U.S. FOOD & DRUG ADMINISTRATION

Center for Veterinary Medicine (CVM)

Public Meeting: Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs

Johns Hopkins University – Montgomery County
9601 Medical Center Drive, Rockville, MD 20850
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Biographies

Margie Bell MS

For nearly 30 years, Margie has been providing statistical support and data management for clinical trial data. She has worked on Phase 1, Phase 2, Phase 3 and post-marketing studies in both human and animal health. She was the primary statistician for several products recently approved by the CVM. Margie received her MS in Mathematics with an emphasis in Probability and Statistics from Northern Illinois University.

Margie joined ACI in April of 2019. Her primary responsibilities include the successful coordination and execution for all projects involving biostatistics and/or data management, including management of all aspects of EDC systems. Margie's extensive experience and knowledge provides our clients with the security to know that their data and analyses will be produced accurately and in a timely manner.

When not busy analyzing data, Margie also enjoys hiking, running and golfing. Margie lives in Fort Collins, Colorado with her husband and black Labrador retriever, Ellie.

Dorothy Cimino Brown MS DVM DACVS

Dr. Brown is the Senior Director of Companion Animal Research at Elanco Animal Health, She received a B.S. in Zoology from the University of Maryland and DVM from the Virginia-Maryland Regional College of Veterinary Medicine. At the University of Pennsylvania, she completed her internship and surgical residency in the School of Veterinary Medicine and a Master's degree in Clinical Epidemiology in the School of Medicine. She stayed on, becoming a Professor of Surgery and the Executive Director of the Veterinary Clinical Investigations Center, overseeing the design, implementation, and analysis of clinical studies across a wide variety of therapeutic areas. She had a sponsored research program focusing on the measurement and management of chronic pain in companion animals, developing and validating outcome assessment instruments, including the Canine Brief Pain Inventory, for use in chronic pain studies. Since joining Elanco in 2017, her focus has been on the design and implementation of translational studies, as well as the discovery, development and registration of new drugs for animal health.

Aloka Chakravarty PhD

Aloka Chakravarty is the [Acting or Deputy] Director of the Office of Biostatistics in CDER, FDA. Dr. Chakravarty joined CDER in 1992 and brings to her current position considerable experience in CDER. She is an internationally recognized thought leader in multi-regional clinical trials, safety evaluation, surrogate markers and biomarkers in drug development and has presented and published widely on it. Her research interests include MRCTs, surrogate endpoint methodology, biomarkers, interim analysis, meta-analysis, Bayesian methodology,

safety evaluation and statistical computing. Dr. Chakravarty served as an Adjunct Faculty in Department of Statistics, Foundation for Advanced Education in the Sciences, National Institutes of Health.

Dr. Chakravarty has received numerous awards, including the FDA Award of Merit in 2008 and Dr. Frances O. Kelsey Drug Safety Excellence Award in 2012. Aloka received her Ph.D. in Statistics from Temple University, and M.Stat from Indian Statistical Institute. Dr. Chakravarty is a Fellow of the American Statistical Association and an Associate Editor of Statistics in Biomedical Research.

Sharon Chase DVM MPH

Dr. Sharon Chase is a small animal veterinarian with over a decade of clinical practice experience gained from working in general and emergency hospitals in Massachusetts and Washington, DC. In addition to clinical practice, Dr. Chase served as a reviewer with the Food and Drug Administration's Center for Veterinary Medicine (CVM) for over seven years. She currently works as a regulatory consultant for the veterinary pharmaceutical industry with Schafer Veterinary Consultants, based in Fort Collins, Colorado.

Richard Clemence BSc MSc PhD MBiol MRQA

Richard Clemence obtained his first degree in Agriculture from the University of Edinburgh, Scotland and later completed both a masters degree and PhD at the Centre for Tropical Veterinary Medicine at the same university. After 10 years working in livestock development in a diverse range of developing countries around the world, Richard moved to veterinary pharmaceutical development and registration where he has been for the last 24 years. He has worked for two of the top five global animal health companies and in between ran a small CRO providing development and registration services to some of the biggest animal health companies. He has hands-on experience of running clinical trials and programs in many European Union countries and has successfully led global research and development projects from discovery through to successful registrations and launches in the United States, Europe, and elsewhere, utilizing clinical data from both Europe and North America in the process. Richard is now the Head of Global Clinical at Dechra Pharmaceuticals. He currently lives in the United Kingdom with his wife and dog.

