Advancing Drug Development by Reducing Reliance on Animal Testing

Case Example: Pre-Clinical Animal Models in Lung Toxicology

Hybrid Public Meeting
February 26, 2026 | 10am-4pm (eastern)

Speaker Bios

Per Åberg, MSc, DABT
Senior Director, Clinical Pharmacology and Safety Science, AstraZeneca

Per Åberg has been employed at AstraZeneca since 1991 with the majority of time focused on toxicology project leadership. He has been involved in numerous Discovery and Development programs for drug candidates in the respiratory disease area field, spanning from established therapies like inhaled bronchodilators and corticosteroids as well as drug candidates targeting a range of pharmacologies and modalities. Based on experiences from primarily inhaled drug candidates he has driven and lead various internal initiatives to enhance the understanding and detection of respiratory liabilities in attempts to optimize molecules to ensure safety of inhaled drugs and avoid late-stage failures due to respiratory toxicity. Per holds an MSc in biology from Lund University; Sweden and has been certified DABT since 2004.

Teresa Barnes
Chief Executive Warrior, PF Warriors

Teresa Barnes is a respiratory advocate with special interest in fibrotic diseases, having lost five family members to Pulmonary Fibrosis (PF). She serves as Chief Executive Warrior for patient organization, PF Warriors, and is Chair Emeritus and a current member of the American Thoracic Society's Public Advisory Roundtable (PAR). She is a fellow of the Drug Information Association and a medtech entrepreneur as well as a trained journalist and published author of medical journal and lay media articles. She is an MS Health Communication candidate at the University of Illinois, Urbana-Champaign (May 2026) and holds a journalism degree from the University of North Carolina at Chapel Hill.

Aidan K. Curran, PhD
Principal, Curran Nonclinical Consulting

Aidan Curran is an independent consultant and principal at Curran Nonclinical Consulting. Aidan is a pulmonary physiologist by training, with extensive experience in both the academic and professional worlds. Following award of his PhD from the National University of Ireland in 1995 he spent the next decade as an academic researcher and professor, predominantly at the University of Wisconsin and Dartmouth Medical School, focused on the neurophysiology of sleep disordered breathing and sudden infant death syndrome. In 2005 Aidan moved to industry and has worked at all stages of drug development including discovery at Schering-Plough, toxicology and safety pharmacology at Huntingdon Life Sciences CRO and nonclinical, translational, early clinical and executive management at Pulmatrix Inc.

Rachel L. Eddy, PhD
Imaging Scientist, Clinical Development, VIDA

Dr. Rachel Eddy is an Assistant Professor in the Departments of Radiology and Pediatrics University of British Columbia, Vancouver, Canada. Dr. Eddy also bridges industry work as an Imaging Scientist with VIDA Diagnostics Inc. Dr. Eddy's expertise is in quantitative CT and MRI of the lungs to for early detection and to provide a deep understanding of chronic lung disease.

Lorna Ewart, BSc, DSc, PhD
Chief Scientific Officer, Emulate, Inc.

Lorna Ewart is Chief Scientific Officer at Emulate, Inc., where she provides strategic leadership for the company's research and development. With more than 20 years of experience in the pharmaceutical industry, Lorna has deep expertise across drug discovery, development, and translational science. She has also played a pivotal role in advancing regulatory science, particularly in shaping discussions around the scientific value and ethical considerations of animal use in research as well as supporting multiple drug candidates through the discovery and development pipeline. Lorna has more than 55 peer-reviewed publications, is a fellow of the Royal Society of Biology and the British Pharmacological Society.

John Fahy, MD, MSc
Professor of Medicine in the Division of Pulmonary and Critical Care Medicine, University of California-San Francisco

John Fahy is a Professor of Medicine at the University of California San Francisco (UCSF), where he directs a translational clinical research laboratory focused on uncovering disease mechanisms and advancing new treatments for patients with asthma, COPD, and other muco-obstructive lung diseases. Dr. Fahy received his medical degree from University College Dublin and a master's degree in molecular medicine from Trinity College Dublin. He completed clinical and research training in pulmonary and critical care medicine at UCSF before joining the pulmonary and critical care

division at UCSF as faculty in 1993. During his career Dr. Fahy's research program made fundamental discoveries related to clinical and molecular subtypes of asthma and COPD, especially in relation to type 2 immune dysfunction and airway mucus pathology. His laboratory invented a standardized scoring system to quantify mucus plugs burden in the lungs. He also led a multidisciplinary NIH funded academic team to develop a thiol-saccharide drug technology for mucus plug lysis. This led to the spin out from UCSF of Aer Therapeutics, a life science biotechnology company that is advancing an aerosol thiol saccharide formulation to the clinic for the treatment of COPD. Dr. Fahy was elected to the American Association of Physicians in 2016, received scientific achievement awards from the American Thoracic Society in 2015 and 2017, and was awarded the Gold Medal in Asthma from the European Respiratory Society in 2019. He delivered the UCSF Faculty Research Lecture in Translational Science in 2020.

