MACHINE INTELLIGENCE FOR QUANTITATIVE MODELING IN DRUG DISCOVERY & DEVELOPMENT APPLICATIONS WORKSHOP

15-16 SEPTEMBER 2022

Speaker / Panelist / Moderator Biographies

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

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Dr. Jiang Bian

Professor of Biomedical Informatics, University of Florida, College of Medicine

Dr. Bian serves as the Chief Data Scientist for the University of Florida (UF) Health, Director of Cancer Informatics Shared Resource, Associate Director of the Biomedical Informatics Program for the UF Clinical and Translational Science Institute (CTSI), and the Chief Data Scientist for the OneFlorida+ Clinical Research Consortium. His research serves an overarching theme: data science with heterogeneous data, information, and knowledge resources. His research areas can be divided into 2 logical sections under this overarching theme: (1) data-driven medicine—applications of informatics techniques, including machine learning methods in medicine on solving big data problems; and (2) development of novel informatics methods, tools and systems to support clinical and clinical research activities such as tools for data integration, clinical trial generalizability assessment, and cohort discovery.

Dr. Richard Bonneau

Co-founder and Executive Director, Prescient Design, Genentech

Richard Bonneau is an American computational biologist and data scientist who leads Prescient, a molecular design accelerator at Genentech, a member of the Roche Group, that pioneers new methods using machine learning (ML) and molecular modeling. Bonneau's primary research spans multiple levels of biological structure and includes learning and modeling biological networks designing protein and biomimetic structures and building ML to carry out social science with social networks. Bonneau received his Ph.D. at the University of Washington studying under Dr. David Baker, where he pioneered new methods to predict biomolecular structures (roughly 1 million years ago). At Prescient within Genentech Research and Early Development (gRED), Bonneau and his team play a small part in the overall effort at Genentech to revolutionize molecular design and drug discovery with computational advances.

Dr. Fabio Broccatelli

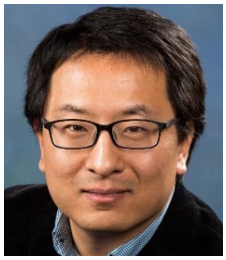
Associate Director DMPK Group Leader, Bristol Myers Squibb

Dr. Fabio Broccatelli received his Ph.D. in computational chemistry from the University of Perugia working with Professor Gabriele Cruciani. During his Ph.D., focusing on machine learning-based predictions of ADME properties, he was a visiting scientist at UCSF in the Leslie Benet PK lab. He went on to a Post Doc at the Institute of Cancer Research London and then joined Genentech, where he worked for 8 years building an in silico ADME group within the DMPK department. Dr. Broccatelli currently works

as Associate Director leading the DMPK group for the Oncogenesis Thematic Research Center at the BMS; his responsibilities include leading the San Diego based in vitro ADME, bioanalysis, and translation pre-clinical DMPK groups. His main areas of focus include ML/AI, PBPK, IVIVc, and ADME-informed chemical design. Dr. Broccatelli has published over 30 peer-reviewed articles, patents, and book chapters and serves as a reviewer for over 15 scientific journals. Dr. Broccatelli initiated and co-led the in silico ADME IQ group.

Dr. Youfang Cao

Director of Pharmacometrics, Eisai Inc.



Youfang obtained his Ph.D. in Mathematical Biology and had a long interest in AI and Machine Learning. Youfang is an expert in Quantitative Systems Pharmacology (QSP) modeling and has successfully developed and implemented mechanistic QSP modeling strategies for multiple drug development programs. He is particularly interested in leveraging AI/ML and NLP to address the challenges in mechanistic modeling and QSP.

Dr. Prashant Desai

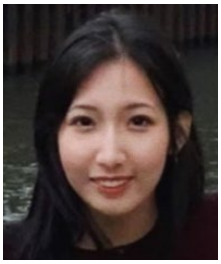
Senior Principal Scientist, Genentech

Prashant Desai is currently a Senior Principal Scientist in the DMPK function of Genentech. Prior to this role, he was a Senior Director in the ADME (DMPK) department of Eli Lilly and Company, responsible for in silico and in vitro modeling groups namely, Computational ADME, Mechanistic PK, and Investigational Drug Disposition. He received a BS in Pharmacy, an MS in medicinal chemistry, and a Ph.D. in Biophysics and Computational Chemistry from the University of Bombay (India).

