REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Global Harmonization for Data Access & Exchange Public Meeting

Thursday, November 5, 2026 | 1 PM ET

Speakers

Patrick Crooks, PhD
Senior Manager, Regulatory Innovation, Accumulus Synergy



Dr. Patrick Crooks is a healthcare and life sciences industry leader with 13+ years of experience across patient-focused drug development, patient engagement, regulatory policy, and healthcare innovation roles. His work focuses on advancing public health and health equity through strategic partnerships, global collaboration, and innovative, human-centered solutions. Patrick holds a doctorate degree in bioethics and health policy from Loyola University Chicago, a MS in bioethics from Columbia University, and a BS in chemistry from the Pennsylvania State University.

Panel 1

Julian Beach, MBA
Executive Director of Operations, Medicines and Healthcare products Regulatory Agency (MHRA)



Julian Beach, MBA, oversees the portfolio that is designed to ensure the quality and access of products to the UK market - this includes scientific advice, licensing assessment, marketing authorizations for all innovative and established medicines.

A committed professional with over 15 years of Director/Board level experience with a broad demonstrated history at the Medicines and Healthcare products Regulatory Agency, Novartis, Pfizer and GSK in pharmaceuticals. Flexibly skilled in regulatory, compliance, quality, health and safety, operations with passion for people development with results and improvement focus. Quickly adaptable with strong links to industry and regulatory bodies with country, scientific, commercial and business focuses. Working with industry and regulators to influence legislation to

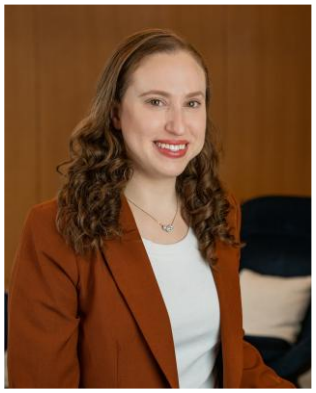
benefit both patients and business. He is a Fellow of the RSC, with an MBA from Henley Business School, adding to BSc (Hons), Chartered Chemist and Chartered Scientist.

Rich Brennan, MA
Vice President of Federal Affairs, The ALS Association



Rich Brennan, MA, is responsible for developing and executing The ALS Association's federal advocacy agenda and leading engagement efforts with federal agencies and the White House to proactively influence federal decisions on issues important to people living with ALS. Rich's federal advocacy experience spans over 20 years as a health policy expert and lobbyist who engages with the White House, federal agencies, and Congress on health care and innovation policies. He has led successful efforts to influence federal initiatives by building effective patient grassroots' advocacy and comprehensive government affairs strategies. His efforts have contributed to the expansion of federal reimbursement for health care services, secured federal funding for telehealth services and electronic health records, increased investments and biomedical research, expanded services for chronically and critically ill patients, and improved the accessibility and convenience of health care in home and community-based settings. Rich is knowledgeable and experienced working in collaboration with associations, healthcare providers, insurers, patient advocacy groups, corporations, universities, investment firms, health technology entrepreneurs, and public policy think tanks to advance innovation in health care through coalition partnerships, strategic planning, policy analyses, and national advocacy.

Rebecca Nebel, PhD
Director of Regulatory Policy & Intelligence, Amgen



Dr. Rebecca Nebel is Director of Regulatory Policy & Intelligence at Amgen, where she leads a range of U.S. regulatory policy initiatives including artificial intelligence (AI), regulatory submission modernization, precision medicine, rare disease, and CMC/manufacturing. In this role, she develops policy positions and engages with regulators, industry associations, and other stakeholders to help shape policies that advance innovation in medicine development and review.

Prior to joining Amgen, Dr. Nebel served as Deputy Vice President of Science and Regulatory Advocacy at PhRMA, where she led industry advocacy on regulatory policy issues, including AI, digital health, regulatory information

technology, real-world evidence, combination products, and vaccines. She also supported PDUFA negotiations, led FDA engagement efforts, and collaborated with stakeholders across industry to advance science-based regulatory policy. Earlier in her career, she held positions at the National Institutes of Health, the Society for Women's Health Research, and the National Academies of Sciences, Engineering, and Medicine. Dr. Nebel earned her PhD in Biomedical Sciences from Albert Einstein College of Medicine and her BS in Biological Sciences from Binghamton University.

Raju Rayavarapu, PhD
Senior Regulatory Solutions Director, DNAnexus



Dr. Raju Rayavarapu is the Senior Regulatory Solutions Director at DNAnexus. He is the architect of Trusted Regulatory Spaces (TRS) Commons, a secure cloud platform for regulatory innovation. The platform lets sponsors, regulators, and partners exchange regulatory data, promote the development and implementation of regulatory standards and has built cloud solutions to support the FDA Project PRISM and other cloud based regulatory innovations. Before joining DNAnexus, Raju spent more than six years at the U.S. FDA. Most recently he was Senior Technical Advisor and Lead Data Scientist to the Chief Data Officer, guiding policy on AI governance, cloud strategy and data science. He holds a PhD in Biological Science from the University of Notre Dame and was a Postdoctoral Research Associate at St. Jude Children's Research Hospital.

Sachin Shah, MBA
Project Manager in the Office of Data Platform Engineering, U.S. Food and Drug Administration (FDA)



Sachin Shah, MBA, is a Project Manager in the U.S. Food and Drug Administration's Office of Data Platform Engineering, within the Office of Mission IT Services. He brings more than 15 years of experience leading enterprise transformations in data, analytics, operations, and planning. His work connects technology, science, and policy to advance public health through initiatives including Project PRISM, Data Analytics as a Service, enterprise technology programs, and supply chain monitoring and response.

