Dear all,

The ASA NJ Chapter Spring symposium in 2020 has been converted into a series of webinars due to the pandemic. The first webinar is on June 19 with a very interesting topic on the design of Covid-19 Vaccine trials using RWD/RWE. Please see below for more details on this webinar.

ASA NJ Spring Symposium Committee:
Shiling Ruan, Jing Gong, CV Damaraju, Steve Ascher, Dirk Moore, Eunhee Kim

ASA NJ Chapter Webinar Series: June 19, 2020, 11:00-12:00 EDT

Webinar Title: Statistical Considerations in the Design of COVID-19 Vaccine Trials Using Real-World Data and Evidence

Speaker: Jie Chen PhD and Richard Baumgartner, PhD, Biostatistics and Research Decision Sciences, Merck & Co., Inc., Kenilworth, NJ 07033, USA

WebEx links: If you would like to add the invite to your calendar, please click the link below and register (take less than 1 minute). Your will receive the WebEx invite by email.

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Abstract:
The COVID-19 pandemic has triggered explosive activities in searching for cures, including vaccines against the SARS-CoV-2 infection. As of April 30, 2020, there are at least 102 COVID-19 vaccine development programs worldwide, the majority of which are in preclinical development phases, five are in phase I trial, and three are in phase I/II trial. Experts caution against rushing COVID-19 vaccine development, not only because the knowledge about SARS-CoV-2 is lacking (albeit rapidly accumulating), but also because vaccine development is a complex, lengthy process with its own rules and timelines. Clinical trials are critically important in vaccine development, usually starting from small-scale phase I trials and gradually moving to the next phases (II and III) after the primary objectives are met. In this talk, we will first review the vaccine development process and then discuss how real-world data and evidence (RWD & RWE) can assist COVID-19 vaccine clinical development in the pandemic paradigm. Specifically, we will discuss the rationale, design options, challenges, possible remedies, and illustrative examples of other vaccine effectiveness trials for regulatory decision-making. The
take-home message is that RWD & RWE can be leveraged to expedite COVID-19 vaccine development.

**Jie Chen Bio:**

![Jie Chen](image)

Jie is a Distinguished Scientist in Methodology Research at Merck Research Laboratories of Merck Sharp & Dohme (MSD). Before rejoining Merck in February 2017 (he worked at Merck from 1995-2009), Jie worked in China for six and a half years, leading statistics and statistical programming groups for global pharma companies to support drug development globally and in China.

Jie received an M.D. in 1984 from Shanghai First College of Medicine, an MPH in 1994 in biostatistics & epidemiology from the University of Oklahoma Health Science Center, Oklahoma City, and a Ph.D. in 2003 in statistics from Temple University, Philadelphia, Pennsylvania.

Jie’s experience includes statistical methodology research and applications in non-clinical and pre-clinical research, clinical development, and post-licensure product life-cycle management. He has given short courses at FDA/Industry statistics workshop, EMA statistics symposium and many invited talks at academic institutions and statistical conferences. He has published a book on medical product safety and ~40 papers in peer-reviewed statistical and medical journals.

**Richard Baumgartner Bio:**

![Richard Baumgartner](image)

Dr. Baumgartner is a Sr. Principal Scientist with Biometrics Research Department, Biostatistics and Research Decision Sciences (BARDS), Merck and Co. While at Merck, he has been supporting
early clinical and preclinical studies with imaging component including functional Magnetic Resonance Imaging (fMRI), dynamic contrast-enhanced MRI (DCE-MRI) and Positron Emission Tomography (PET) imaging for neuroscience, inflammation and cardiovascular therapeutic areas. Currently he is also involved in several projects in Real World Data (RWD) space and he contributes to the BARDS RWD working group. Previously he was Associate Research Officer with the Institute for Biodiagnostics, National Research Council Canada in Winnipeg, Canada, where he pioneered development of methods for exploratory analysis of fMRI. At the Institute for Biodiagnostics, he also worked on metabolomic applications to develop diagnostic biomarkers for prediction of pathogenic fungi and breast cancer.