) fun and attractive, but avoid over-crowding them. Simple color scheme and a little animation will go a long way.
- Project confidence and use positive langugage. The presentation should be fun for us and the audience. The audience can tell right away if we are having a good time. Remember that positivity is contagious.
- Catch the audience's attention early and strive to retain it throughout. Personal stories are good attention-catchers. If we lose the audience's attention early on, it will be hard to get it back. Remember the first-three-minute rule.
- Practice the presentation with a friend if we need additional assurance. Ask the friend for honest feedback and accept it with grace. Time the presentation during the practice to ensure adequate time for the main message and a recap.
- Embody the Nike motto—Just Do It.

It Is Up to Us

As with any self-improvement project, the key to success is an inner desire to improve. The wise men before us say that the power to effectuate change for the better is within us, not in the favorableness of circumstances. While circumstances could affect the speed of our progress, the driving force needs to come from within.

We learned how to communicate by emulating our elders when growing up. Similarly, we learned from our teachers who gave lectures and our leaders who delivered speeches. Some of us were lucky to have good role models who helped shape our styles and skills during the formative years of our lifes. While our upbringings greatly influenced our styles, there is always room for self-directed change and adaptation later in our lives. As we gain maturity, we are responsible for selecting our own role models and chartering our own courses.

Even with repeated practices, some of us may never feel completely comfortable speaking in public. This is totally fine because "being completely comfortable" is not a pre-requisite for a good presentation. I was deeply moved by the 2010 movie entitled "King's Speech." The movie won an Academy Award for Best Picture in the following year. The movie describes Prince Albert's struggle to overcome a stuttering condition he endured during his youth. His stuttering became a huge issue for him personally (and perhaps for the then United Kingdom) when he became King George VI upon his brother King Edward VIII's abdication to marry Mrs Simpson. The movie shows how the new King worked tirelessly with an Australian speech therapist to prepare and deliver an important radio message to millions of UK citizens on why UK should fight against the Nazi Germany in World War II. The movie described the struggle, the humiliation and ultimately the triumph of human tenacity.

Surely, we can all learn from the story behind the King's Speech and remember the tale of human resilience and drive.

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USING YOUR ANALYTICAL SKILLS AS STATISTICIANS IN CROSS-FUNCTIONAL LEADERSHIP

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We can do so much more with our talents

Everyone has different career paths by which they decide to become a statistician. However, most statisticians determined that this was a good career path because they had the analytical skills to take a problem and to work through it in an ordered and logical manner to obtain an answer or solution. Initially, the use of such analytical skills became evident during our academic training in mathematical statistics as we worked through the solutions to proving different theorems and rules that form the foundation of the statistical methodology that we use in our daily lives. As we progress in our careers in the real world, we learn quickly that the opportunities to show someone a mathematical proof of the "Weak Law of Large Numbers" may be limited. What sometimes may not be apparent is that the analytical training we received has many uses above and beyond our lives as statisticians on the different projects in which we are involved.

As statisticians, especially those working in the pharmaceutical industry, we are often in situations where we are members of cross-functional teams where we may be the only statistician on a multi-disciplinary team that involves individuals with highly variable technical and non-technical skills. The value that we provide to the teams as statisticians is not always necessarily in the traditional way of providing the statistical guidance needed for the design, execution, and analysis of clinical trials; but, in our ability to work through and solve multi-dimensional cross-functional problems which may help determine whether or not a team succeeds or fails in its objectives. With these skills becoming more evident to a wider audience, increasing opportunities are becoming available to statisticians to lead multi-disciplinary cross-functional teams and projects that allow our analytical skills and talents to be visible to a wider and more public audience. For some, such roles and responsibilities are a natural transition, while for others, some refinement of skills are needed in order to be able to maximize your knowledge and skills with all who you collaborate with on a daily basis.

Figure 1. Who do biostatisticians in the pharmaceuticals industry need to communicate with?

Successful leadership of non-statisticians requires us to succeed outside of the traditional boundaries. Not only will it be necessary for us to maximize the use of all of our analytical skills. In addition, it will requires us to spend a good amount of time outside of our traditional comfort zone being surrounded by statisticians. This will allow for growth in our leadership capabilities so that we are able to captivate the teams that we are leading to ensure plans developed are successfully executed.

The starting point to being a successful leader of non-statisticians should be to learn all that can be learned about the individuals on the team who you have been tasked to lead. In the pharmaceutical industry, statisticians will often touch a wide range of different job functions on a daily basis and have to understanding specific problems from the perspective of their team members. This will allow analytical skills to be used to

find connections between seemingly unrelated objects. The diagram in Figure 1 (Mesenbrink 2015) highlights all of the different types of roles that a statistician in the pharmaceutical industry may have to interact and work with to obtain solutions to tasks and problems.