Sachin has held project and program management roles across FDA and the Department of Health and Human Services, following earlier private-sector experience. He holds an MBA from Johns Hopkins University's Carey Business School

and a BA in Political Science from the University of Mary Washington. He lives in Silver Spring, Maryland, with his family.

Panel 2

Crystal Allard, MSIT
Senior Director of Government Strategy, Veeva Systems Inc



Crystal Allard, MSIT is Senior Director, Government Strategy at Veeva. With 15 years of experience at the FDA, she works with regulators and industry to shape the future of the submissions ecosystem and increase speed to market. She also contributes to Veeva's product strategy and public policy leadership in health data and regulatory standards. Prior to joining Veeva, Crystal held senior leadership roles at the FDA, including Director in the Office of Data, Analytics, and Research (ODAR) and Director of Regulatory Science Informatics in the Center for Tobacco Products.

Hussein Ezzeldin, PhD
Director of the Division of Artificial Intelligence, Office of Innovation and Clinical Trial Modernization, Office of Medical Policy, FDA



Dr. Hussein Ezzeldin serves as Director of the Division of Artificial Intelligence in the Office of Innovation and Clinical Trial Modernization at the Office of Medical Policy (OMP) at the FDA. Since joining OMP as a Senior Public Health Advisor, he has advanced initiatives in AI, digital health technologies (DHTs), and real-world evidence (RWE), strengthening OMP's role in promoting RWD utilization and regulatory data considerations. Prior to CDER, Dr. Ezzeldin was Associate Director for Advanced Technologies at the Center for Biologics (CBER)'s Office of Biostatistics and Pharmacovigilance, where he established CBER's DHT review team and led programs including the HOME natural history study for metachromatic leukodystrophy and the BEST IM Initiative. Over his 13+ years at FDA, he has consistently contributed to agency-wide efforts to integrate innovative data sources and technologies into regulatory decision-making.

Sandy Krogulski, MA
Senior Director of Regulatory Digital Strategy and External Engagement, Bristol Meyers Squibb



Sandy Krogulski, MA, is a Senior Director, Regulatory Digital Strategy and External Engagement at Bristol Myers Squibb. She leads efforts to advance regulatory digital transformation through innovative approaches to data standards, structured content, AI-enabled capabilities, and regulatory modernization. Sandy is responsible for shaping external engagement strategies with health authorities, industry consortia, and others to help accelerate the adoption of data-driven regulatory submissions. With over 15 years of experience in regulatory operations, digital strategy, and global health authority engagement, she is passionate about advancing interoperability, data exchange, and collaborative solutions that improve the efficiency and effectiveness of regulatory processes.

Rebecca Li, PhD
CEO, Vivli



Dr. Rebecca Li is the CEO of Vivli and on faculty at the Center for Bioethics at the Harvard Medical School. Previous to her current role she was the Executive Director of the MRCT Center of Brigham and Women's Hospital and Harvard for over 5 years and remains a Senior Advisor at the Center. She has over 25 years of experience spanning the entire drug development process with experience in Biotech, Pharma and CRO environments. She completed a Fellowship in 2013 in the Division of Medical Ethics at Harvard Medical School. She earned her PhD in Chemical and Biomolecular Engineering from Johns Hopkins University.

Andrew S. Robertson, PhD, JD
Senior Vice President of Global Regulatory Affairs and Quality, Denali Therapeutics



Dr. Andrew S. Robertson is Senior Vice President of Regulatory Affairs and Quality at Denali Therapeutics, where he leads the company's global regulatory and development quality functions. His work focuses on advancing innovative therapies for neurodegenerative diseases while building a future-ready organization that applies AI, regulatory data, and modernized ways of working to strengthen strategy and accelerate development.

Andrew has more than 20 years of experience across biopharma, government, and academia at the intersection of science, law, and policy. Before joining Denali, he held regulatory leadership roles across the biopharmaceutical sector. His work has included initiatives in regulatory applications of generative AI, cloud-based regulatory submissions, data-driven regulatory strategy, and global regulatory modernization. Earlier in his career, he served as a science policy advisor at the U.S. Department of Health and Human Services and was a member of the faculty at the Wellcome Trust Sanger Institute. Andrew holds a JD from UC Berkeley and a PhD in Structural Biochemistry from the University of Cambridge, where he was a Gates Cambridge Scholar.

Mariann Yeager, MBA
CEO, The Sequoia Project



Mariann Yeager, MBA, has more than 20 years of experience in the health information technology field. She serves as CEO for The Sequoia Project, a nonprofit solely focused on advancing secure, interoperable nationwide health data sharing in the U.S. Ms. Yeager leads the Recognized Coordinating Entity) team, in support of the Assistant Secretary of Technology and Policy to develop, implement and maintain the Trusted Exchange Framework and Common Agreement. Under her leadership, Sequoia launched its Interoperability Matters program, engaging experts from across the healthcare and healthcare IT communities to identify, prioritize and collaborate on the most pressing, discrete challenges to nationwide health information sharing. Prior to her tenure at The Sequoia Project, she worked with the HHS Office of the National Coordinator for five years on nationwide health information network initiatives. She also led the launch and operation of the first ambulatory and inpatient electronic healthcare record certification program in the U.S.

Moderator

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA



Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, and other stakeholders with a neutral forum to address domestic and global issues. As Chief of Staff for the FDA (2007-2009), Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her law degree magna cum laude from Georgetown University Law Center. She is an APhA Fellow, served as an elected member of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025) and Chair of that Board from 2019 to mid-2025. In 2023, she received the Distinguished Alumni Award of the Food and Drug Administration Alumni Association and, separately, was awarded the Osterhaus Medal for Lifetime Achievement by the Univ. of Iowa College of Pharmacy.