

# 2020 Section on Medical Device and Diagnostics Business Meeting

*2020 Section on MDD Officers*

*September 1, 2020, 8 – 9 am PST*

# 2020 MDD Business Meeting Agenda

Welcome from MDD Chair

Martin Ho (FDA CBER)

Program Chair

Tyson rogers (NAMSA, Inc.)

Section Representative

Joanne Lin (Biogen)

Treasurer

Chava Zibman (FDA CDRH)

Student Paper Committee Chair

Bin Wang (FDA CDRH)

Communication Secretary

Howard Yao (FDA CDRH)

2021 Chair

Scott Evans (GWU DDB)

2021 Program Chair

Laura Yee (NIH NCI DCTD)

Questions, Comments and Ideas?

Special Thanks to Hongfei Guo (Abbott),  
our Corresponding Secretary!

# Your Chair

Martin Ho, MS

Associate Director, Office of Biostatistics & Epidemiology  
Center for Biologic Evaluation & Research, FDA



- **Welcome!**
- **Meeting video will be recorded and made available**
- **Congrats the Officers-Elect 2021**
  - 2022 Chair, Norberto Pantoja-Galicia (FDA CDRH)
  - 2022 Program Chair, Tracy Bergemann (Medtronic)
- **Invited Sessions Proposal due by September 8, 2020!**
- **Accomplishments in 2020**

# Our Program Chair

Tyson Rogers, MS

Product Development Strategist, Biostatistics

NAMSA Inc.



## JSM 2020 Virtual Meeting

Thank you to organizers, presenters, and chairs!

- **Invited Sessions (2)**

- Wearable/Implantable Device Data in Clinical Trials [Allocated]
- Recent Statistical Advances in Diagnostic Medicine [Competition!]

- **Topic-Contributed Sessions (2)**

- Current and Future Challenges in Diagnostic Device Evaluation
- Benefit-Risk Methods for Medical Devices and Diagnostics

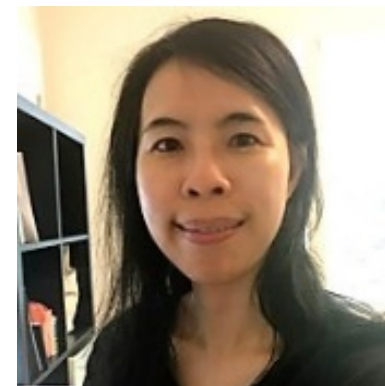
## Our Program Chair (cont.)

- **Contributed Paper Sessions (4)**
  - Methods Tailored to Unique Data and Trial Features
  - Methods and Modeling for Medical Device and Clinical Studies
  - Biomarker and Diagnostic Test Evaluation
  - Topics in Biostatistics
- **Contributed Poster Session (1)**

Looking forward to seeing everyone next year in Seattle.

# Our Section Representative

Ja-an (Joanne) Lin, PhD  
Sr. Principal Biostatistician  
Biogen



- **Encourages MDD to nominate ASA Fellows on its behalf**
- **Encourage MDD to recognize the service of its members**
- **Call for ideas to diversify the background of members in the section**
- **Sep 08 – 2021 JSM Invited Session proposal due (1 for MDD)**
- **Dec 10 – 2021 JSM Topic Contributed Session submission due**
- **MDD's turn to present award in 2021 JSM!**

# Our Treasurer

Chava Zibman, PhD  
Mathematical Statistician  
Center for Device and Radiological Health, FDA



- **Family duty**
- **Student paper awards in process**
- **Will provide financial report through announcement**

# Our Student Paper Competition Committee Chair

Bin Wang, PhD  
Mathematical Statistician  
Center for Device and Radiological Health, FDA



## Committee Members

- Bipasa Biswas, Ph.D. (FDA)
- Terri Johnson, Ph.D. (Dexcom)
- Qizhai Li, Ph.D. (AMSS)
- Aiyi Liu, Ph.D. (NIH)
- Laura Yee, Ph.D. (NIH)
- Wei Zhang, Ph.D. (NIH/AMSS)