In interacting with a wide range of different individuals, shown in Figure 1, who may have different levels of knowledge in the areas for which you are strongest, it is important to understand how the different individuals view and interpret data and what are their individual objectives as part of the project team. This will help you to use your analytic skills to define concise team objectives and to help refine the individual objectives of the different team members, as appropriate. For those objectives to be concise and touching the needs of all business functions that are a part of the team, it is very important that we are able to understand how others view information from their perspective and not just how that information is viewed through the eyes of a statistician. For example, someone who specializes in marketing may be interested in how the outcomes observed from clinical trial(s) may help differentiate the product from the competitors. In contrast to this, pharmacologists will be interested in how concentration and drug exposure are related to the derived and collected outcome variables and whether or not a model can be developed to explain and justify the dose(s) that are selected for confirmatory experiments and hopefully eventually regulatory approval. Passively, it may seem like the needs of the two individuals are not connected. However, this is where analytic thinking comes into play to help connect these concepts together to help common team objectives to be met.

In additional to analytic thinking the following skills are helpful in being a successful leader of a cross-functional team:

- Time management
- Active listening
- Organization
- Prioritization
- Flexibility
- Always be willing to learn
- Be proactive rather than reactive
- Knowing how to collect the right information

In addition to all of these areas, the importance of oral and written communication cannot be underestimated (Mesenbrink 2015, Chuang-Stein 2017). As the leader of a cross-functional team, you are the spokesperson for that team and often may be responsible for the key internal and external communications that originate from that team. This may require a communication style that is different from what a statistician may be most familiar with in their daily work. For example, when making oral presentations sometimes one is only allowed to present recommendations based on a single slide. As a result, messaging should be clear and concise and one needs to be able to explain technical results in a manner that they can be understood by an audience without an advanced degree in statistics. When answering questions verbally, the answer to any question as a general rule should not exceed a minute in length, if you need to provide an answer longer than a minute, there is a strong chance that the audience could be lost and the information would be more suitable to be provided in a written format. When providing written information or summaries, one needs to remember how information is viewed in the constantly changing technology age in which we live. I always tell people to remember the "scroll rule" which refers to any email summary of information that will require more than two scrolls to be read will likely not be read in its entirety.

As we grow in our opportunities as leaders of cross-functional teams and as leaders of other statisticians, we will continue learning how to make best use of our technical and non-technical skills as well as our analytic skills. For this to occur, we need to fully understood what the scope of these analytic skills is and realize that the more exposure we receive to others sciences and disciplines, the more we will continue to evolve these analytic skills. Richards J Heuer Jr. once explained that "Thinking analytically is a skill like carpentry or driving a car. It can be taught, it can be learned, and it can improve with practice. But like many other skills, such as riding a bike, it is not learned by sitting in a classroom and being told how to do it." (Heuer 1999). Most statisticians are born with a strong core of analytical skills. This is one of reasons why subconsciously we move into the field of statistics or biostatistics from other areas of science that may have been our starting point in our academic professional

journey. Our successes as leaders can be maximized by understanding how to maximize the use of these analytic skills and continue evolve their scope over time.

The key to being successful as a cross-functional leader of non-statisticians is getting your team to recognize that your knowledge and expertise expands beyond the statistical aspects of the projects in which you are involved. Many of us have been in this common social situation as part of project teams:

> **Project Team Lead:** "Please meet our project statistician, he/she knows all of the data for all of the studies in the program, and you can ask him/her anything."
>
> **New Team Member:** "That is great, I have budget for 100 patients can you help me to design a new study to test the question that has been bothering me the last few weeks?"
>
> **Project Statistician:** "Okay. What is the primary objective of this study and how will you define the trial to be successful?"
>
> **New Team Member:** "Well, I want to gain patient experience in my country, so my main goal is to just describe the efficacy and safety in the local population to make physicians more confident to use Drug X"

I think we have all experienced situation like this during our lifetimes both in the real world and during our academic consulting experiences. Such situations are very frustrating for many statisticians. However, these situations occur most often when we are very introverted and not active participants in the teams for which we are a member. Thus, the first step to making the leap to leading cross-functional teams is to be a strong team member. The most important step in becoming a strong team member is: having the ability to see the "Big Picture" and understanding how all of the functions on the team fit together to make a high performing project team. Whenever I join a new cross-functional/multidisciplinary team, I try to meet 1-1 with all of the core team members to introduce myself and try to understand some key fundamental questions:

- In your area of expertise, what are the activities that need to occur successfully for this project to be a success?
- Are we the first to try doing things in this way or does literature or background information exist to explain why this is the best approach to the situation?
- What do you see as the risks that could prevent the objectives from being met or the project from being a success?

