Duke | MARGOLIS CENTER for Health Policy

Pharmacodynamic Biomarkers for Biosimilar Development and Approval

Virtual Public Workshop

September 20, 2021 | 10:00 am – 2:30 pm ET

September 21, 2021 | 10:00 am – 2:30 pm ET

Speaker Biographies

Patrick Archdeacon is the Associate Director for Therapeutics in the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) in the Office of New Drugs at the Food and Drug Administration. In that role, he leads the diabetes team within DDLO. Previously, Dr. Archdeacon held positions within Office of Medical Policy and within the Division of Special Pathogens and Transplant Products (now the Division of Transplant and Ophthalmology Products). He attended medical school at Columbia University's School of Physicians and Surgeons. Prior to joining FDA, he completed his training in internal medicine at the New York Presbyterian Hospital and in nephrology and transplant nephrology at the University of North Carolina.

Abjihit Barve is the Chief Medical Officer at Viatris where he is responsible for all clinical development and medical affairs activities for a diverse portfolio of established brands, biosimilars, novel molecules, as well as complex and simple generics across the globe. Viatris, which was formed via merger of Mylan and Upjohn in Nov 2020, has one of the largest biosimilars portfolio in the industry. Abhijit has been with Mylan since 2015 and prior to that he was President of R&D for Biocon, where he was responsible for leading R&D, Regulatory Sciences and IP across a varied product portfolio. He has been extensively involved in the development of biosimilars for the past decade and has seen the space evolve with respect to regulatory requirements from a quality and clinical perspective across the globe. Abhijit was instrumental in leading the approval of the world's first biosimilar trastuzumab in India and first interchangeable biologic in the US. Trained as a physician scientist, he has more than 20 years of global drug development and medical affairs experience, including more than a decade at Fujisawa and Astellas Pharma. Abhijit graduated from the University of Mumbai with both a bachelor's degree in medicine/surgery (M.B.B.S.) and a doctor of medicine (M.D.) He also obtained Ph.D. from Dept of Biopharmaceutical Sciences at University of Illinois and M.B.A. in Finance & Strategy from the University of Chicago's Booth School of Business.

Leah Christl is Executive Director, Global Biosimilars Regulatory Affairs and Regulatory and R&D Policy at Amgen. She serves as head of the global regulatory affairs team within GRAAS-Global CMC, Device & Biosimilar Regulatory Affairs, and Business Operations with responsibility for development and execution of global regulatory strategy for Amgen's biosimilars portfolio. Dr. Christl also leads the global biosimilars regulatory and R&D policy with responsibility to develop and advance Amgen's regulatory and R&D policy positions. Prior to joining Amgen, Dr. Christl served as the Associate Director for Therapeutic Biologics in the Office of New Drugs in the U.S. FDA and was also the director of the Therapeutic Biologics and Biosimilars Staff. Dr. Christl

is a scientific, regulatory, and policy expert on biosimilar products and a strategist and lead for international activities related to biosimilars and other policy areas. Dr. Christl received her PhD in Molecular and Cellular Biology and Pathobiology – Marine Biomedicine and Environmental Science from the Medical University of South Carolina.

Jeffry Florian is an Associate Director in the Division of Applied Regulatory Science (DARS) within the Office of Clinical Pharmacology at the FDA. His primary responsibilities include clinical trial design, drug-disease modeling, and biomarker identification for biosimilar development. Dr. Florian has been involved in expanding the clinical study research capabilities within DARS since joining, spanning topics such as sunscreen absorption, biomarker identification for biosimilar development, opioid safety with concomitant medications, opioid antagonist drug development and use, and urinary excretion of ranitidine metabolites.

Janet L. Franklin is an Executive Medical Director at Amgen Inc. and is a Global Development Lead within the Global Clinical Development group. She has worked on a series of Hematology/Oncology novel drug development programs with increasing levels of responsibilities during her first several years at Amgen. Since 2019, she has taken on a new challenge with a transition to the Biosimilars Inflammation drug development program where she also leads the Biosimilars Scientific Affairs team. As of 2020, she has also been appointed the R&D lead for the Diversity, Inclusion, and Belonging initiative. She is a pediatric hematologist/oncologist by training and had an academic medicine career prior to her current industry work. Her interest in childhood leukemia and lymphoma diseases included clinical trial research, clinical practice, and education of residents and fellows as the Clinical Director of the Leukemia/Lymphoma program at Childrens Hospital Los Angeles (CHLA) and Assistant Professor of Pediatrics at University of Southern California (USC) School of Medicine. Janet received her BA in Biology from Wesleyan University, MPH from University of Texas, Houston, School of Public Health and her MD from Georgetown University School of Medicine. She completed her pediatric residency training at Texas Children's Hospital and her research immunology fellowship at Baylor College of Medicine. She completed her pediatric hematology/oncology fellowship at the NCI Pediatric Branch.