- Each paper was evaluated by 3 committee members
- Evaluation criteria
  1. Clarity
  2. Contribution to statistics
  3. Applicability to MDD
- Select 2 winners



# 2020 Student Paper Competition Winners

## 1<sup>st</sup> Place

**Xiaochen Zhu** (George Mason University) “Order constrained ROC regression with application to facial recognition”

## 2<sup>nd</sup> Place

**Piyali Basak** (Florida State University) “Median regression models for clustered, interval-censored survival data -- An application to prostate surgery study”

**Fengyun Gu** (University College Cork, Ireland) “A statistical evaluation of alternative techniques for kinetic analysis of multiple injection dynamic PET scans”

# Our Communication Secretary

Zhihao (Howard) Yao, MS, MBA  
Mathematical Statistician  
Center for Device and Radiological Health, FDA



## ASA MDD Website

<https://community.amstat.org/mdd/home>

Join us at the 2020 MDD Section Business Meeting on Tuesday, September 1 at 11 am EST!

What's New

- 1. Check out our new section below highlighting two outstanding female statisticians of the Section each month in 2020.
- 2. Members in the News
  - a. Podcast of Biopharmaceutical Section: MaJuan Li (Episode 75)
  - b. Pool of Asclepius: Martin Ho and Greg Malsin (January 8, 2020)
- 3. Congratulations to the Winners of this year's Student Paper Competition!
  - a. First place: Mr. Xiaochen Zhu (George Mason University, USA, Advisor Martin Slawski.)
  - b. Second place: Ms. Priya Basak (Florida State University, USA, Advisor Debajyoti Sinha)
  - c. Second place: Ms. Fengyun Gu (University College Cork, Ireland, Advisor Finbarr O'Sullivan.)
- 4. Latest Section Officer Meeting Minutes
- 5. Meet your Section Officers

New! Statisticians of the Month

To celebrate Women in Statistics, each month we highlight two members who have made significant contributions to statistics of medical devices and diagnostics.

MaJuan Li

Zheyu Wang

Latest Discussion

Invitation: 2020 MDD Business Meeting September 1 at ...

FDA-ORISE RESEARCH FELLOW position in STATISTICS for ...

SBR is now making its new issue available online

# ASA MDD Website

## Statisticians of the Month: June 2020



Usha Govindarajulu

**Q:** Can you tell us a bit about your background and your connection to statistics?

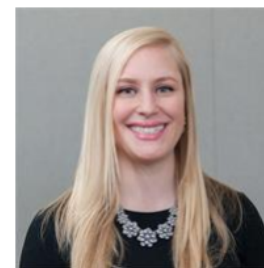
**Usha:** I was born in Lexington, Kentucky and I grew up there as well. My interest in statistics came from inspiration from my father, who was a longtime statistician and professor. He inspired me to switch from biology background obtained in college and I then obtained my first master's degree to biostatistics, which he felt would allow me to combine both biology and statistics. I came to enjoy the field in a Master's degree and continued on to do a doctorate in biostatistics from Boston University as well as post-doctoral work at Harvard School of Public Health.

**Q:** What got you interested in medical devices and diagnostics?

**Usha:** A cardiologist with whom I worked at Brigham & Women's Hospital, Dr. Fred Resnic, was doing research in medical device safety surveillance and I became involved. From there, he guided me in learning curve research in cardiac device safety. I then continued doing this research as a consultant for him and generated three first author publications, where I extended the method to survival analysis in the third publication. This research gained repeated interest from the Food & Drug Administration statisticians when they saw our research presented at the annual Joint Statistical Meetings between the years, 2017-2019, and I have advised them about my methods. Our research was also featured in a syndicated national radio broadcast called "Public Health Minute" and continues to be featured on their website.

**Q:** Any words of wisdom to other statisticians who may be just starting out?

**Usha:** I would say, try to be inspired by what is around you in terms of the real world and try to find a good mentor who can really guide you and inspire you. Also, keep pushing yourself to learn every day.