Johann “Hans” Coetzee BVSc Cert CHP PhD DACVCP DACAW DECAWSEL

Dr. Hans Coetzee is a Professor and Head of the Department of Anatomy and Physiology at Kansas State University. He earned his Bachelor of Veterinary Science degree from the University of Pretoria, South Africa in 1996. After graduation he worked for four years in mixed animal practice in Northern Ireland followed by 2 years in pharmaceutical research and development at Norbrook Laboratories Ltd. He earned a specialist Certificate in Cattle Health and Production from the Royal College of Veterinary Surgeons (London) in 2000 and a doctorate in Veterinary Microbiology from Iowa State University in 2005. He holds dual board certification in the American College of Veterinary Clinical Pharmacology and American College of Animal Welfare and is a European Specialist in Animal Welfare Science, Ethics and Law. His professional interests include the development of pain assessment techniques and practical analgesic drug regimens for use in food animals. He has published 150 peer-reviewed scientific papers and received over $10 million in research funding. In his free time he enjoys spending time with his wife and his twin daughters.

Laura Hungerford DVM MPH PhD CPH FNAP

Dr. Laura Hungerford is a veterinary epidemiologist and has been Head of the Department of Population Health Sciences at the Virginia-Maryland College of Veterinary Medicine, Virginia Tech campus since 2016. Her department houses MPH, DVM/MPH, MD/MPH, BSPH and Certificate in Public Health programs; the Center for Public and Corporate Veterinary

Medicine; and the Center for Public Health Practice and Research. Dr. Hungerford received her DVM from Michigan State University. She then completed a food animal internship, training in diagnostic microbiology, and a PhD in veterinary epidemiology at the University of Illinois College of Veterinary Medicine. She also received an MPH in epidemiology and biometry from the University of Illinois School of Public Health. She was previously a tenured Associate Professor at the University of Illinois and the University of Nebraska; a tenured Professor, Director of the Graduate Program in Epidemiology and Human Genetics, and of the Epidemiology track of the UMB MPH program, at University of Maryland School of Medicine; and a Senior Advisor for Science and Policy at FDA.

Dr. Hungerford has been active in teaching a wide range of epidemiology and public health courses to graduate, medical and veterinary students, as well as providing continuing education for veterinarians and other health professionals. She is a member of numerous professional associations and was elected as a Distinguished Fellow in the National Academies of Practice. Her publications, grants and research interests include collaborative studies that take a One Health approach to risk factors for infectious and zoonotic diseases, application of geographic information system and spatial statistical analyses, and dynamic modeling in multidisciplinary health problems. She has collaborated on developing innovations for drug review at FDA, human infectious disease modeling, and projects with zoos and wildlife agencies involving raccoons, deer, frogs, sea turtles, big cats, birds, and aquatic mammals.

Mary Jane Ireland MSc DVM MBA

Dr. Ireland is the Director General of Health Canada's Veterinary Drugs Directorate. The Veterinary Drugs Directorate works to protect human and animal health and the safety of Canada's food supply. The Directorate evaluates and monitors the safety, quality and effectiveness of veterinary drugs, sets standards for food safety and promotes the responsible use of veterinary drugs for pets and food-producing animals. Dr. Ireland has been extensively involved in leading various regulatory and policy initiatives aimed at the responsible use of antimicrobials in animals. She participates in a number of international committees including the VICH Steering Committee and the Transatlantic Task Force on Antimicrobial Resistance. Dr. Ireland champions regulatory cooperation with international regulatory authorities and co-leads the Regulatory Cooperation Council Veterinary Drug Initiative with the United States Food and Drug Administration – Center for Veterinary Medicine.

Terry Katz MS

Terry Katz is Head of Global Data Management and Statistics at Merck Animal Health. Previously he was Head of Biometrics at ImClone Systems, Senior Manager of Analysis & Reporting for PRA, and a Statistician at Schering-Plough. He holds Accreditation as a Professional Statistician, and Certifications as a Quality Engineer and in Six Sigma. He is Chair of DIA's GCP-QA Community, on the Core Committee for NJ CDISC User Group, and former Chair of Statistical Taskforce for the Animal Health Institute. Terry recently completed a 3 month Fellowship in Kenya to improve capacity to run oncology clinical trials.

Elizabeth Lund DVM MPH PhD

Elizabeth Lund, DVM, MPH, PhD is currently President, DataDogs, LLC. Dr. Lund is a companion animal population research consultant with over 25 years professional experience leveraging digital pet health data to generate evidence and insights to drive organizational strategy and success. Over her career, she has worked in diverse sectors of animal health, including academia, corporate veterinary practice and, public health.

Lisa Meier McShane PhD

Lisa Meier McShane, Ph.D., is an Acting Associate Director for the Division of Cancer Treatment and Diagnosis (DCTD), U.S. National Cancer Institute, National Institutes of Health. Dr. McShane heads the Biometric Research Program (BRP) within DCTD. BRP comprises the Biostatistics and Computational and Systems Biology Branches with members including statisticians, bioinformaticians, and computational biologists. Dr. McShane is internationally recognized for her expertise on development of tumor markers for prognosis, therapy selection, and disease monitoring; omics-based predictors for clinical use; biomarker-based clinical trial design; and reporting guidelines for health research studies. She holds a Ph.D. in Statistics from Cornell University and is a Fellow of the American Statistical Association. Her statistical research interests include precision medicine clinical trial design, analysis of high-dimensional omics data, multiple comparisons methods, surrogate endpoints, measurement error models, and biomarker assay analytical performance assessment. She co-led efforts to develop "Reporting guidelines for tumor marker prognostic studies (REMARK)" and "Criteria for the use of omics-based predictors in clinical trials." She has coauthored numerous statistical and biomedical papers and the book *Statistical Design and Analysis of DNA Microarray Investigations*.

