Building Quality into the Design and Conduct of Clinical Studies: Integrating Quality by Design (QbD) and Risk-Based Monitoring (RBM) Approaches

Duke-Margolis Institute for Health Policy
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Speaker Biographies

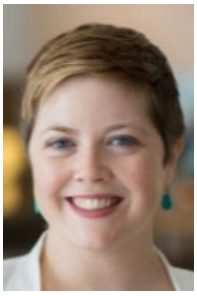
Eda Baykal-Caglar, Director of Clinical Research at The Michael J. Fox Foundation (MJFF), focuses on advancing the Foundation's patient-centric mission through patient engagement in research to accelerate progress toward a cure for Parkinson's Disease. She leads MJFF's patient engagement team that forges partnerships with patients, research volunteers, industry and academic scientists, and the online smart-match tool Fox Trial Finder to increase the flow of participants into Parkinson's disease clinical trials. Eda started her career as a physicist but driven by her interest in creating an impact through science to advance community health, patient advocacy, and education, she switched careers to work in nonprofits and healthcare. She holds a Ph.D. in Physics and an MS in Biotechnology and Physics Education. In her free time, she enjoys hiking, listening to podcasts, reading, and traveling with her husband and daughter.

Danilo Branco, Bachelor of Science, Pharmacy and Biochemistry, Director of Central Monitoring at Fortrea, is a passionate, optimistic, tech savvy clinical trials Risk Based Quality Management, Central Monitoring, Project Management and Clinical Operations professional with 20 years' experience managing complex studies in both big Pharma and CRO settings. He co-leads a team of 50+ employees globally in the mission of improving data quality while bringing efficiencies to Clinical Trials conduct throughout earlier risks detection and meaningful mitigations actions implementation. Last 8 years dedicated to lead and encourage teammates to achieve their best potential on RBQM processes creation, continuous assessment, and refinements to maximize the positive impact of the methodology adoption in full alignment with regulatory expectations.

Sabrina Comic-Savic is responsible for quality management at Population Health Partners. She spent almost 30 years working in clinical development and quality management with pharmaceutical industry. Sabrina participated in various projects with Clinical Trials Transformation Initiative since 2011 and is passionate about sensible approaches to clinical trial design, conduct and operations.

M. Khair ElZarrad is the Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER). He has served as the Deputy Director of OMP since 2017. As Director of OMP, Dr. ElZarrad leads the development, coordination, and implementation of medical policy programs and strategic initiatives. He works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Before joining FDA, he served as senior science policy analyst and Director of the Clinical and Healthcare Research Policy Division at the Office of the Director of the National Institutes of Health (NIH). He also served as a fellow on both the FDA's Interagency Oncology Taskforce, as well as the National Cancer Institute's Cancer Prevention Fellowship Program within the Division of Cancer Control and Population Sciences. Dr. ElZarrad earned his doctoral degree in medical sciences with a focus on understanding cancer metastases from the University of South Alabama College of Medicine, his Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health, and his bachelor's degree in biochemistry from Samford University.

Kenneth Getz is the Executive Director and a professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine, where he conducts grantfunded research on pharmaceutical R&D management and execution; protocol design optimization; contract service provider and investigative site management; e-clinical technology and data usage; and patient and community engagement. He is also the chairman of CISCRP – a nonprofit internationally-recognized organization that he founded to educate and raise public and patient awareness of the clinical research enterprise – and president of the Otsuka Patient Assistance Foundation. A well-known speaker at conferences, symposia, universities, investor meetings and corporations, Ken has published extensively in peer-review journals, books and in the trade press and writes a bi-monthly column nominated for a Neal Award in Applied Clinical Trials. He holds a number of board appointments in the private and public sectors and serves on the editorial boards of Pharmaceutical Medicine, Life Science Leader and Therapeutic Innovation and Regulatory Science. Ken received an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University. He is the founder of CenterWatch, a leading publisher in the clinical trials industry, and one of several businesses that he has created and sold.