Anne Eaton

**Q:** Can you tell us a bit about your background and your connection to statistics?

**Anne:** I have loved math since I was a kid, and I became interested in biostatistics and medicine after taking AP Biology in high school. During college, I had the opportunity to participate in SIBS at the University of Wisconsin, where I started to understand the wide scope of biostatistics. I also observed that biostatistics attracts a certain type of person who I enjoy working with: analytical problem solvers who value improving health and practical solutions. After college, I did my MS in Biostatistics at the University of Minnesota and then worked for six years as a biostatistician at Memorial Sloan Kettering Cancer Center. Now, I am back in school, pursuing a PhD in Biostatistics at Minnesota. My research is in survival analysis, and I'm enjoying developing methods to fill in the gaps I saw when I was working.

**Q:** What got you interested in medical devices and diagnostics?

**Anne:** First of all, I'm awed by the science and technology that make devices and diagnostics possible, and I enjoy learning more about them. Secondly, on a personal level, these products are improving the health of people I love everyday.

**Q:** Any words of wisdom to other statisticians who may be just starting out?

**Anne:** For those who are interested in doing statistical methodology research, a useful lesson I am still learning is to stay focused. Many of us have studied a lot of math, and our tendency may be generalize: to try to find universal solutions and explore every possible case. To make progress, we may need to rein ourselves in. When we're doing data analysis, the available data help keep the scope limited, but when we're doing statistical methodology research, we need to do it ourselves.

# ASA MDD Website

## Statisticians of the Month: July 2020



Telba Irony

Dr. Irony is Deputy Director of the Office of Biostatistics and Epidemiology at CBER. She joined FDA to implement the use of Bayesian statistics for the regulation of medical devices and led the Decision Analysis initiative including Bayesian statistics, benefit-risk determinations, and science of patient input. Telba received the 2014 FDA Excellence in Analytical Science Award for spearheading innovative regulatory science studies culminating in the release of novel guidance documents, supporting policy decision making, and changing the submission review paradigm. She has a PhD from Berkeley, is a fellow of the American Statistical Association, and elected member of the International Statistical Institute.

### Can you tell us a bit about your background and your connection to statistics?

I started as a Physics major at the University of Sao Paulo in Brazil and the most engaging professors were in Statistics. I decided to get a second major in Statistics and really enjoyed it because of the ability to apply it to many different areas and because I had great and inspiring instructors. I finished college with a double degree in Physics and Statistics and started to work in the Decision Support group at the second largest private bank in Brazil. One of our projects was to predict inflation, which was huge at that time. To that end, we used econometric models and time series. We also had to estimate how much cash to leave at teller machines over the weekends. Too much and the bank would incur a significant loss due to high inflation. Too little and the clients would be unhappy. We used cluster analysis and decision analysis to solve the problem. Since I was torn between an academic career and working at the bank, where my skills were applied to solve urgent and real problems, my boss encouraged me to pursue an MS degree in Bayesian Statistics while working at the bank. After finishing my studies, I received a scholarship to complete my doctorate at the University of California, Berkeley. My advisor was Prof. Richard Barlow who had a joint appointment at the department of Statistics and the Department of Operations Research in the School of Engineering. Due to my interest in Bayesian Statistics, both Prof Barlow and Professor David Blackwell, who was my mentor, encouraged me to join the Department of Operations Research whose program was concentrated in Bayesian Statistics and Decision Analysis.

### What got you interested in Medical Devices?

After completing my PhD at Berkeley, I started an academic career at the department of Operations Research at the George Washington University.

A few years later, Dr. Greg Campbell, the director of the division of Biostatistics at the Center for Devices and Radiological Health at the Food and Drug Administration started an initiative to use Bayesian Statistics for the regulation of medical devices. I was hired and, along with my colleague Dr. Gene Pennello, helped to introduce Bayesian Statistics in the regulation of medical devices at the FDA. It has been a wonderful ride and working at the FDA has been a blessing. I encountered the most interesting practical problems to be solved using quantitative methods and got to contribute to public health.