Answers from your team members to these key questions, will allow you to see the "big picture" on that project and use your analytical skills to define how previously unrelated activities can be linked together and where the dependencies may exist for the future success of the project.

It is also important to have a working knowledge of the clinical science in your project so that you are able to establish a clear vision for the project. If you are new to the area, do as much background reading as possible on the area in which you will be leading and see if there are upcoming training situations that can accelerate your learning curve (the evolution of the webinar has made learning increasingly easy without the need for more travel than is necessary). You will continue to learn over time and continuous learning will also allow your analytic problem solving skills to be refined as you gain more knowledge and experience in the clinical science of the project that you are leading.

The introductory discussions you have with your team members upon your arrival as a project team leader will also help you establish what are the skill sets of each of the individuals on the team and will allow you to determine what their strengths and weaknesses are and how they will help make your team a success. This is important because one of the keys to transitioning from an individual contributor to a team leader is recognizing that you no longer have ability to perform and complete all of the tasks that determine your success. Instead, you have the accountability for the successful completion of all the tasks performed by the project team. As part of the accountability that accompanies this leadership, you must have broad enough knowledge to understand whether any plans implemented to complete a specific task have a reasonable of probability of success. In addition, you need to be able to advise team members on changes to strategy when certain tasks are at risk of delaying timelines so that the impact of any delays can be minimized.

Understanding beforehand when success or failure may be coming, allows statisticians to use their analytical skills to evaluate different situations and plan out different paths to success depending upon the outcomes that could be observed. This has the flavor sometimes of a giant stochastic process with many nodes with the difference being that there is likely more than one "end" state depending on the outcomes that may occur. With these analytic skills and the ability to lead a team in the development of a strategic plan, one realizes the importance of flexibility and the need to have many different paths to success and have risk mitigation if obstacles come along the way to impede the path to success. Those who decide from the onset to pursue a career in project management dedicate their lives to refining these skills because without the skills to plan and address conflicts their path to success will be a difficult one. All statisticians when given the first opportunity to lead a project or team should request the opportunity to take a project management course so you can see where the gaps in your skill set exist and an action plan for improvement can be developed.

The best possible experience that allows one to receive the ideal on the job training as a cross-functional leader is when one has the opportunity to be involved in due diligence activities within the pharmaceutical industry. In this setting, an opportunity is identified where a product may exist at another company which may be beneficial to your company's near term and long-term portfolio. When the potential opportunity is identified, a cross-functional multidisciplinary team is formed to evaluate whether or not the identified opportunity would be a good business venture and develop the plan by which one would become involved in the success of that external product. As part of this evaluation, a cross-functional team that involves disciplines ranging from pre-clinical research to translational medicine to clinical research to marketing to intellectual properties as assessed by legal counsel becomes involved in an intense deep dive of the data and information available for that product. In leading such a team successfully, it is essential for the leader of the due diligence team to have at least a basic understanding of how all of the information from the different team members contributes to the recommendation made to your company's management on the action that should be taken with the external company on that product. There have been many due diligence projects that I have been involved with where the clinical data was very strong and the statistical methodology used in the design and analysis of the clinical trials was very robust. However, when evaluating the challenges in technical development (i.e. what is needed to produce drug product in large quantities to conduct Phase 3 clinical trials) the project may possess too high a business risk and cost and would incur major delays which would prevent the product from having a positive commercial value in the long run. Leading and actively participating in such teams is a challenging and rewarding situation that allows us as statisticians to maximize the use of our full analytical skill set.

As statisticians, we have much to contribute to the "big picture" and as we become increasingly involved in situations where we need to go beyond what is expected of the traditional statistician, we will realize the full potential of our analytical capabilities and be recommended more for successfully leading cross-functional projects to great rewards and successes.