Prashant has been working in the field of in silico, in vitro, and in vivo ADME for the past 15+ years. He started his career at Lilly as a computational ADME scientist in 2007 and has been instrumental in building the infrastructure for machine learning models for predicting ADME properties, among other cheminformatics tools. He has also served as ADME project leader across various therapeutic areas during his career. As a scientific leader in preclinical ADME research, Prashant's primary focus has been on the effective integration of in silico, in vitro, and in vivo ADME models during the early phase of drug discovery in line with the mechanistic pharmacokinetics principles. He has contributed to more than 50 papers in peer-reviewed journals and book chapters.

Dr. Jenny Ding

Research Advisor, Eli Lilly and Company



Jenny received her BS in Microbiology, Immunology, and Molecular Genetics from UCLA and her MS in Healthcare Analytics and Information Technology from Carnegie Mellon University. She had prior research experience building clinical decision support tools to predict disease prognosis from EHRs and developing neural networks to understand viral divergence from sequencing data. In her role as a data scientist at Merck's Quantitative Pharmacology and Pharmacometrics department, she used Natural Language Processing algorithms to automate literature selection for meta-analysis and ML models to reduce dimensionality for Parkinson's Disease digital biomarkers data. Most recently, she will be joining Northwestern University's Biomedical Informatics Ph.D. program to develop multi-modal models to understand disease subtypes and aid the development of precision medicine.

Dr. Nicholas Ellinwood

Research Advisor, Eli Lilly and Company

Nicholas Ellinwood received a B.S. in Neuroscience from the University of California, Los Angeles, and completed a Ph.D. in Pharmacology & Toxicology form the University of California, Davis. He also has an M.P.H. in Applied Biostatistics from the University of Colorado, Denver, and has worked in academia, government agencies, non-profit organizations, and biotechnology companies over the past 15 years. In 2019, Nick joined Eli Lilly & Company in Indianapolis, IN, as a Research Advisor in the Global PKPD department. His research primarily focuses on Quantitative Systems Pharmacology modeling but includes using mechanistic modeling in the pre-clinical/drug discovery space and applying artificial intelligence and machine learning to augment pharmacometric analyses.

Dr. Jonathan L. French

Fellow II, Statistics Science Advisor, Metrum Research Group

Dr. Jonathan French is Fellow II and Science Advisor at Metrum Research Group where he leads statistical excellence initiatives and research and development projects. He is a Biostatistician by training, having received a doctorate in Biostatistics from Harvard University where he studied Bayesian methods and applications in missing data. Prior to joining Metrum, his previous industry appointments include over 10 years at Pfizer, Inc., where he held positions of increasing responsibility, including

pharmacometrics group leader for both Inflammation and Oncology products. Over the course of his pharmacometrics career, Jonathan has developed expertise in decision analysis, model-based meta-analysis, and disease progression modeling, typically applying these using Bayesian methods. He is a Fellow of the International Society of Pharmacometrics and a member of the CPT:PSP Editorial Board.

Dr. Nigel Greene

Senior Director, Imaging and Data Analytics, AstraZeneca

Nigel Greene is a Senior Director in Imaging and Data Analytics within Clinical Pharmacology and Safety Sciences at AstraZeneca. His research interests include the application of machine learning and artificial intelligence methods to understand the structural basis of drug-induced toxicity, understanding their mechanisms from high-content data sets such as transcriptomics as well as their translation to clinical patient populations.

Dr. Greene received his B.Sc. in Chemistry and Computational Science and his Ph.D. in Organophosphorus Transition Metal Chemistry from the University of Leeds in the UK.
During his career, Dr. Greene has published over 60 peer-reviewed articles and book chapters and has been a member of SOT since 2003, serving as an officer in the Computational Toxicology Specialty Section since its inception in 2017, and is the current President.