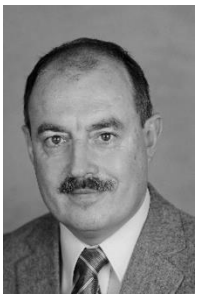
Salaheldin Hamed is the Acting Biosimilars Lead in DCP1 and DCP2 at the U.S. Food and Drug Administration. Dr. Hamed received his Bachelor's and Doctorate degrees in Biomedical Engineering from Rutgers University. He completed his postdoctoral training at the University at Buffalo in Pharmacokinetic and Pharmacodynamic modeling of chemotherapeutic drugs. He joined the FDA in 2012 as a research fellow in the Division of Applied Regulatory Sciences. He worked on the PKPD modeling of narrow therapeutic index drugs and several other projects. He joined the Division of Cancer Pharmacology in the Office of Clinical Pharmacology in October 2015. Salah has been serving the Acting Biosimilars Lead in DCP1 and DCP2.

R. Donald Harvey III is Director, Phase I Clinical Trials Section and Medical Director of the Clinical Trials Office at the Winship Cancer Institute and a Professor in Hematology/Medical Oncology and Pharmacology at the Emory University School of Medicine. Dr. Harvey received his Pharmacy degrees from the University of North Carolina (UNC) and completed residency training at the University of Kentucky and Hematology/Oncology specialty training at UNC. Dr. Harvey is a former President of the Hematology/Oncology Pharmacy Association and past 2chair of the ASCO Cancer Research committee, and has over 150 peer-reviewed publications in hematology/oncology and clinical pharmacology. His research focuses on early phase trials and the application of clinical pharmacology principles to improved development and patient care.

Shiew-Mei Huang is currently Deputy Director, Office of Clinical Pharmacology, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration. She received her B.S. in Pharmacy from National Taiwan University, School of Pharmacy in 1975 and her Ph.D. from University of Illinois, Medical Center in Pharmacokinetics and Biopharmaceutics in 1981. She has 15+ year drug development experience (Ortho pharmaceutical Corp. and Dupont-Merck Pharmaceutical Company) before joining the FDA in 1996. She has over 160 publications focusing on topics in clinical pharmacology, drug metabolism/transport interactions, and physiologically-based pharmacokinetic modeling and pharmacogenomics areas. She was an associate editor for a high impact journal "Clinical Pharmacology and Therapeutics" from 2007-2019. She has received many awards, including an FDA Outstanding Achievement Award, FDA Clear Communication Award, and FDA Distinguished Service Award. Dr. Huang is an AAPS (American Association of Pharmaceutical Scientists) Fellow, a JSSX (Japanese Society for the Study of Xenobiotics) Fellow. She is a diplomate of the American Board of Clinical Pharmacology. She has been an Adjunct Professor at the School of Pharmacy, University of Maryland since 2010. She was President of the American Society for Clinical Pharmacology and Therapeutics (ASCPT) from 2009 to 2010. She has received ASCPT Awards "Gary Neil Prize for Innovation in Drug Development" in March 2014 and "Henry Elliott Distinguished Service Award" in March 2016.

Paula Hyland is currently Genomics Lead in the Division of Applied Regulatory Science, OCP, FDA. Her job functions include genomics support for reviews in rare diseases and research focusing on the identification of biomarkers of drug response, resistance, and toxicity. Paula is a PI and co-PI for biologics- and antibiotic-related research projects. She is a member of the OCP's pharmacodynamic (PD) biomarker working group where she is currently exploring new approaches using novel high-throughput techniques in the detection of PD biomarkers for biosimilarity. Before joining the FDA in September 2017, Paula worked at the National Cancer Institute, NIH, in the Division of Cancer Prevention from 2009 to 2011, and in the Genetic Epidemiology, and the Integrative Tumor Epidemiology Branches in the Division of Cancer Epidemiology and Genetics from 2012 to 2017. Her work experience extends from molecular projects evaluating the efficacy and adverse effects of drugs to omics discovery research in cancer susceptibility and etiology. Dr. Hyland was trained in molecular biology and molecular epidemiology in the UK.