### Any words of wisdom to other statisticians who may be just starting out?

Embrace the uncertainty that comes with life. As a statistician, you will get to work with all kinds of applications, even with some that we cannot imagine today. Be willing to experiment and use your creativity. You will be taken to wonderful places.



Donna McClish

Dr. Donna is Professor at Department of Biostatistics, Virginia Commonwealth University. Early in her research career, accuracy was generally assessed by the area over the entire range of possible false positive rates. However, she recognized that not all false positives may be of clinical interest. Therefore, she developed a method to assess accuracy by only looking at partial area under a clinically-relevant portion of the ROC curve. [McClish, 1989] Her other contributions on ROC curve include identifying the range of false positive rates for which ROC curves, and hence tests differ in accuracy [McClish, 1990]; developing methods to combine accuracy measures across strata or studies such as in meta-analysis [McClish, 1992] and comparing area under more than 2 ROC curves [McClish, 1987]. More recently, she and her students have been developing methods to efficiently combine information from medical tests by performing them in sequence, e.g., a new, less costly combination strategy that only requires a second test when results of the first test are indeterminate [Ahmed, 2011], testing strategies with sensitivity non-inferior to the best achievable sensitivity [Ahmed, 2013], and optimal thresholds for these sequential testing strategies [McClish, 2019]. She co-authors the book "Statistical Methods in Diagnostic Accuracy" (1<sup>st</sup> and 2<sup>nd</sup> editions).

### Can you tell us a bit about your background and your connection to statistics?

I was a math major in the honors college at University of Michigan, but I didn't have a direction for a career after graduation. As an upperclassman I was able to make a few dollars by grading for a statistics professor. He urged me to consider going to graduate school in statistics, which was the first time I had considered such. Then he told me that they would pay my way! Even better! I ended up at University of North Carolina – Chapel Hill, in the Mathematical Statistics department. Hadn't really escaped pure math. After a couple years, somehow, I was offered an assistantship in the Dept of Biostatistics. That changed my life. It was exciting to apply statistics to practical problems in the public health and medical fields. My father always wanted me to go to medical school. I wouldn't/couldn't do that (can't stand blood!) but I could work in the medical field using my math background.

### What got you interested in medical devices and diagnostics

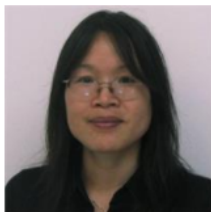
I first learned about ROC curves in the context of mortality predictions in the ICU. Then clinicians began asking me what to do when ROC curves crossed. Such an interesting question led me to partial ROC curves and many other similar issues.

### Any words of wisdom to other statisticians who may be just starting out?

Be open. When possible, let specific applications and research questions inspire you, possibly taking you in a different direction than you might not have initially anticipated. It could be fun.

# ASA MDD Website

## Statisticians of the Month: August 2020



Meijuan Li

### Can you tell us a bit about your background and your connection to statistics?

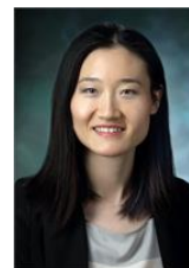
Dr. Meijuan Li is currently VP, Head of Biomarkers and Biometrics, Foundation Medicine, manage the Biometrics and Biomarkers team, including functional units of Biostatistics, Data Management, and Biomarker analysis and Development. Prior to joining FMI, Dr. Meijuan Li was the chief of Diagnostic Statistics in the Center for Devices and Radiologic Health (CDRH) at the U.S. Food and Drug Administration. Dr. Li has extensive regulatory statistical review experience including many cutting-edge genetic/genomic diagnostic devices and is one of leading statistical experts in the area of companion diagnostics. She has published numerous manuscripts and book chapters in various areas including Bayesian statistics, survival analysis, missing data, and personalized medicine.