Andrew Goodwin, PhD
Director, Division of Pharmacology-Toxicology for Immunology and Inflammation, U.S. Food and Drug Administration

Andrew Goodwin serves as the Director of the Division of Pharmacology-Toxicology for Immunology and Inflammation within the FDA/Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND). He leads the scientific staff that provide nonclinical review and advice in support of drug development programs across five clinical divisions. In addition, Dr. Goodwin serves as a member of the OND Pharm-Tox Senior Leadership Team and contributes to cross-cutting policy and guidance development initiatives across the Center and Agency. Andrew earned a B.S. In Biology from the College of William and Mary and a PhD in Cellular and Molecular Medicine from the Johns Hopkins School of Medicine. Dr. Goodwin joined FDA in 2012 and served as a reviewer and supervisor prior to assuming his current role in 2020.

Karin Hoelzer, DVM, PhD
Senior Director, Patient Advocacy
Biotechnology Innovation Organization (BIO)

Karin Hoelzer currently serves as the Senior Director of Patient Advocacy at the Biotechnology Innovation Organization, a position held since October 2024. Previously, Karin held the role of Senior Director of Policy and Regulatory Affairs at the National Organization for Rare Disorders from July 2022 to October 2024. Karin's experience also includes serving as Senior Director of Public Health Data Analytics at Maximus, and roles at The Pew Charitable Trusts, where Karin advanced from Officer to Senior Officer in Health Programs between 2015 and July 2020. Early career positions included an ORISE fellow at the FDA, a Research Associate at Cornell University, and various internships in the pharmaceutical and veterinary fields. Karin holds a PhD in Comparative Biomedical Sciences from Cornell University and a Doctor of Veterinary Medicine from the University of Veterinary Medicine Hannover, with additional study at Ecole nationale vétérinaire de Lyon.

Jorrit Hornberg, PhD, MSc
Vice President, Global Head of Safety Sciences, AstraZeneca

Jorrit Hornberg has over 20 years of experience in drug discovery and development at Organon, Bayer, Lundbeck and AstraZeneca. Jorrit joined AstraZeneca in 2015 and held several leadership positions, becoming Vice-President, Global Head of Safety Sciences in 2024. In this role, Jorrit is accountable for non-clinical safety across the AstraZeneca portfolio.

Jorrit has developed and implemented integrated proactive safety strategies and driven technological innovations to discover and develop safe new medicines for patients. His strategic priorities are to Enhance Human Safety Predictions and to Accelerate the Delivery of Candidate Drugs using novel approach methodologies.

Jorrit has a MSc in Molecular Cell Biology and a PhD in Systems Biology and has ~40 peer reviewed publications.

David R. Jones, BSc, MSc, CBiol, FRSB, ERT, FBTS
Consultant, Regulatory Pharmaco-Toxicologist, ApconiX

After spending 8 years in Contract Toxicology, 11 years as a Toxicologist in the Pharmaceutical Industry, Mr. Jones joined the Medicines and Healthcare products Regulatory Agency (MHRA) in London in 1996. He retired at the end of 2021 after 25 years at the agency, latterly as an Expert Pharmaco-Toxicologist and the most senior nonclinical assessor within the Agency.

Mr. Jones's role at the MHRA principally involved assessing nonclinical data for Clinical Trial Authorisation (CTA) Applications and Marketing Authorisation Applications (MAA), both for non-biological and biological products, including advanced therapy medicinal products (ATMPs) and Drug-Device combinations. He assessed every UK application regarding COVID 19 in 2020 and 2021.

A further aspect of his job was to offer scientific and regulatory advice to companies on behalf of the MHRA.

Mr. Jones represented the EU in the ICH revision of the M3 Guideline, on the ICH S10 Guideline, on the Q&A document for ICH S3 (Toxicokinetics) guideline and on the ICH S11 (Nonclinical Studies to Support Paediatric Medicine) guideline. He also added input into most other ICH Safety Guidelines.

