BBSW2020 Virtual Symposium

2 Balancing Speed and Evidence in Developing COVID-19 Therapies

Program Book and Speakers Bio

Nov 5th, 8:30 AM – 12:30 PM PST

8:30am	Welcome and Raffle
8:40am	*Keynote* **Peter Bach, MD, MAPP** ***The inflexible paradox of scientific research: Urgency demands patience***
9:15am	**Thomas Jaki, PhD** ***Designing efficient clinical trials during a pandemic: Some personal lessons from the RECOVERY trial***
9:50am	**Natalia (Natasha) Mühlemann, MD, MBA** **Rajat Mukherjee, PhD** ***A Bayesian design for COVID-19 trials with focus on***
10:35am	**Julia Niewczas, PhD** ***Statistical challenges of designing COVID-19 therapeutic and prophylaxis trials***
11:10am	**Hemal B. Mehta, PhD** ***Balancing speed and evidence in COVID-19 trials***
11:25am	Panel Discussion
12:25pm	Closing

Peter Bach, MD, MAPP

Director, Center for Health Policy and Outcomes
Memorial Sloan Kettering Cancer Center

Balancing speed and evidence in COVID-19 trials

Dr. Bach is a physician, epidemiologist, researcher, and healthcare policy expert who studies US health care policy at Memorial Sloan Kettering, is a Senior Scholar at the International Agency for Research on Cancer within the World Health Organization and Chairs the Medicare committee charged with evaluating Coverage Policy. In 2012, he and other Memorial Sloan Kettering physicians drew attention to the high price of the cancer drug Zaltrap, leading the company to halve its US price. Along with Mark Trusheim, he developed the subscription based "Netflix" model now being used to finance [illegible] in Louisiana and Washington. His work on how cancer drugs are packaged in excessively large containers has led to legislation that is estimated to return more than $1B to Medicare over the next decade. Dr. Bach is a graduate of Harvard College, the University of Minnesota Medical School, and the Harris School for Public Policy at the University of Chicago. He has published more than 100 peer-reviewed articles and editorials in scientific journals such as the New England Journal of Medicine and the Journal of the American Medical Association and has been inducted into the National Academy of Medicine, the American Society for Clinical Investigation, the American Academy of Physicians, the Council on Foreign Relations, and the Johns Hopkins Society of Scholars.

BBSW Bay Area Biotech+Pharma Statistics workshop

Thomas Jaki

Professor in Statistics
Department of Mathematics & Statistics, Lancaster University

Designing efficient clinical trials during a pandemic: Some personal lessons from the RECOVERY trial

Thomas Jaki is Professor of Statistics at Lancaster University and Programme Leader at the MRC Biostatistics Unit at the University of Cambridge. He is an NIHR senior research fellow and Co-I of the UK-RECOVERY trial and co-leads its adaptive designs working group. His work focuses on efficient trials using adaptive and Bayesian methods.

Hemal B. Mehta, PhD

Assistant Professor
Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins

Balancing speed and evidence in COVID-19 trials

Dr. Hemal B. Mehta is an Assistant Professor in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. His research focuses on studying the utilization, safety and effectiveness of medications, primarily in older adults. He uses large administrative claims and electronic health records data to generate real-world evidence to guide clinical decision making and health policy decisions. He also conducts methodologic research to control confounding and selection bias in real-world studies. He is actively involved with National COVID Cohort Collaborative (N3C) and co-leads a task team on pharmacoepidemiology for COVID-19 research. Dr. Mehta received Master's and Ph.D. in Pharmacy Administration from the University of Houston and Bachelor's degree in Pharmacy from India.

Natalia (Natasha) Mühlemann, MD, MBA

Vice President, Strategic Consulting, Cytel

A Bayesian design for COVID-19 trials with focus on vaccines development

Natalia Muhlemann has over 15 years of experience in General Management, International Marketing, Business Development and Clinical Development in Life Sciences across several therapeutic areas, including intensive care, surgery, oncology, neurology, rehabilitation and diabetes.

Natalia combines medical and strategic expertise enhancing business value through clinical and real world evidence generation, medical & scientific interactions and stakeholders' engagement. Natalia has years of experience in direct-to-patient marketing.

In her recent positions of Global Business Manager, Medical Devices and Global Category Head, Acute Care – Oncology – Devices at Nestle Health Sciences, Natalia have been leading due diligences, business plan development, technical and clinical development, RA plans and market access strategy for new technologies. Natalia has been invited to European MedTech meetings as panel speaker and expert jury member.

Natalia has been leading the integration of adaptive designs into comprehensive evidence development strategies that combine clinical, regulatory, market access and commercial plans. At Cytel, Natalia leads Clinical Development, Regulatory, Market Access and Commercialization practice.

Member of European Society of Intensive Care Medicine, American Heart Association, European Society for Medical Oncology and European Stroke Organization, Natalia continues her professional development through conferences, participation to Working Groups and Executive Education programs.

Rajat Mukherjee, PhD

Research Fellow, Strategic Consulting, Cytel

A Bayesian design for COVID-19 trials with focus on vaccines development

Rajat Mukherjee, has over 20 years of professional experience as a statistician both in industry and academia. As a distinguished member of Cytel's Strategic Consulting team, Rajat was awarded a Research Fellowship in 2020. Rajat's research activities focus on several areas of statistics including design and analysis of clinical trials, Bayesian clinical trials, adaptive designs, design and analysis of complex epidemiological studies, survival and longitudinal analysis, statistical computing, nonparametric and semiparametric inference, statistical classification, machine-learning and high-dimensional data.

Prior to Cytel, Rajat was a Senior Biostatistician at Nestlé Global R&D Centre in Switzerland. He was also lead biostatistician for a number of epidemiological and behavioral studies in the areas of infectious diseases and cardiovascular disease at the New York Academy of Medicine and during his tenure as an assistant professor at the Indian Institute of Public Health.

At Cytel, in parallel to his research activities, Rajat leads quantitative strategy and data science projects in the areas of complex innovative design, devices and diagnostics, biomarker discovery and real-world evidence.

Rajat has a strong background and interest in development and implementation of innovative statistical methodology. Recent projects include: Bayesian and frequentist adaptive designs for medical devices & diagnostics, drugs & biologics in rare diseases, oncology, cardiovascular and neurodegenerative disease; FDA/EMA interactions; implementation of pivotal COVID trials for vaccines and therapeutic interventions; machine learning; the development of custom Bayesian software for the design and analysis of clinical trial and real-world data.

Julia Niewczas, PhD

Principal Clinical Trial Design Methodology Expert / Principal Statistician, AstraZeneca

Statistical challenges of designing COVID-19 therapeutic and prophylaxis trials

Julia is a clinical trial design methodology expert in the Biopharmaceuticals Statistical Innovation team at AstraZeneca. Her areas of expertise include adaptive designs and multiplicity. She consults teams on complex trial designs in Phase 2 and 3. Recently she has been supporting project teams in designing therapeutic and prophylaxis COVID-19 trials. She received her BSc and MSc at Lancaster University in the UK and holds a PhD in Biostatistics from Medical University of Vienna.