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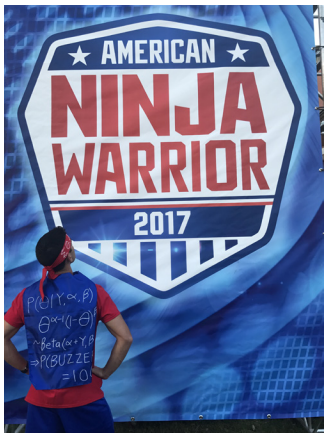
STAT NINJA WARRIOR

Ben Saville, PhD, is a Statistical Scientist for Berry Consultants, where he specializes in the design of innovative Bayesian adaptive clinical trials. Away from work, he is a fitness enthusiast and loves to tackle obstacle courses. He recently competed in NBC's television reality show "American Ninja Warrior" in San Antonio Season 9 as the "Stats Ninja." Approximately 77,000 applicants nationwide sent in video applications with hopes of competing this season, and Dr. Saville was one of only 600 athletes in the country to receive the invitation. When asked how he became interested in American Ninja Warrior, Dr. Saville said "My two sons love the show, and they inspired me to send in an audition video. In my audition I emphasized my family, my unique biostatistics background, and my dedication to fitness, and the producers liked what they saw."



His competition aired on NBC June 19th, but unfortunately NBC did not showcase his run (of the 100 athletes that competed in San Antonio, only about 20 are chosen by NBC to be shown on TV). Dr. Saville put in his best effort, but failed on "Tick-Tock," the second of six obstacles. Despite failing to advance in the competition, he remains optimistic, "It was an amazing experience and I'm so grateful for the opportunity. I love challenging myself, whether it's hard statistical problems or seemingly impossible ninja obstacles. I'll use this year's experience as a building block to train and hopefully compete again next year!" ■

Photos by Jenny Saville

Ben Saville, a statistical scientist for Berry Consultants participated in an episode of "American Ninja Warrior," in San Antonio.

"I love challenging myself, whether it's hard statistical problems or seemingly impossible ninja obstacles."

—Ben Saville

ASA BIOPHARMACEUTICAL SECTION
REGULATORY-INDUSTRY STATISTICS WORKSHOP

SEPTEMBER 25–27, 2017 | WASHINGTON, DC

WORKSHOP UPDATE

Martin Ho and Weili He, Workshop Co-chairs

On behalf of the Steering Committee, we are pleased to invite you to attend the 2017 ASA Biopharmaceutical Section Regulatory-Industry Statistics Workshop on September 25-27 (Monday – Wednesday) at the Marriott Wardman Park Hotel in Washington DC. The theme for the Workshop is "Value to Patients: Benefits, Risks, and Costs." This year's program includes two plenary sessions, 42 parallel sessions, eight short courses, 32 roundtable discussions, and 20 posters. There will be a mixer in the late afternoon of September 26. Detailed information on the workshop can be found via the link at *ww2.amstat.org/meetings/biopharmworkshop/2017*.

We want to first highlight some brand new features introduced this year to enrich the attendees' quality of experience. For the first time in the Workshop's history, we can offer some financial support to domestic and international experts who share their thoughts at the plenary sessions. Moreover, the Workshop's very first app will be available for attendees to help them navigate between the Workshop's many interesting sessions. To make the poster competition more rewarding to participants, the Workshop will offer financial awards to the winners. Also, new in this year, we will host a special town hall luncheon discussing a very interesting emerging topic on the Use of real word evidence and real world data for FDA approval and clearance. Finally, we have listened to the attendees' feedback to increase the audio/video support for each session for the best communications between the audience and the speakers. These improvements are made possible by the generous financial support of the Biopharmaceutical Section, the excellent logistic support of the ASA staff, and the outstanding leadership of the Steering Committee members.

This year's workshop will begin with presentations and discussions by leading academic, regulatory, and industry experts on key issues, case studies, methodologies, and future directions of the patient-centric benefit-risk assessment. The first plenary session features keynote speaker, Professor Deborah Ashby of Imperial College London. The title of her speech is "Patient-centric benefit-risk decision-making in the regulation of medicines." A panel discussion will follow, with expert panel members including Drs. Ian Hirsch, AstraZeneca, Telba Irony, FDA-CBER, Lisa LaVange, FDA-CDER, and Ram Tiwari, FDA-CDRH. The second plenary session showcases recent development in BR assessment methodologies incorporating patient preference information. Martin Ho will open the session with an overview of FDA CDRH efforts in soliciting and utilizing patient preference information in regulatory decision making. Professor Roger Lewis, David Geffen School of Medicine at UCLA, will speak on "Using a Patient-Centered Utility to Drive a Bayesian Adaptive Enrichment Trial of Treatments for Acute Stroke," and Dr. Scott Evans, Harvard University, will present "Pragmatic Benefit:Risk Evaluation: Healthy Disruption for Clinical Trials and Diagnostic Studies."