Mr. Jones now works as an Independent Pharmaco-Toxicology consultant. He is also a guest lecturer at a number of universities and a frequent presenter at conferences around the world.

Steven Kozlowski, MD
Chief Scientist - Office of the Chief Scientist, U.S. Food and Drug Administration

Steven Kozlowski, MD, is the FDA's Chief Scientist. The Chief Scientist promotes, leverages, and leads cross-cutting, collaborative activities and initiatives that catalyze FDA science, innovation, and research to help the agency address its most pressing regulatory and public health questions and respond to emerging issues. The Office of the Chief Scientist supports the research foundation, science, and innovation that underpins the FDA's regulatory mission. It does this through a broad framework that encompasses scientific collaborations, laboratory safety, the transfer of FDA inventions to the private sector, scientific integrity in FDA policy and decision-making, the professional development of regulatory scientists, and conducting applied research and testing at the FDA, including in its National Center for Toxicological Research, Office of Analytical and Regulatory Laboratories, and Office of Specialty Laboratories and Enforcement Support.

Prior to assuming the role of Chief Scientist, Dr. Kozlowski served as Director of the Office of Product Quality Assessment III (OPQA III) in the Office of Pharmaceutical Quality (OPQ) in the FDA's Center for Drug Evaluation and Research (CDER). In that role he led a team responsible for ensuring the quality of all the active ingredients and substances in products overseen by CDER, which includes everything from over-the-counter analgesics to complex biological products. QPQA III was created as part of a major reorganization of the Office of Product Quality, an important initiative designed to support greater agility, connectedness and influence. Dr. Kozlowski was part of the strategic planning and change management involved in that effort.

Prior to the OPQ reorganization, Dr. Kozlowski served for 18 years as the Director of the Office of Biotechnology Products (OBP) in CDER's Office of Pharmaceutical Quality, overseeing the quality of therapeutic biological products and a laboratory program with research in manufacturing science, immunology and bioassays. His tenure coincided with a phenomenal growth in the use and impact of biological products, including the development of a new regulatory pathway for biosimilar biological products.

Megan R. LaFollette, MS, PhD
Executive Director, The 3Rs Collaborative

Dr. Megan LaFollette is the Executive Director at the 3Rs Collaborative, where she leads over 100 volunteers across the globe in advancing replacement, reduction, and refinement. With over a decade of experience in practical animal welfare and 3Rs solutions, she has been instrumental in advancing widespread implementation of evidence-based strategies such as refined mouse handling, rat tickling, workplace wellness programs, environmental health monitoring, and microphysiological systems. She holds a PhD in Animal Behavior and Welfare from Purdue University and sits on the American Veterinary Medical Association (AVMA)'s steering committee for human-animal interactions. Dr. LaFollette is driven by a deep belief in the power of collaboration to advance better science - for both people and animals.

Alexandra Maertens, PhD
Assistant Professor - Bloomberg School of Public Health, Johns Hopkins University

Dr. Maertens is an Assistant Professor at the Johns Hopkins Bloomberg School of Public Health, Center for Alternatives to Animal Testing, where she works at the intersection of artificial intelligence and public health. She has published on everything from cancer genomics to chemoinformatics. She is currently the leader of the Green Toxicology Network and the author of "Green Toxicology," the first textbook in the field.

Mary McElroy, MSc (Tox), PhD, MBA
Head, Discovery Pharmacology and Toxicology, Charles River Laboratories

Dr. Mary McElroy is a senior toxicology leader at Charles River Laboratories (CRL) with extensive experience in regulatory toxicology and nonclinical safety assessment. Her team, in collaboration with Mattek/Satorius are currently working on a project funded by the American Chemical Council to validate and qualify in vitro alternatives for chemical inhalation toxicity studies. Dr. McElroy is an advocate for translating innovative, human-relevant toxicology approaches into successful, regulator-accepted outcomes.

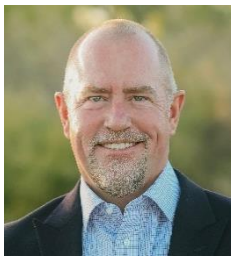
Timothy J. McGovern, PhD
Co-Founder; Principal Consultant, **White Oak Regulatory Tox, LLC**

Dr. Timothy McGovern is co-founder and a Principal Consultant at White Oak Regulatory Tox, LLC where he provides regulatory advice and nonclinical support for all aspects of nonclinical drug development. Tim recently completed a 22-year career at the US Food and Drug Administration (FDA) where he most recently served as an Associate Director for Pharmacology and Toxicology in the Office of New Drugs (OND) at the Center for Drug Evaluation and Research (CDER). In this role, he was a member of the Pharmacology/Toxicology Senior Leadership Team within OND and a standing member of CDER's Executive Carcinogenicity Assessment Committee.