Marianne Hamilton Lopez is the Senior Research Director of Biomedical Innovation, an adjunct associate professor, and core faculty at the Duke-Margolis Institute for Health Policy in Washington, DC. She leads the strategic design and direction of the Institute's Biomedical Innovation portfolio, with a focus on medical products development and regulation, real world evidence, infectious disease preparedness, and payment, pricing, and coverage of drugs and medical devices. She also oversees the Value for Medical Products Consortium and partners with Duke University faculty, scholars, and external health experts to advance this work. Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a senior program officer with the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System and provided strategic direction and oversight of the Consortium's Science and Technology portfolio and Clinical Effectiveness Research Innovation and the Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community

Advisor for the United States Cochrane Center; and the Federal Women's Program Manager and American Indian/Alaska Native Employment Program Manager for the National Institutes of Health.

Sameera Ibrahim joined BMS in December 2020 as the Strategy & Business Operations lead for R&D Quality. Prior to BMS, Sameera worked at Pfizer, GSK, Johnson & Johnson and IQVIA. She has 20 years of global clinical trial execution experience with roles of increasing responsibility in Clinical Operations, Quality Assurance, Inspection Management and Data Analytics. Sameera is a Board Member with Research Quality Association (RQA), a Steering Committee member with Clinical Trial Transformation Initiative (CTTI) and is currently working with Transcelerate on ICH E6 (R3) adoption workstreams. At CTTI, she was involved in developing QbD adoption tools, including the maturity model, metrics framework and implementation guide.

Kerstin Koenig is a global Quality Executive with in-depth knowledge of current GxPs recognized for shaping and leading quality assurance strategies and audit processes. Known as a visionary leader, her current focus is on the "Future of Quality" and the "Evolution of Quality Management Systems", including the digitalization of quality processes, automation, data analytics and Quality by Design. Kerstin is known for her commitment to enhance collaboration with key stakeholders and influencing the external environment. Kerstin is the VP, Global Quality Assurance at GSK. In this role, she is responsible for the development and oversight of the world-wide quality assurance activities in the areas of GLP, GCP and GVP. Before that, Kerstin lead the R&D Quality team at BMS and Merck KGaA, where she established proactive, solution-oriented quality organizations. Kerstin presents at industry conferences on ICH GCP Renovation, Quality by Design and Innovation and has been the EFPIA topic lead for ICH E8 (R1) renovation. Kerstin has a Diploma and a PhD in Nutrition Science from the University Bonn, Germany.

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Institute for Health Policy at Duke University. Dr. McClellan is a doctor and an economist who has addressed a wide range of strategies and policy reforms to improve health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical innovation. At the center of the nation's efforts to combat the pandemic, Dr. McClellan is the co-author of a roadmap that details the steps needed for a comprehensive COVID-19 response and safe reopening of our country. His current work on responding to the COVID-19 public health emergency spans virus containment and testing strategies; reforming health care toward more resilient models of delivering better, more equitable care; accelerating the development of therapeutics and vaccines, and building a more robust global response to the pandemic. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and academic research.

Patrick Nadolny has over 30 years of industry experience across pharmaceutical, device and biologics as well as technology solution development. He has been involved with RBM for the last 10 years. Mr. Nadolny is a pragmatic leader focusing on technology, innovation, strategic planning, change management, and the setup of new capabilities. Mr. Nadolny is the Global head of Clinical Data Management at Sanofi which include Centralized Monitoring. In addition to being the Chair of the SCDM board, he led the SCDM innovation committee from 2018 to 2024 which released many papers on the evolution of Clinical Data Management toward Clinical Data Science.