The workshop also features eight short courses, including state of art and contemporary topics in modern statistical methodologies and clinical development. The eight short courses present the following topics:

- Generalized linear mixed models with applications to clinical pharmacology and personalized medicine
- Data Visualization in the Life Sciences

- Futility Analyses in Confirmatory Clinical Trials – Methods and Procedures
- Multi-Regional Clinical Trials and the ICH E17
- Bayesian Adaptive Designs for Immunotherapy and Drug Combination Trials
- Patient-Reported Outcomes: Measurement, Implementation and Interpretation
- Advancing Drug Development through Precision Medicine and Innovative Clinical Designs: Concepts, Rationale, and Case Studies
- Defining Treatment Effects in Randomized Trials

The 42 parallel sessions cover a wide range of topics on statistical methods and clinical development topics and some of these sessions will surely suit your interests. The online program is available here:*ww2.amstat.org/meetings/biopharmworkshop/2017/onlineprogram/index.cfm.*

We would like to express our sincerest gratitude to many people involved in the workshop planning and execution: To the ASA Biopharmaceutical Section Executive Committee for their guidance and support; To ASA meeting planning support, especially Ms. Christina Link; and to all the Workshop Steering Committee and sub-committee members, session, short course, and roundtable organizers, session speakers, panel members, discussants, short course instructors, roundtable leaders, and poster submitters. They are the leaders and leading experts in the statistical and clinical trial community. Their in-depth knowledge, thought-provoking ideas, and practical advice based on a collective wealth of experience will surely ensure the success of this workshop. For that, we are forever indebted. ■

BIOPHARMACEUTICAL SECTION AT THE 2017 JOINT STATISTICAL MEETINGS

JULY 29 – AUGUST 3, BALTIMORE, MARYLAND, USA

The 2017 Joint Statistical Meetings will convene at Baltimore Convention Center in Baltimore from July 29 to August 3. The theme of the 2017 meetings is "Statistics: It's Essential." The ASA Biopharmaceutical Section has been instrumental in helping to put together an outstanding program, including sponsoring numerous courses, sessions, roundtables and posters.

Two full day courses and one half day course are sponsored by the Biopharmaceutical Section and will be presented this year:

Full Day courses

- **Statistical Analysis of Medical Product Safety Data and Benefit-Risk Assessment**
  Jie Chen, Joseph Heyse, Tze Leung Lai
- **Analysis of Clinical Trials: Theory and Applications**
  Devan Mehrotra, Alex Dmitrienko, Jeff Maca

Half Day course

- **Multi-Regional Clinical Trials and the ICH E17**
  William Wang, Aloka Chakravarty, Lisa LaVange, Bruce Binkowitz

Invited Sessions

The section contributed four invited sessions:

Session 6: New Methods and Software for Adaptive Designs. Sunday, July 30, 2017, 2:00 p.m.–3:50 p.m..

Session 140: The Challenges and Advantages of Utilizing Bayesian Statistical Methodology in Extrapolation of Adult Use Data to Pediatric Study Designs and Evaluation. Monday, July 31, 2017, 10:30 a.m.–12:20 p.m.

Session 386: Estimands: What is Essential is Invisible to the Eye. Tuesday, Aug. 1, 2017, 2:00 p.m.–3:50 p.m.

Session 438: Real World Evidence in Clinical Trial: New Era of Informed Decision Making Session. Wednesday, Aug. 2, 2017, 8:30 a.m.–10:20 a.m.

BALTIMORE JSM2017

Topic Contributed Sessions

Additionally, the section is sponsoring 18 Topic Contributed sessions on a variety of topics:

- Increasing Efficiency and Integrity of Randomized Trials: Covariate-Adjusted Randomization and Monitoring Patient Accrual and Selection Bias
- Adaptive Design and Statistical Consideration in Clinical Trials
- ICH E17 and Multi-Regional Clinical Trials (MRCTs) (Panel)
- Clinical Outcome Assessments: Measurement, Evaluation, and Interpretation
- Enrichment Clinical Trials: Novel Designs, Statistical Inferences and Case Studies
- Efficient Designs and Better Decision-Making Strategies in Complex Clinical Trials: Multiple Arms, Multiple Endpoints and Multiple Stages
- Clinical Trials: Recent Statistical Advances for Enabling Personalized Medicine
- Characterizing Clinical Dose Response Studies
- New Guidance on Specifying the Target Difference (Effect Size) for a Randomised Controlled Trial