Ping Ji is the biosimilar scientific lead in the Division of Inflammation & Immune Pharmacology (DIIP), Office of Clinical Pharmacology, FDA. She has over 17 years of regulatory and industrial experience and has published numerous manuscripts in peer-reviewed journals and book chapters. Dr. Ji received her PhD in pharmaceutics from the University of Minnesota after obtaining BS in pharmacy from Peking University Health Science Center.



Wojciech Kryzanski is Associate Professor in the Department of Pharmaceutical Sciences, University at Buffalo. He obtained Ph.D. in Applied Mathematics and M. A. in pharmacology from SUNY at Buffalo. Dr. Krzyzanski has expertise in pharmacokinetic and pharmacodynamic modeling, particularly in applications of models which describe effects of various drugs on hematopoietic cell populations. His research focuses on therapeutic effects of erythropoietin and granulocyte colony stimulating factor. His group has established PK/PD models for recombinant human analogs of these hormones in animals, healthy human subjects, and patients. Some of them have been instrumental in biosimilarity analysis of protein drugs approved by EMA and FDA. He has published over 100 papers in peered reviewed journals.

Bernd Meibohm is a Professor of Pharmaceutical Sciences and Associate Dean for Research and Graduate Programs at the College of Pharmacy, The University of Tennessee Health Science Center, Memphis, Tennessee. He received his pharmacy degree and doctoral degree in pharmaceutics from Technical University Carolo-Wilhelmina, Braunschweig, Germany. After completion of a clinical pharmacology research fellowship at the University of Florida in 1997, he joined the faculty of the University of South Carolina, and in 1999 the University of Tennessee. Dr. Meibohm's scientific interests include pulmonary infectious and inflammatory diseases, pediatric pharmacotherapy and the application of quantitative modeling and simulation techniques in preclinical and clinical drug development, with specific focus on therapeutic proteins. His research work has attracted more than $40 million in extramural funding as principal and co-investigator and has resulted in over 190 scientific papers and book chapters (h-index 51), three textbooks, 180 abstracts, and over 200 invited scientific presentations to national and international audiences. Dr. Meibohm is a Fellow of the American Association of Pharmaceutical Scientists (AAPS) and the American College of Clinical Pharmacology (ACCP). He was the President of ACCP 2014-2016 and served on its Board of Regents 2008-2018. He also served as 2010 Chair for the 'Pharmacokinetics, Pharmacodynamics and Drug Metabolism' section of AAPS, and served 2016-2019 as Member-at-Large on the Board of Directors of AAPS. Dr. Meibohm is also serving as associate editor for The AAPS Journal, and is a member of the editorial advisory boards of 7 other peer-reviewed journals.

Shinichi Okudaira is Deputy Review Director in Office of Cellular and Tissue-based Products, PMDA, Japan. Dr. Okudaira graduated from Graduate School of Pharmaceutical Sciences, the University of Tokyo in 2009. He has been a reviewer in PMDA since 2013.

Stacey Ricci is the Director of the Scientific Review Staff in the Office of Therapeutic Biologics and Biosimilars (OND/CDER/FDA). Dr. Ricci leads a multidisciplinary team that provides oversight of biosimilar and interchangeable products at all stages of their development and ensures consistency in the cross-disciplinary scientific and regulatory advice provided to sponsors for their products. During her 16-year tenure at FDA, Dr. Ricci's work has focused primarily on the scientific and regulatory review of biotechnology-derived therapeutic proteins, including major contributions to FDA guidance and standards development for biosimilars and other protein therapeutics. Prior to joining FDA, Dr. Ricci completed post-doctoral research at the University of Pennsylvania, received a Doctor of Science in Molecular Toxicology from Tulane University, and a Master of Engineering and Bachelor of Science from Cornell University**.**

Sarah Schrieber is a scientific reviewer in the Office of Biologics and Biosimilars (OTBB) in the Office of New Drugs within CDER. Prior to joining OTBB, she served in various leadership roles within the Office of Clinical Pharmacology, including as Co-Director of the Therapeutic Biologics Program. She received her Bachelors in Cell and Molecular Biology from Missouri State University, and her Bachelors in Pharmacy and Pharm. D. from Saint Louis College of Pharmacy. She completed a general pharmacy practice residency at Cox Health Systems in Springfield, Missouri followed by a postdoctoral fellowship in drug development at the University of North Carolina at Chapel Hill and United Therapeutics Corp. Sarah is committed to advancing public health through innovation of regulatory science.