David Nickerson joined EMD Serono (Merck KGaA, Darmstadt, Germany) in 2016 as the Head of Clinical Quality Management in Global Development Operations. In this role he has global responsibility for the strategy, implementation, oversight, and improvement of risk-based approaches to quality management for the clinical development portfolio and associated business processes. Prior to joining EMD Serono, Dave spent 23 years with Pfizer, most recently as Senior Director of Clinical Development Quality where he was responsible for the development and implementation of a comprehensive approach for quality by design and quality risk management in clinical trials. Dave was a member of the Expert Working Group for the development of ICH E6 R2 and is currently a member of the EWG for ICH E6 R3.

Kelsie Pearson leads the Scientific and Network Partnerships team at the Cystic Fibrosis Therapeutic Development Network Coordinating Center (CF TDNCC). She holds an MBA in healthcare management and joined Seattle Children's in 2012 as a basic neuroscience researcher. Following two years in bench research, Kelsie transitioned to the CF TDNCC. She is currently involved in leading scientific and network strategy for the TDN as well as partnering with industry programs on CF clinical trial design, implementation, and regulatory considerations.

Leslie Sam, President of Leslie Sam and Associates, LLC, has over 25 years of clinical trial research, quality management, and leadership experience. As a seasoned professional with a Six Sigma Black Belt certification, Leslie is committed to transforming clinical quality management systems through collaborative efforts with clients. Her contributions earned her an invitation from TransCelerate, an industry organization, to co-develop and co-author a groundbreaking conceptual framework for clinical quality management systems and issue management. Additionally, Leslie served as a reviewer for TransCelerate's conceptual risk management framework, underscoring her dedication to advancing industry standards. With a deep understanding of industry best practices and regulatory guidelines, Leslie excels in defining and implementing strategic risk-based approaches to clinical trial and quality management. She was recently sought out to apply Risk-Based Quality Management (RBQM) principles, strategies, and tactics to a Mass Drug Administration study in Kenya, involving over 25,000 participants.

Moke Sharma joined BMS in October 2022 and serves as Head of Global Development Operations. He is accountable for leading an end-to-end, development operations function charged with the global clinical trial execution of the BMS product portfolio (Phase I – IV). He also leads a major initiative to transform Drug Development at BMS to accelerate the delivery of new medicines to patients. Moke previously worked at Alexion Pharmaceuticals where he was the Head of Development Operations and Quantitative Sciences, accountable for creating and leading an integrated, rare disease development engine. Prior to joining Alexion, Moke held senior positions with Novartis Oncology including Head of Global Development Operations, Head of R&D in Japan, and Head of Project Management. He also held clinical program leadership roles at Pfizer and GSK. Moke is a graduate of the University of Leeds in the UK with a degree in chemical engineering and holds an MBA.

Kristin Stallcup is a subject matter expert in risk-based quality management co-leading a highly skilled RBQM Operations team at Takeda. With extensive experience in clinical trials operations and technology, she brings valuable expertise to the table. Kristin's passion lies in cross-functional collaboration to achieve exceptional quality results through RBQM methodology. Outside of work, she cherishes time with family, enjoys kayaking, biking, practicing pilates, and exploring new cultures through travel.

Nicole Stansbury joined Premier Research in May 2023 as the Senior Vice President and Head of Global Clinical Operations. Prior to joining Premier, Nicole spent 25 years in the CRO industry where she served in leadership roles including Global Head of Clinical Trial Management, Global Head of Central Monitoring, and Head of Global Clinical Performance, a team responsible for SOPs, metrics, training, clinical systems, and clinical quality. Nicole's 30 years of industry experience has included positions at the site level and other CRO roles such as CRA and Project Manager. Nicole's therapeutic experience has primarily been in Dermatology, Gastroenterology, Urology and Women's Health; however, Nicole has leadership experience overseeing trials in Oncology, Neuroscience and General Medicine. Nicole has a Bachelor's in Animal Science from Texas A&M University and has a Lean Six Sigma Yellow Belt. Nicole has served as Co-Lead for the Association of Clinical Research Organization's (ACRO) Risk-Based Monitoring (RBM) Working Group since 2014 where she works with TransCelerate and global regulatory authorities on driving RBM adoption in the industry. Nicole is a member of PhUSE, collaborates regularly in industry publications, and is a frequent presenter and panelist at SCOPE, DIA, and other industry conferences.