- Quantitative Safety Monitoring: Regulatory Landscape, Statistical Methodology and Cross-Disciplinary Scientific Engagement (Panel)
- Different Approaches to the Increase of a Sample Size When the Unblinded Interim Estimate of the Treatment Effect Looks Promising
- New Challenges in Subgroup Analyzes and Enrichment Designs
- Biopharm Safety Monitoring Working Group: Bayesian and Graphics Approaches Based on Regulatory Guidance
- Simulation Report for Designing Adaptive Clinical Trials: Current Practices and Recommendations to Industry
- More Emerging Topics in Benefit-Risk Assessment in Clinical Development Decision-Making
- Recent Advances on Missing Data Methods: From Estimands to Assumptions for Primary and Sensitivity Analyzes
- On the Use of Computer Intensive Methods in Pharmaceutical Research
- Perception and Use of Adaptive Designs in Industry and Academia -- Comparison of the Four DIA Adaptive Design Scientific Working Group Surveys Conducted from 2000 Through 2015

The Biopharmaceutical Section received 108 abstracts and is supporting 14 contributed sessions, in addition to speed sessions and contributed posters, in diverse topics including adaptive designs, Bayesian methodology and applications, biomarkers, missing data, multiplicity issues and solutions, non-inferiority trial challenges, statistical methods in different therapeutic areas and many more. Contributed session 231 includes presentations from the 2017 Biopharmaceutical Section Student Paper Competition winners.

We provided 15 roundtable discussion topics to the program, including Bayesian methodology, multiple endpoints, big data, precision medicine, statistical considerations in clinical trials and many more, to which our members will have a chance to contribute their perspectives to the discussions. The section is also co-sponsoring other contributed sessions jointly with other ASA sections and statistical societies.

Thanks to everyone who put forth an idea or proposal, leading to this excellent program. Additionally we thank members who have volunteered to chair contributed and speed sessions, and everyone who helped us to have such an exciting program this year.

For more information on the 2017 JSM program, please see: *ww2.amstat.org/meetings/jsm/2017/onlineprogram/index.cfm.*

We look forward to the 2018 Joint Statistical Meetings next year in Vancouver, British Columbia, Canada. We are fortunate to have Qi Jiang be the Biopharmaceutical Section representative to the 2018 JSM Program Committee. Online submission of invited session proposals for JSM2018 will open in July 2017 but if you have ideas already feel free to contact Qi at *qjiang@amgen.com*. ■

ASA Biopharmaceutical Section

PUBLICATIONS OFFICER UPDATE

Richard Zink, JMP Life Sciences, SAS Institute

Hi, Folks! Here is an update on Publication Team activities.

See paper and poster award winners and view winning posters. Be sure to congratulate upcoming winners from JSM 2017 and the 2017 Regulatory-Industry Statistics Workshop! *http://community.amstat.org/biop/awards/pastwinners*

View events of interest from the Biopharm Section and related professional organizations. *http://community.amstat.org/biop/events/recentcommunityeventsdashboard.*

- Register for the 2017 Regulatory-Industry Statistics Workshop. Guess what? It's time to register! Do it now! Advanced registration ends August 30th. *http://ww2.amstat.org/meetings/biopharmworkshop/2017/registration.cfm*
- Get the latest news on the Nonclinical Biostatistics Conference.
- View the webinar archive or find upcoming webinars. Be sure to register, webinars are free for BIOP members! *http://www.amstat.org/education/weblectures/index.cfm*

  This fall, webinars include:

  Applying a Bayesian Decision-Theoretic Framework to Design Biomarker-Driven Studies in Early Phase Clinical Development. Danny Yu (Eli Lilly & Co), Friday, September 29, 2017.

  Quantitative Sciences for Safety Monitoring during Clinical Development. Greg Ball (Merck), Judy Li (Regeneron) & William Wang (Merck), Tuesday, October 10, 2017.

- Take a half- or full-day online course with the Online Training Program

Check out the new menu for Scientific Working Groups (SWGs). Visit the Nonclinical Biostatistics Working Group (*http://community.amstat.org/biop/workinggroups/ncbwg/index*), explore the new Clinical Trial Designs with Re-Randomization of Subjects SWG (*http://community.amstat.org/biop/workinggroups/rrs/rrs-home*), or review the publications and efforts of the Safety SWG (*http://community.amstat.org/biop/workinggroups/safetywg*). Get so inspired, submit a proposal for your own SWG (*http://community.amstat.org/biop/aboutus/new-item/swg)*.