Martin Schiestl is responsible for the Global Regulatory Affairs Policy at Sandoz Biopharmaceuticals. Dr. Schiestl received his doctoral degree in chemistry with a specialization in bioanalysis from the University of Innsbruck in Austria in 1996. In the same year, he started his work on Biosimilar medicines at Sandoz where he built up the analytical and pharmaceutical development departments in charge of the biosimilar portfolio and other biological medicines of Sandoz. He moved into the regulatory policy field in 2009, further fostering regulatory sciences for biosimilar medicines. His most relevant contributions to the public scientific discussion include publications on: The path towards a tailored clinical biosimilar development. (Schiestl et al., BioDrugs (2020) 34:297–306); Acceptable changes in quality attributes of glycosylated biopharmaceuticals. (Schiestl et al., Nature Biotechnology (2011) 29: 310-312); and Similarity assessment of quality attributes of biological medicines: the calculation of operating characteristics to compare different statistical approaches. (Stangler et al., AAPS Open (2019) 5:4).

Andrej Skerjanec is Head Clinical Pharmacology, Biosimilars, Sandoz Biopharmaceuticals, Novartis AG. Dr. Skerjanec is a graduate of University of Alberta in Edmonton, Canada and has over 20 years of drug development experience at Eli Lilly and Novartis. His work focuses on clinical pharmacology, translational sciences, PK/PD modeling and regulatory submissions across a broad spectrum of therapeutic areas, with small molecules and biologics. Over the last 6 years, he built a leading clinical pharmacology organization at Sandoz AG, covering all aspects related to biosimilars development. The contributions of his team led to successful registration of several biosimilar products globally and was recognized with Novartis Leading Scientist Award in 2020.

David Strauss is a physician-scientist, internationally recognized researcher, and medical product regulator with over 11 years of experience at FDA spanning the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH). He currently serves as Director of FDA/CDER's Division of Applied Regulatory Science, which seeks to move new science into the FDA review process and address emergent regulatory and public health questions. The Division also conducts regulatory consults/reviews for challenging premarket or postmarket issues that cannot be addressed by the primary review divisions. He previously served as Senior Advisor for Translational & Experimental Medicine in CDER and Medical Officer in CDRH, conducting many premarket medical device reviews. Dr. Strauss received a B.A. in chemistry and M.D. from Duke University, a Ph.D. in clinical physiology from Lund University, Sweden, and additional post-doctoral training at Johns Hopkins University. He has published over 150 peer-reviewed articles with >5,900 citations. He was the senior author on 3 original research JAMA articles in the past two years, including the most-read JAMA article of 2019. Additional activities include serving as Associate Editor of Clinical Pharmacology & Therapeutics, Executive Committee member of the Foundation for the National Institutes of Health Biomarker's Consortium, and Rapporteur (lead) of the International Council for Harmonisation (ICH) Guidelines for nonclinical (ICH S7B) and clinical (ICH E14) assessment of cardiac safety for drugs.

Qin Sun is the Therapeutic Biologics Program (TBP) biologics lead in the Office of Clinical Pharmacology (OCP), CDER, FDA. Her key job functions include guide and support reviews and policy development for new molecular entity (NME) biologics or biosimilar products. In addition, Qin is PI or co-PI for biologics related research projects. Qin is a key member in OCP's pharmacodynamic (PD) biomarker working group to promote a broader application of PD biomarker in biosimilar development. Qin joined FDA in 2016. Before that, she worked at Pharmaceutical Product Development (PPD) in the Department of Clinical Pharmacology and Biostatistics from 2015 to 2016, and at Bristol-Myers Squibb in the Department of Drug Metabolism and Pharmacokinetics from 2008 to 2014. Qin received her PhD from University of Virginia and her BS from Nanjing University, China. Her work experience extends from drug discovery to drug development, and finally to regulatory review, focusing on biologics and biosimilars currently.