Dr. Greene began his career working for Lhasa Ltd. where he pioneered computational toxicology as a scientific discipline and later moved to Tripos Inc, (1999-2001) where he became more involved in traditional computational chemistry. In 2001, Dr. Greene emigrated to the USA spending 14 years working for Pfizer Inc. in Groton, CT starting in Molecular and Investigative Toxicology in Drug Safety R&D and later transitioning to the Compound Safety Prediction group in Medicinal Chemistry in 2009. In 2015 he moved to AstraZeneca where he is currently based in Boston, MA.

Nigel's other activities and positions of responsibility outside of AstraZeneca have included serving as the Chair of the Board of Trustees for Lhasa Ltd from 2013-2015. He has also served on multiple National Research Council committees sponsored by the US Environmental Protection Agency, the US Food and Drug Administration, and the National Institutes of Health.

Dr. Cornelis "Marcel" Hop

Vice-President, Genentech

Dr. Cornelis "Marcel" Hop is Vice-President at Genentech and supervises the DMPK department. He leads a team of about 85 scientists involved in the acquisition and interpretation of ADME data in support of drug discovery and development ranging from early-stage research to NDA and beyond. Before that, he was a Senior Director at Pfizer and a Senior Research Fellow at Merck. He has extensive experience in ADME sciences with a particular focus on PK optimization, human PK prediction, biotransformation, bioanalysis, and the use of artificial intelligence and machine learning in drug discovery. He has authored more than 185 publications and made more than 85 external oral presentations. In addition, he co-authored one of the best-selling books in the ADME field: Drug Metabolism and Pharmacokinetics Quick Guide.

Dr. Meng Hu

Team Lead, Division of Quantitative Methods and Modeling, Office of Research and Standards (ORS) OGD | CDER | US Food and Drug Administration

Dr. Hu received both his Bachelor of Engineering in Biomedical Engineering and Ph.D. in Physics from Zhejiang University, China. He conducted his post-doctoral training at Drexel University, Philadelphia. He joined the FDA's Center for Drug Evaluation & Research as a staff fellow in 2015 and currently serves as a team leader in the Division of Quantitative Methods and Modeling under the Office of Research and Standards in the Office of Generic Drugs. His main research interests include the development and application of advanced data analytics tools to promote business intelligence in government, big data management, generation of real-world evidence, and quantitative methods to facilitate assessment for in-vitro bioequivalence study. His published works include machine learning (ML) based time-to-event analysis, predictive analysis of first abbreviated new drug application (ANDA) submission for new chemical entities based on ML methodologies, equivalence assessment of complex particle size distribution, quantitative method to facilitate active pharmaceutical ingredient (API) sameness assessment for complex peptide products, and analysis of dissolution failure of solid oral drug products in field alert reports.

Dr. Beth Joshi

Executive Director, Discovery Metabolism and Pharmacokinetics, Bristol Myers Squibb

Elizabeth Joshi received her Ph.D. in Chemistry from the University of Virginia in 2004 studying chemical mechanisms of idiosyncratic drug reactions. During her career, she has held positions of increasing responsibility with Eli Lilly (Indianapolis, IN) and Merck & Co (Kenilworth, NJ). Beth is currently the Executive Director of Discovery Metabolism and Pharmacokinetics at Bristol Myers Squibb (Lawrenceville, NJ). Her research interests include leveraging in silico DMPK tools to augment early decision-making across programs, as well as understanding the physicochemical properties which influence dose optimization.

Dr. Sarah Kim

Assistant Professor, Department of Pharmaceutics, University of Florida College of Pharmacy