Get involved with the mentoring program! *http://community.amstat.org/biop/aboutus/new-item/mentoring*

Bored? Listen to a podcast! You can subscribe via iTunes (*www.buzzsprout.com/16296*). 2017 Episodes include:

- **Episode 37:** Aloka Chakravarty, Laurie Letvak & Bill Wang discuss multiregional clinical trials.
- **Episode 38:** Amanda Golbeck discusses her book Leadership and Women in Statistics.
- **Episode 39:** Alex Dmitrienko discusses multiplicity and the BIOP pilot online training program.
- **Episode 40:** Yuki Ando, Frank Bretz, Rob Hemmings & Tom Permutt discuss estimands.
- **Episode 41:** Liz Stuart discusses the Health Policy Statistics Section and the upcoming 2018 International Conference on Health Policy Statistics.
- **Episode 42:** Reneé Moore & Janelle Charles discuss the ASA Committee on Minorities in Statistics.
- **Episode 43:** Andy Grieve, Nigel Howitt, John Lewis & Lucy Rowell celebrate the 40th Anniversary of Statisticians in the Pharmaceutical Industry (PSI)
- **Episode 44:** Weili He & Martin Ho tell us what to expect at the 2017 Regulatory-Industry Statistics Workshop.

If you have an idea for a webinar, podcast, or an article for the Biopharmaceutical Report, please get in touch at *richard.zink@jmp.com*.

DIA BAYESIAN SCIENTIFIC WORKING GROUP KOL LECTURE SERIES

The DIA Bayesian Scientific Working Group (BSWG) was formed in 2011 with a vision to ensure that Bayesian methods are well understood and broadly utilized for design and analysis throughout the medical product development process and to improve industrial, regulatory, and economic decision making. The group is fast-growing, currently comprised of over 100 individuals from academia, industry and regulatory authorities. This working group is further supported by more than 10 subteams, each focusing on a specific topic such as missing data, pediatrics/small population drug development, and education. For the last few years, the working group members have actively participated in organizing multiple professional meetings and workshops while publishing several papers in peer-reviewed journals. Moreover, the members enjoy the network and collaboration provided by this group for research purposes and beyond.

The BSWG is excited to announce that starting in June of this year we have initiated a key opinion leader (KOL) lecture series as part of the continuing education and outreach effort to enable the use of Bayesian methods in drug development. The KOLs will be held on a monthly basis, targeting the third Friday of the month. They are completely free of charge, lasting up to 2 hours (1 hour of presentation, and the rest of time allows flexibility for going over case studies, Q&A, etc). The series was successfully kicked off by a presentation from Dr. Scott Berry on "Bayesian Methods in Pharmaceutical Development and Clinical Trial Design." Nearly 150 people joined remotely, afterwards expressing appreciation of both the relevancy of the content and quality of the presentation. This presentation and future KOL presentations can be accessed via our website: *www.bayesianscientific.org/kol-lecture-series*.

The BSWG looks forward to continuously furthering Bayesian research and is open to anyone who is interested in joining this effort. To join the group and receive KOL lecture announcement, you can simply provide your name and email here: *www.bayesianscientific.org/join-us*. More information on the BSWG can be found at *www.bayesianscientific.org*. ■

THE 73RD ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

The Annual Deming Conference on Applied Statistics provides a learning experience on recent developments in statistical methodologies. The conference is composed of 12 3-hour tutorials of current advanced methodologies; poster sessions; and a one hour plenary regulatory session on each of the first three days. It is followed by two 2-day parallel short courses. Authors of recently published statistical books as well as experienced statisticians working in regulatory, industry, and academics are invited to teach the tutorials and the short courses. The conference sells the books used in the tutorial and short courses at a 40% discount. Registrants are welcome to submit abstracts to present and display posters during the conference.

Sponsored by:

American Society For Quality
NY/NJ Metropolitan Section & Statistics Division

American Statistical Association
Biopharmaceutical Section

When: December 4–8, 2017

Where: Tropicana Casino and Resort, Havana Tower, Atlantic City, New Jersey

Register: Online registration will open by the end of August, 2017

The complete program will be on ***www.demingconference.com***.

SEE THE COMPLETE CONFERNCE SCHEDULE ON **PAGE 16**

SEVENTY THIRD ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

MONDAY DECEMBER 4

Registration: 6:30 a.m.–8 a.m.
Hot Breakfast 7 a.m.–8 a.m.

8 a.m. –9 a.m. Roles of Biostatisticians In New Drug Development and Regulatory Review

■ Dr. Yuki Ando; Senior Scientist for Biostatistics; Pharmaceuticals and Medical Devices Agency; Japan

SESSION A
Hot Topics in Clinical Trials: Multiple Outcomes and Benefit: Risk

■ Dr. Toshimitsu Hamasaki, Osaka University and National Cerebral and Cardiovascular Center, Japan

■ Professor Scott R. Evans; Harvard School of Public Health

Moderator: Ivan S. F. Chan

SESSION B
Missing Data Analysis Using SAS®

■ Drs. Frank Liu (Merck) and Fang Chen (SAS® Institute)
Moderator: Xiaoming Li

Lunch (On Your Own)
12 p.m. – 1:30 p.m.