Peter Stein is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters. A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at

Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience. Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.

Fergus Sweeney has a Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986). Fergus worked in industry from 1982 to 1999, covering phase I-IV clinical research, pharmacovigilance and laboratory activities, primarily in the field of quality assurance. Prior to his retirement, in May 2022, Fergus was Head of the Clinical Studies and Manufacturing Taskforce at the European Medicines Agency. He joined the Agency Inspection Sector in 1999, was Head of Sector, Compliance and Inspections from 2009, Head of Division Inspections and Human Medicines Pharmacovigilance from 2013 (and Scientific Committee Services from 2016). Whilst at EMA he served as chair or delegate in various working groups with experts from regulators, the pharmaceutical industry, academia, and civil society, including patients. Among these he has been the regulatory chair of three ICH Expert Working Groups involving the revision of ICH E8 - General Considerations on Clinical Trials and both revision 2 and revision 3 of ICH E6 Good Clinical Practice.

Michael Torok, Vice President and Global Head of Quality Assurance Programs at Roche/Genentech, has over 25 years of experience in innovating Operations and Quality practices to accelerate therapeutics to sick and dying patients. In his role, he is focused on harmonizing Risk Based Quality Management (RBQM) practices through sponsors, CROs, and clinical sites to effectively address the needs of patients, regulators, and business stakeholders. With a background in Quality and Operations, on both sponsor and CRO sides, he is expanding Clinical Quality Management frameworks by enhancing quality culture (critical thinking, open dialog, and organizational learning) in order to amplify RBQM practices (critical to quality factors, quality by design, and effective risk and issue management) from the lens of impact to trial participant safety and data reliability. Michael has lectured widely on RBQM, Quality Culture, and Inspection Readiness. He is a champion of applying industry standard quality analytics (open source code via IMPALA) to clinical programs, increasing regulator transparency (study quality status via quality briefs), and exploring quality engineering concepts leveraging generative artificial intelligence. Michael earned a Ph.D. in Biochemistry and Molecular Genetics from the University of Virginia School of Medicine and a certificate in Data Analytics from the University of Chicago.

Michael Walega is the Head of Centralized Monitoring at Bristol Myers Squibb. In this capacity, he is responsible for providing protocol teams with actionable insights to achieve higher quality, ensure that centralized monitoring processes are aligned to relevant regulatory requirements, and championing risk-based quality management approaches to clinical trial monitoring activities. He is a co-lead of the PHUSE Risk-Based Quality Management Working Group, which is focused on providing the industry with innovative approaches in risk management and data analytics to proactively manage data quality and participant safety risks. Additionally, the Working Group supports the

pharmaceutical industry with change management recommendations related to moving towards risk-based approaches. He was previously at LabCorp/Covance, where he led the team responsible for development and growth of Covance's Risk-Based Monitoring (RBM) technology solutions, processes, and operational delivery to customers. Additionally, while at Covance he also led the Late-Stage Biostatistics and Programming groups, as well as the Process Excellence team. Mike is a qualified Biostatistician and a Six Sigma Master Black Belt.

Janet Woodcock is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions. She served as the Acting Commissioner of Food and Drugs from Jan. 20, 2021, until Feb. 17, 2022. Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER) where she served as the Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure. In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), leading the Center's work that is the world's gold standard for drug approval and safety. In 2004, Dr. Woodcock became the FDA's Deputy Commissioner and Chief Medical Officer. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer. In 2007, Dr. Woodcock returned as Director of CDER until she was asked to be the therapeutics lead for "Operation Warp Speed" in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19. Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She is board certified in internal medicine.