Dr. Sarah Kim is a practicing pharmacometrician with a background in Applied Mathematics and an Assistant Professor in the Department of Pharmaceutics at the University of Florida College of Pharmacy. She is passionate about model-informed drug discovery and development (MID3). Since her postdoctoral training in pharmaceutical sciences focused on pharmacometrics, she has received recognition from the international MID3 scientific community, including the David Goldstein Award and Presidential Trainee Awards from the American Society for Clinical Pharmacology and Therapeutics. As an early-stage Principal Investigator, she is currently leading several computational modeling projects to create and innovate quantitative solutions in healthcare. The shared goal of these projects is to develop model-based clinical trial simulation tools. These tools will help drug developers optimize clinical trial designs to detect therapeutic effects more efficiently, therefore reducing clinical trial times, expenses, and participant burden. Using Artificial Intelligence (AI), her team is further developing an imaging analysis and informatics tool to improve understanding of disease progression using imaging data. Her experience includes being a session chair of AI hands-on tutorials at the American Conference on Pharmacometrics. Since 2020, she has served as an AI initiative committee member at the University of Florida College of Pharmacy.

Dr. Frank Kloprogge

Wellcome Trust Sir Henry Dale Fellow, University College London

As a clinical pharmacological modeler, Dr. Kloprogge is interested in parameterising the relationship between drug levels and the drug effect. At the University College London Institute for Global Health his main research focus is around three themes.

The first theme is in-vivo pharmacokinetic-pharmacodynamic properties of anti-tuberculosis drugs and explore candidate biomarkers for cure. Dr. Kloprogge designs and runs population pharmacokinetic-pharmacodynamic studies and observational cohorts in the UK and abroad. Second, Dr. Kloprogge also investigates biomarkers for bacterial sub-populations that can survive treatment. He has setup in-vivo mimicking in-vitro experiments (hollow fibre experiment of infection) at UCL. Finally, Dr. Kloprogge is one of the co-founders of PKPDai, an initiative that brings together quantitative pharmacometric knowledge into a single open-source platform, thereby making it amenable to the application of machine learning. PKPDai has been leveraging natural language processing as due to the size of publicly available data manual curation is not a viable option.

Dr. James Kozloski

Principal Research Scientist, IBM

James Kozloski joined IBM Research in May 2001, where he's worked in the Computational Biology Center at the T.J. Watson Laboratories in Yorktown Heights, NY.

He was named an IBM Principal Research Scientist in 2022 and leads IBM's department of Hybrid Biological-AI Modeling, working with external collaborators in Neuroscience, Cardiology, and Pharmacometrics, and modeling brain and heart function from synaptic plasticity in neural circuits to myocyte contraction to active heart and brain tissues. As a manager, James oversees efforts to use AI to solve stochastic inverse problems for biophysical models of disease and drug mechanism of action. His team focuses on quantitative systems pharmacology and PKPD for model-based therapeutic design and triaging, applying deep learning methods and generative models to population parameter inference. In 2017 he was inducted into IBM's Academy of Technology.

In addition to publishing his scientific work, James has over 250 issued patents in the areas of neuroscience, neurotechnology, and computer science. In 2010, he was named an IBM Master Inventor. In 2015, James began an IBM initiative to model computation in the neocortical, thalamic, and basal ganglia circuit, which has grown under his leadership into IBM's Systems Neuroscience Approach to General Intelligence (SynAGI).

Dr. Qi Liu

Associate Director for Innovation & Partnership in the Office of Clinical Pharmacology (OCP), OTS, CDER, US Food and Drug Administration

Dr. Qi Liu is currently the Associate Director for Innovation & Partnership in the Office of Clinical Pharmacology (OCP), OTS, CDER, FDA. She leads OCP's innovative initiatives through strategic partnership. She helped developing OCP's capacity/portfolio on machine learning/artificial intelligence, real world evidence and digital health technologies, collaborating with internal and external experts to help keep the Office stay abreast of current trends in innovative approaches. During her career at the FDA, she also contributed to over 200 NDA/sNDA reviews, 20 BLA/sBLA reviews, and numerous IND reviews to support drug development. She co-authored over 50 manuscripts and presented on many topics at FDA Advisory Committee meetings and scientific conferences. She worked on several working groups for FDA guidance documents and Manual of Policies & Procedures development. She contributed to the Real-Time Oncology Review (RTOR) and Assessment Aid Pilot Programs. In addition, Dr. Liu leads OCP's Innovative Data Analytics program and Machine Learning Review Team. In addition, she is a member of the FDA Digital Health Advisory Board AI/ML subcommittee. Dr. Liu is a Fellow of the American College of Clinical Pharmacology. She is on the editorial board of the American Association of Pharmaceutical Scientists Journal, Clinical Pharmacology and Therapeutics, Clinical and Translational Science: Pharmacometrics and Systems Pharmacology, and of Clinical and Translational Science.