SESSION C ★
Regulatory Science and Drug Development in China

■ Professor Naiqing Zhao (Fudan University) and Dr. Jie Chen (Merck)

Moderator: Xiaoming Li

SESSION D ★☆
Phase II Clinical Development of Drugs

■ Drs. Naitee Ting (Boehringer Ingleheim) and Shuyen Ho (UCB)

Moderator: Ivan S. F. Chan

7:00 p.m. Speaker's Dinner (Optional Added Fee Event)

TUESDAY DECEMBER 5

Registration: 6:30 a.m.–8 a.m.
Hot Breakfast 7 a.m.–8 a.m.

8 a.m. –9 a.m. Bridging Study Evaluation and MRCTs in Taiwan: Regulatory Perspectives and Experiences

■ Dr. Guei-Feng Tsai; Statistical Team Leader; Division of New Drugs; Center for Drug Evaluation; Taiwan

SESSION E ★☆
Generalized Linear Models

Professor Alan Agresti, University of Florida

Moderator: Wenjin Wang

SESSION F ★
Likelihood-Based Methods for Continuous Safety Monitoring of Pharmaceutical Products

Drs. William Wang (Merck), Krishan P. Singh (GSK) and Ram Tiwari (FDA)

On Behalf of the ASA Safety Monitoring Working Group

Moderator: Kalyan Ghosh

Lunch (On Your Own)
12:15 p.m.–1:45 p.m.

SESSION G
ICH E17 and Multi-Regional Clinical Trials (MRCTs)

Dr. William Wang, Merck

Moderator: Kalyan Ghosh

WEDNESDAY DECEMBER 6

Registration: 6:30 a.m.–8 a.m.
Hot Breakfast 7 a.m.–8 a.m.

8 a.m. –9 a.m. Regulatory Hot Topics in Europe

■ Frank Pétavy; Biostatistics and Methodology Support, R&D Division; European Medicines Agency; London, UK

SESSION I ★
Benefit–Risk Assessment and Utility of Real World Evidence in Medical Product Development and Life Cycle Management

■ Drs. Weili He (Abbvie) and Qi Jiang (Amgen)

Moderator: Alfred H. Balch

SESSION J ★
Dose-Finding in Clinical Development

Dr. Qiqi Deng, Boehringer Ingleheim

Moderator: Naitee Ting

Lunch (On Your Own)
12:15 p.m.–1:45 p.m.

SESSION K
Statistical & Strategic Considerations in Development of Oncology Immunotherapies

Dr. Cong Chen, Merck

Moderator: Naitee Ting

SESSION L ☆
Meta-Analysis and Network Meta-Analysis in Clinical Trials

Dr. Joseph C. Cappelleri (Pfizer) and Prof. Din Chen (UNC Chapel Hill)

Moderator: Walter R. Young

THURSDAY DECEMBER 7

Short Course Registration: 6:30 a.m.–8 a.m.

Hot Breakfast 6:30 a.m.–8 a.m.

8:00 a.m. – 9:30 a.m. Lecture

9:30 a.m. 9:50 a.m. Break

9:50 a.m. – 11:20 a.m. Lecture

11:20 a.m. – 12:40 p.m.
Lunch on Your Own

12:40 p.m. – 2:10 p.m. Lecture

2:10 p.m. – 2:30 p.m. Break

2:30 p.m. – 4:00 p.m. Lecture

4:00 p.m. – 4:20 p.m. Break

4:20 p.m. – 5:50 p.m. Lecture

GUIDE Approach to Subgroup Identification and Analysis for Precision Medicine

Professor Wei-Yin Loh, University of Wisconsin

Moderator: Ivan S. F. Chan

Multiplicity Issues in Clinical Trials ☆

Dr. Alex Dmitrienko, Mediana, Inc.

Moderator: Alfred H. Balch

Text: Multiple Testing Problems in Pharmaceutical Statistics

FRIDAY DECEMBER 8

Hot Breakfast 7 a.m.–8 a.m.

8:00 a.m. 9:30 a.m. Lecture

9:30 a.m. 9:50 a.m. Break

9:50 a.m. – 11:20 a.m. Lecture

11:20 a.m. – 12:00 p.m.
Lunch on Your Own

12:00 p.m. – 1:30 p.m. Lecture

★ Sessions will have their breaks extended by 15 minutes for Poster Presentations

☆ Presentation is based on a recently published text

All tutorial & short course titles, presenters and moderators from 1989 onwards can be found on www.demingconference.com