### What got you interested in medical devices and diagnostics

Dr. Li was an accomplished molecular biologist before she became interest in statistics, and she had over ten-year working experience in genetic and genomics with a joint patent on maize drought resistance biomarker. Dr. Meijuan Li received her PhD in biostatistics from the University of Minnesota in 2008. There, she worked with Dr. Cavan Reilly on developing statistical methods for genetic association studies and genomic studies. Her interest has always been in statistical methods for genetics, genomics, and diagnostic medicine, in medical devices and diagnostics. In particular, Dr. Li focuses on statistical methods for detecting, mapping, and isolating genes involved in complex diseases such as cancer. Through these methods, she hopes to provide targets for molecular and precision medicine.

### Any words of wisdom to other statisticians who may be just starting out?

As a statistician, you must ensure the conclusions which can be supported by data and careful assumptions. You must not stop with the obvious or even the most likely explanation of data, but find ways to examine them so that all rational viewpoints can be informed. This means that you will work harder and longer than anyone who reads your reports will ever know.



Zheyu Wang

### Can you tell us a bit about your background and your connection to statistics?

I was a math major with a focus in statistics at Peking University. Mathematics and its applications but more generally, sciences, have always interested me. The reasons are probably their factuality combined with uncertainty. I had a few undergraduate projects related to disease diagnosis, website classifications, etc. The more systematic training in biostatistics was during my study at the University of Washington, which is also where I start to concentrate my focus from statistics to biostatistics. Surprisingly, I learned afterward that my grandfather, who was considered a doctor, actually spend quite some effort in biostatistics/epidemiology and was probably one of the first generations in China: he wrote books and notes on these topics that circled in the hospitals and research communities, at which time statistics was not a stand-alone field whereas biostatistics was rarely heard of.

### What got you interested in medical devices and diagnostics

The initial exposure was during an undergraduate project, where the aim was to assess the diagnostic accuracy of traditional Chinese medicine doctors. How I landed the project has a lot of randomness and luck, but I was and still am interested in the theory, connections, and differences of traditional Chinese medicine and western medicine. During my graduate school, the University of Washington and Fred Hutchinson Cancer Research Center provided the best environment for researches in medical diagnosis. I was lucky enough to have worked with many of the leaders in the field, such as Drs. Andrew Zhou, Margaret Pepe, and Patrick Heagerty. And my undergraduate project has also grown further and become part of my dissertation. I continue to work in this area after joining the faculty at Johns Hopkins University. The deeper and wider involvement in the research process as a faculty made me further appreciate the impact of diagnostic related research: it is the first step toward successful treatment, especially with the effort to improve individualized healthcare; the advancement in the field can help traditionally correctly diagnosed patients to have more tailored healthcare, it can also prevent traditionally misdiagnosed patients to miss the optimal intervention opportunity or to have unnecessary stress. Improving treatment is certainly important and there is a lot of effort in that, but I was shocked by the magnitude of harms and its societal burden that resulted from diagnostic errors and could have been prevented. In response, I am leading the biostatistical methodological development in a collaborative research effort to reduce diagnostic errors based on claims data and electronic health records.

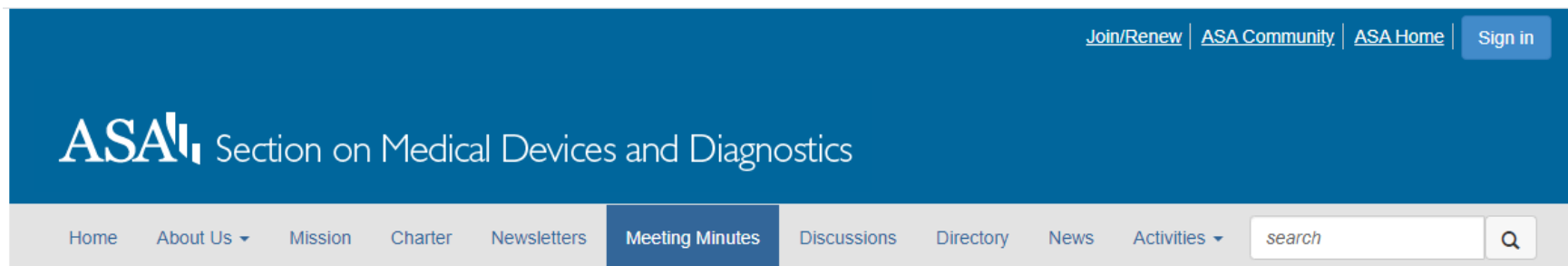
### Any words of wisdom to other statisticians who may be just starting out?