Dr. McGovern was formally trained in the field of inhalation toxicology and began his career at the FDA as a reviewer in the Division of Pulmonary and Allergy Products and then Supervisor in that division. During this time, he represented FDA in discussions with industry regarding approaches in evaluating nonclinical inhalation toxicology data and how those data are applied in supporting clinical dosing. He also represented FDA on a multi-stakeholder effort in developing consensus recommendations on the safety qualification of extractables and leachables in orally inhaled and nasal drug products organized by the Product Quality Research Institute. Dr. McGovern was active in policy and guidance development on nonclinical and regulatory issues including FDA and International Council for Harmonization (ICH) initiatives including S1B (Testing for Carcinogenicity of Pharmaceuticals), Q3C (Residual Solvents), Q3D (Elemental Impurities) M7 (DNA reactive impurities) and served as a member of CDER's Task Force on Nitrosamines in Drug Products, providing nonclinical expertise in developing risk assessment policies, addressing clinical safety issues, and interacting with other Drug Regulatory Agencies and industry representatives.

Dr. McGovern is also a Past President of the American College of Toxicology, a current Councilor for the Society of Toxicology Regulatory and Safety Evaluation Specialty Section (RSESS) and a recipient of the 2024 RSESS Outstanding Contribution to Regulatory and Safety Evaluation Award.

Matthew D. Reed, PhD, DABT, F-ATS
Principal, Coelus LLC



Dr. Matthew D. Reed, PhD, DABT, Fellow ATS, is recognized in inhalation toxicology and respiratory drug development with more than 25 years of experience advancing inhaled and intranasal therapeutics from concept through clinical translation. As Principal of Coelus LLC and Chief Scientific Officer of Nob Hill Therapeutics, he integrates nonclinical development, regulatory strategy, formulation science, aerosol device engineering, translational pharmacology, and translational respiratory delivery to de-risk and accelerate respiratory programs. Prior to starting his consulting firm and joining Nob Hill, Dr. Reed was VP of Applied Toxicology and Nonclinical Development at Lovelace Biomedical. Dr. Reed received his PhD in pharmacology and toxicology from Texas A&M University followed by postdoctoral training in mechanistic and biochemical toxicology at the University of Texas MD Anderson Cancer Center and the University of New Mexico College of Pharmacy.

Emily Richardson, PhD
Biology Group Leader, CN-Bio Innovations

Dr. Emily Richardson is a Biology Group Leader at CN-Bio Innovations, where she oversees the development and validation of microphysiological systems (MPS) for toxicology and safety assessment. She joined CN-Bio in 2020 as a Senior Scientist and played a central role in creating the company's lung and lung-liver MPS models, advancing their use in the evaluation of inhaled therapeutics and infectious disease research. Since, she has led the development of MPS to determine cross-species safety concerns and investigative toxicology. Dr. Richardson has led multiple collaborative and grant funded programmes and serves as a key liaison across academic partners, pharmaceutical organizations, contract research organizations, regulatory bodies and standardization groups.

Her expertise spans complex cell biology and real-world drug discovery, informed by industry experience in cellular therapeutics and specializes in complex in vitro modelling. She received her degree in biochemistry and molecular medicine from the University of Nottingham and a PhD from the University of Leicester, where her work in 3D cell culture focused on mechanisms driving highly metastatic lung cancers and continues to shape her approach to developing more predictive and robust human relevant models.

Steven M. Rowe, MD, MSPH
Executive Vice President and Chief Scientific Officer, Cystic Fibrosis Foundation

Dr. Steven M. Rowe, MD, MSPH, is the Executive Vice President and Chief Scientific Officer for the Cystic Fibrosis (CF) Foundation, where he leads the Foundation's scientific strategy, including efforts to develop new therapies for CF. He is also a Professor at the University of Alabama at Birmingham (UAB) School of Medicine, where he directs a translational research laboratory focusing on cystic fibrosis and related conditions.

Dr. Rowe's pioneering work in cystic fibrosis has shaped the development of CFTR modulators, therapies that treat the underlying cause of CF. He has led or co-led numerous national and international clinical trials, including the landmark GOAL, PROSPECT, and PROMISE studies, which have transformed CF care and personalized therapy. Dr. Rowe is also a leader in genetic therapies for CF, having led national and international discovery efforts targeting CF nonsense mutations for which there are currently no approved therapies.