Jian Wang is the Division Manager of Clinical Evaluation Division – Radiopharmaceuticals/Haematology (CED-RH). He manages a team of scientific, clinical and medical evaluators responsible for pre-market assessment of scientific and clinical data. His division has regulatory responsibility for assessing non-clinical, pharmacology and clinical data for biological drugs, including gene therapies and biosimilars, for the treatment of haematological, oncological, and infectious diseases. The Division also regulates radiopharmaceuticals (for all indications). Dr. Wang has broad regulatory experience in pre-market drug regulations for generics, biologics, biosimilars and radiopharmaceuticals. He joined the Health Canada Pesticide Management Regulatory Agency in 1996. He started working for the Therapeutic Products Directorate (TPD) in early 1999. Then in 2001, Dr. Wang moved to BRDD. He actively participates in various Health Canada, ICH, WHO and DIA working groups and expert committees. Dr. Wang has received his medical degree in China and his PhD from the University of British Columbia in Canada.

Yow-Ming Wang is the Associate Director for Biosimilars and Therapeutic Biologics in the Office of Clinical Pharmacology at the FDA. Dr. Wang leads the Therapeutic Biologics Program which has a mission to promote scientific and regulatory excellence in biologic product development through: developing clear policies, enhancing excellence in review, facilitating knowledge sharing, and building collaboration & outreach.

Elena Wolff-Holz is a senior regulator and medical assessor at the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, with particular areas of expertise in development of biosimilars and therapeutics for cancer and autoimmune disease. Since 2016, she is Chair of the Biosimilar Medicinal Products Working Party (BMWP) of the European Medicines Agency (EMA) and also serves as a member of the Scientific Advice Working Party (SAWP) of the CHMP. Overall, Elena has 25 years of professional experience, including 14 years in the biotech industry where she held various positions in clinical development and medical marketing functions at Centocor Inc (now J&J) and Amgen in the US and in Germany. Her work has resulted in several (co-) authorships in scientific journals and several presentations at (inter-)national conferences. Elena is a physician by training with an M.D. degree from Heidelberg University and a postdoctoral fellowship at Harvard Medical School.

Gillian Woollett leads the FDA practice at Avalere. She provides the "prequel" of scientific and regulatory strategic policy expertise that supports medicinal products gaining approval at the FDA in a manner that allows them to be successful in the public and private reimbursement world. She is building a bridge for Avalere clients from the FDA space into the traditionally separate Centers for Medicare & Medicaid Services and healthcare policy/business world. Prior to joining Avalere, Gillian was chief scientist at Engel & Novitt, LLP, and was vice president, Science and Regulatory Affairs, at the Biotechnology Industry Organization (BIO). She joined BIO after being associate vice president at the Pharmaceutical Research and Manufacturers of America. She has been an appointee on federal advisory committees to the CDC and the Department of Commerce. Trained as a molecular biologist/immunologist, Gillian publishes in peer-reviewed literature

on biotechnology topics and is a frequent speaker on emerging biosciences and their ability to support better and more focused therapies. Gillian has a DPhil in immunology from the University of Oxford and an MA and BA in the natural sciences tripos (biochemistry) from the University of Cambridge.

Sarah Yim is the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND). She has been with FDA since 2005 in various roles, including 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology regulatory review. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.

Hong Zhao is one of the team leaders responsible for clinical pharmacology review of oncology drug products at the FDA. Dr. Zhao earned her PhD degree in Pharmaceutical Sciences from the University of Connecticut. She joined FDA in 1998 as a clinical pharmacology reviewer in the Office of Clinical Pharmacology (OCP) and became a team leader in 2006 responsible for clinical pharmacology review of all biological product submissions in CDER. Over the years, Dr. Zhao has led her team and conducted many regulatory research projects on biologic products to address review questions and contributed to the biologics specific guidance development. She has developed her expertise on biological products with extensive experience and contributed significantly to the biologic product development and regulatory review and approval.

Issam Zineh is Director of the Office of Clinical Pharmacology (OCP) at the U.S Food and Drug Administration (FDA). He has held various leadership positions at FDA including Associate Director for Genomics in OCP (2008-2012) and Co-Director of the CDER Biomarker Qualification Program (2009-2015) and serves on the CDER Medical Policy Council. Dr. Zineh was formerly on faculty at the UF Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. He is a recognized expert in the fields of drug development and evaluation, clinical pharmacology, pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of over 260 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.

Duke-Margolis Moderator

Mark McClellan is the Robert J. Margolis, M.D., Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. Dr. McClellan is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.