Even though my research focus in diagnosis seems a straight path, I asked my advisor, and he kindly agreed, to take a year and exploit other research fields in biostatistics before entering my dissertation project. That did not end up changing my research focus or contribute to my dissertation, but I still think it has been a very beneficial "sidestep" for me, as many of the topics are surprisingly connected. In addition, follow what interests you rather than what is hot. I was suggested to change to clinical trials rather than focus on diagnosis because diagnosis has a rather narrow outlet at the time, but look at how it has grown today.



# ASA MDD Website

## MDD Officer Meeting Memo



### Meeting Minutes

[MDD Officer Meeting Minutes 26Jun2020](#)  
[MDD Officer Meeting Minutes 24Apr2020](#)  
[MDD Conference Call 2017 01\\_minutes.docx](#)  
[MDD Officer Meeting Minutes 03112019](#)  
[MDD officers meeting at JSM 2016.doc](#)  
[MDD Officer Meeting Memo 9\\_20\\_2018](#)  
[MDD Officer Meeting Memo 10\\_18\\_2018](#)  
[MDD Officer Meeting Memo 4\\_19\\_2018](#)  
[MDD Officer Meeting Memo 5\\_17\\_2018](#)  
[MDD Officer Meeting Memo 3\\_25\\_2018](#)  
[MDD Officer Meeting Memo 02\\_15\\_2018](#)  
[MDD officer meeting notes Jan 18 2018](#)  
[MDD Officers Meeting Minutes 2017\\_12](#)  
[MDD Section Officers Meeting 20150809](#)  
[MDD General Meeting 20150810](#)

Thanks to Hongfei Guo (Abbott),  
our Corresponding Secretary for  
taking the excellent minutes!

# ASA MDD Website

## Conferences and Events Banner



# ASA MDD Website

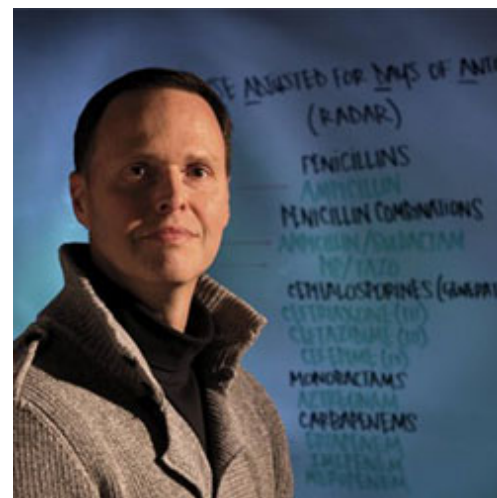
## New Member Welcome Letter

- Month data query
- Automatically send welcome letter email



# MDD Chair 2021: Scott Evans, PhD

- Director of the Biostatistics Center
- Founding Chair and Professor, Department of Biostatistics and Bioinformatics
- Milken Institute School of Public Health
- George Washington University
- ASA Activities
  - President, Boston Chapter (2003-2006)
  - Chair, Section on SIS (2007)
  - Chair, Section on TSHS (2008)
  - Chair Development Committee (2009-2011)
  - Executive Editor, CHANCE (2014-2019)
  - Program Chair for MDD (2016)
  - Board of Directors (2018-2020)
  - Founders Award Committee (2018-2020)
  - Task Force on P-values and Statistical Significance (2019-2020)



# 2021 JSM Program Chair- ASA MDD

Laura Yee, PhD

National Cancer Institute, NIH

Division of Cancer Treatment and Diagnosis

Biometric Research Program



JSM 2021 Timelines:

- Invited Session Proposals Due: **September 8**
- Topic Contributed Session Proposals Due: **December 10**
- Contributed Proposals Due: **February 2**

**Any questions, comments, or ideas for us?**  
*Go to: <https://community.amstat.org/mdd/home!>*