A prolific scholar, Dr. Rowe has authored over 280 peer-reviewed publications in top-tier journals including *Nature*, *New England Journal of Medicine*, and *Science Translational Medicine*. He holds multiple patents in imaging and therapeutic technologies, including innovations in micro-optical coherence tomography for live imaging of the human airway.

Dr. Rowe is a member of the American Society of Clinical Investigation and the Association of American Physicians. He has mentored more than 60 trainees, many of whom now lead CF research and care programs nationwide. Through his translational research, clinical leadership, and educational outreach, Dr. Rowe continues to advance respiratory medicine and improve outcomes for people with cystic fibrosis.

Jeff Tepper, PhD, DABT, DSP
Consultant, Tepper Nonclinical Consulting, LLC

Jeff is a preclinical research and development scientist with over 40 years of experience conducting pharmacology and toxicology studies. His main expertise is inhalation toxicology and respiratory pharmacology, with over 60 peer-reviewed publications in these areas. He earned his PhD in Pharmacology and Toxicology from the University of Rochester and is board-certified in both toxicology and safety pharmacology. Previously, he worked as a Project Scientist on contract to the US EPA Inhalation Toxicology Division, served as a Senior Scientist at Genentech in the Pulmonary and Immunology group, was the Director of Pharmacology at Bayer Biotechnology, and was VP of Pharmacology/Toxicology at Catalyst Biosciences. He also helped establish Aerovance Inc., a respiratory biotech company, and led the Pharmacology/Toxicology department. He is the current Past President of the American College of Toxicology, having previously served similar roles with the Northern California Society of Toxicology and the Roundtable of Toxicology Consultants. Since 2007, Jeff has worked as an independent pharmacology and toxicology consultant supporting virtual to multinational companies developing biopharmaceuticals.

William Thelin, PhD
Senior Vice President of Drug Development, Aer Therapeutics

Bill Thelin, PhD, is Senior Vice President of Drug Development at Aer Therapeutics, where he leads the advancement of novel inhaled therapies for muco-obstructive lung diseases including COPD and asthma. He oversees nonclinical, translational, CMC, and development strategy for AER-01 (fexlamose), a first-in-class mucolytic designed to dissolve airway mucus plugs and restore airflow in COPD, asthma, and other muco-obstructive diseases.

Dr. Thelin brings more than two decades of experience in pulmonary drug development and translational biology. Prior to joining Aer Therapeutics, he served as Chief Scientific Officer at Altis Biosystems and held senior leadership roles at Parion Sciences, where he contributed to the advancement of multiple respiratory programs from preclinical development through clinical proof-of-concept. He has extensive experience in inhalation toxicology, biomarker strategy, regulatory interactions, and integrating translational science into clinical development planning. He is actively engaged in efforts to modernize respiratory drug development, including initiatives focused on reducing reliance on animal testing through application of innovative nonclinical models.

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. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA.

Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions, a national healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Ms. Winckler directly advised CEOs and C-suite executives of life-sciences and pharmaceutical companies, payers, health-care providers, government agencies, employers, and associations on international, federal and state public policy and regulation, business strategy, investments, M&A, and other major business matters. Ms. Winckler also served as Chief Risk Management Officer for the entire Leavitt Partners family of businesses. Before becoming President, her role leading the DC office for Leavitt Partners included serving as Interim Executive Director of the Health Care Transformation Task Force, an alliance of patients, payers, providers, and purchasers committed to moving 75% of their businesses to value-based payment by 2020.

A pharmacist and attorney by training, Ms. Winckler was CEO of the Food & Drug Law Institute, which serves nearly all major law firms' food and drug practices, government regulators, leaders of pharmaceutical, device, food and tobacco companies, and consumers with class-leading legal and regulatory resources, analyses, updates, journals, and conferences. She provided a neutral forum for these stakeholders to address domestic and global food and drug law issues. She also served on FDLI's board.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), Ms. 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 the White House, myriad government entities, and external stakeholders. She was unique among her predecessors in also

simultaneously leading FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. In 2007, she led FDA's medical product negotiation with China's then-State Food and Drug Administration, resulting in the *Product Safety Memorandum of Agreement* between the two nations. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.

Ms. 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, a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council. She previously served on the boards of the Partnership for Safe Medicines and the American Society of Pharmacy Law, and on the executive leadership board for the Univ. of Iowa College of Pharmacy.