Steve Young, Chief Scientific Officer for CluePoints, oversees the research and development of advanced methods for data analytics, data surveillance and risk management, along with providing guidance to customers in RBQM methodology and best practices. Steve worked for three bio-pharmaceutical companies over a span of 15 years where he assumed leadership positions in clinical data management and led the successful enterprise roll-out of EDC at both J&J and Centocor. He spent an additional 6 years with eClinical solution providers Medidata and OmniComm, leading the development of analytics and risk-based quality management (RBQM) solutions and providing RBQM consultation to many organizations. Steve also led a pivotal RBM-related analysis in collaboration with TransCelerate, and is currently leading RBQM best-practice initiatives for several industry consortiums. Steve holds a Master's degree in Mathematics from Villanova University.

Moderators Biographies

Jacqueline Corrigan-Curay is the Principal Deputy Center Director in FDA's Center for Drug Evaluation and Research (CDER). Most recently, she served as the Acting Center Deputy Director for Operations, directing center and agency-level priority and initiative programs and leading GDUFA III reauthorization negotiations. Previously, Dr. Corrigan-Curay was director of CDER's Office of Medical Policy (OMP). In that role, she led the development, coordination, and implementation of medical policy programs and strategic initiatives. She worked collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and as a practicing attorney in Washington, D.C.

Morgan Hanger is the Executive Director of the Clinical Trials Transformational Initiative (CTTI), a public-private partnership between Duke University and the U.S. Food and Drug Administration. She has deep experience convening organizations to solve complex problems related to evidence generation, and is passionate about data ethics and transparency. Prior to CTTI, Hanger worked at health technology companies focused on patients: streamlining receipt of specialty products, simplifying Medicare plan selection, and fostering robust learning through data sharing. Notably, Hanger served as vice president of the online patient research network PatientsLikeMe (PLM), where she led partnerships to utilize patient-generated health data in life sciences and regulatory settings. There she created products to streamline patient input into clinical trial design and to leverage the PLM platform for decentralized trials. Prior to PLM, Hanger worked in advisory services for Avalere Health, where she helped pharma, biotech, and professional societies create more effective research strategies. She has also held positions within the Health Outcomes Group at Memorial Sloan Kettering Cancer Center, supporting research on equity and cost in oncology, and at the Congressional Budget Office, investigating options for federally supported comparative effectiveness research. Ms. Hanger graduated summa cum laude from New York University with a BA in politics and holds a master's degree in public policy from the University of California, Berkeley.

Ann Meeker-O'Connell is the Director of the Office of Clinical Policy in the Office of the Commissioner at FDA. Ms. Meeker-O'Connell has more than 20 years of experience in biomedical research and development in government, academic, and industry settings, including close involvement in FDA efforts related to clinical trial modernization and clinical quality by design. She received an M.S. in Pharmacology and was an NIH Integrated Toxicology Fellow at Duke University.

Laurie Muldowney serves as the Deputy Director of the Office of Scientific Investigations in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. In this role, she works collaboratively with the Office Director to manage the development and implementation of patient focused, risk-based inspection, compliance, and enforcement activities under the Agency Bioresearch Monitoring Program. Dr. Muldowney joined the FDA/CDER in 2009 as a medical officer in the Office of Pharmaceutical Science, where she led Center-wide working groups charged with evaluating drug quality issues with potential impact on the safety or efficacy of drug products and developing strategies to minimize the potential risks. In 2013, she joined the Division of Gastroenterology and Inborn Errors Products within CDER's Office of New Drugs as a clinical reviewer and team leader. Prior to joining the Office of Scientific Investigations, Dr. Muldowney served as Associate Director for Medical Policy in the Office of Translational Science, where she established a Guidance, Policy, and Communications team and helped lead the office strategy related to guidance and policy development. Dr. Muldowney received a Bachelor of Science in chemistry from the College of William and Mary and earned her medical doctorate from Jefferson Medical College in Philadelphia, PA. Following additional postgraduate training, Dr. Muldowney served as a primary care physician with the United States Navy and worked in medical communications.

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