Chad A. Ray PhD

Chad is currently a Senior Scientific Director and Group Leader for the Pharmacokinetics, Dynamics, Metabolism, and Biomarker team at Zoetis. He is responsible for de-risking all therapies with respect to PKPD, and creating a biomarker strategy for each program. Prior to joining Zoetis, he was a Senior Director in the department of BioMedicine Design at Pfizer supporting oncology discovery projects. His group was responsible for pre-clinical non-regulated bioanalysis of protein therapeutics, immunogenicity, and pharmacodynamic biomarkers. Chad has more than 20 years of experience in bio-pharmaceutical industry in bioanalytical and biomarker disciplines covering the entire drug development paradigm. His areas of research interest include the application of pharmacodynamic biomarkers for novel therapeutics, and application of new technology to improve large molecule bioanalytical reliability. Chad received his B.S. in Biology from the University of Evansville and Ph.D. in Pathology Laboratory Medicine from Indiana University. He has been an active participant in the AAPS community delivering invited lectures, serving as the biomarkers in translation focus group chair, organizer of short courses and workshops, and co-author of cross-industry publications.

John Scott PhD

Dr. Scott is Director of the Division of Biostatistics in the FDA's Center for Biologics Evaluation and Research, where he has also served as Deputy Director and as a statistical reviewer for blood products and for cellular, tissue and gene therapies. Prior to joining the FDA in 2008, he worked in psychiatric clinical trials at the University of Pittsburgh Medical Center and did neuroimaging research with the Neurostatistics Laboratory at McClean Hospital, Harvard Medical School. He has authored or co-authored numerous articles in areas including Bayesian and adaptive clinical trial design and analysis, drug and vaccine safety, data and text mining, and benefit-risk assessment. He is the CBER co-lead for 21st Century Cures and PDUFA VI efforts in Complex and Innovative Trial Design and has been heavily involved in a number of FDA's statistical policy and outreach projects, including the 2018 draft Adaptive Design Guidance for Drugs and Biologics and the ICH E9(R1) expert working group on estimands and sensitivity analyses. Dr. Scott holds a Ph.D. in Biostatistics from the University of Pittsburgh, an M.A. in Mathematics from Washington University in St. Louis, and a B.A. in Liberal Arts from Sarah Lawrence College. He is a Fellow of the American Statistical Association and is currently Editor of the journal, Pharmaceutical Statistics.

Kristi O. Smedley PhD

Dr. Smedley has worked in the area of the regulation of animal feed for over 30 years. She is the Vice President and owner of the consulting firm, Center for Regulatory Services. The major focus of Dr. Smedley regulatory advice is animal feed and human food ingredients. She is the author of the two International Feed Ingredient Federation comparative studies on the regulation of feed ingredients among various countries/jurisdictions in the world. Her first 10 years she served with the Center for Veterinary Medicine, Food and Drug Administration in the Division of Animal Feeds and the Petitions and Regulations Branch. During this time, she coordinated the FDA response to the challenge of the selenium regulation, the establishment of federal regulations for the prevention of BSE, as well as, assessment of new feed ingredients (additives). Dr. Smedley received her Bachelor of Science from Penn State (Biology) and her Master and Doctorate degrees from Virginia Tech, in Animal Science (focusing on Ruminant Nutrition).

Robert Temple MD

Robert Temple serves as CDER's Deputy Center Director for Clinical Science and Senior Advisor in the Immediate Office of the Office of New Drugs (OND). As the senior advisor, Bob is a consultant to the OND director and other FDA officials on matters related to clinical program objectives.

Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972, he joined CDER as a review Medical Officer in the Division of Metabolic and Endocrine Drug Products. He later moved into the position of Director of the Division of Cardio-Renal Drug Products.

Before becoming Senior Advisor in OND, Dr. Temple was the Acting Deputy Director of OND's Office of Drug Evaluation-I (ODE-I) which is responsible for the regulation of cardiovascular and renal, neurology, and psychiatry drug products. He served in this capacity for more than 23 years -- since the office's establishment in 1995.

Dr. Temple has a long-standing interest in the design and conduct of clinical trials. He has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control trials, trials to evaluate dose-response, and trials using "enrichment" designs. He has been involved in the development of many International Conference on Harmonization (ICH) guidelines and numerous FDA guidances, including ones on study enrichment and on issues related to the design and interpretation of non-inferiority studies.