Before joining FDA, Dr. Liu was a senior pharmacokineticist at Merck & Co. Inc. She obtained her Ph.D. degree in Pharmaceutics and a concurrent Master's degree in Statistics from the University of Florida in 2004. In addition, she has a Master's degree in Pharmaceutics and a Bachelors' degree in Clinical Pharmacy from West China University of Medical Sciences.

Dr. James Lu

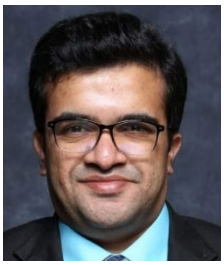
Principal AI Scientist in Modeling & Simulation/Clinical Pharmacology, Genentech

Dr. James Lu is a Principal AI Scientist in Modeling & Simulation/Clinical Pharmacology at Genentech, where he currently leads a team of AI/ML scientists in applying and developing advanced algorithms to clinical data. Prior to that, he worked in modeling roles at Roche in Basel Switzerland, and AstraZeneca in Cambridge UK. He is an applied mathematician by training and obtained a bachelor's degree in Mathematics and Ph.D. in Computational Fluid Dynamics from MIT. After his Ph.D., he performed postdoctoral research in mathematical and systems biology within both academia and industry. Over the past years, he has contributed to Quantitative Systems Pharmacology and AI/ML modeling efforts from both the safety as well as efficacy perspectives, in various

therapeutic areas ranging from lipid metabolism, and ophthalmology to oncology. He has authored over 30 refereed publications in various technical journals and is the co-inventor of several AI/ML patents. He has given presentations at major conferences including PAGE, and he and his team have been selected to receive the ACoP Quality Abstract Awards in 2021-2022 based on their work applying Deep Learning to clinical PK and PK/PD data.

Dr. Kumpal Madrasi

Associate Director of Modeling and Simulation, Pharmacokinetics, Dynamics & Metabolism (PKDM), Sanofi



Dr. Kumpal Madrasi is currently employed as an Associate Director of Modeling and Simulation at the division of Pharmacokinetics, Dynamics & Metabolism (PKDM) in Sanofi. Prior to his position at Sanofi, he was a Principal Scientist at EMD Serono in the Translational Quantitative Pharmacology (TQP) group from 2019 to 2022 and a Senior Scientist at Applied Biomath from 2016 to 2019. He also held postdoctoral fellowships from 2013 to 2016 at Mercer University, and the University of Florida, the latter of which included funding from the ORISE institution that involved collaboration with the FDA. He has a background in biomedical engineering, with a Ph.D. in the discipline from Florida International University and a B.E. from UV Patel College of Engineering in India. His interests involve systems and population modeling with a desire to understand mechanistically. In the long term, he is interested in learning and adapting aspects of Artificial Intelligence and Machine Learning into the work he does.

Dr. Sujatha Menon

Senior Director, GPD, Pfizer. Inc.

Dr. Menon is a Senior Director at Pfizer with over 25 years of experience in clinical pharmacology, including nearly 19 of those at Pfizer, with previous years at Hoffman La-Roche and at Schering-Plough. She received her Ph.D. from the University of Michigan where she worked with Prof. Gordon Amidon. While Sujatha's experience in clinical pharmacology has spanned several disease areas, her focus at Pfizer has been largely in Inflammation, and particularly in Rheumatology. She has always been an advocate of model-based drug development and over the years has successfully led several MIDD-based submissions to approvals. She has co-authored book chapters and several research articles including some publications in high-impact journals like The Lancet, New England Journal of Medicine and other noteworthy rheumatology journals.

Dr. Kamrine Poels

Senior Scientist, Early Clinical Development Quantitative Systems Pharmacology, Pfizer Inc.

Kamrine Poels is a senior scientist in the Early Clinical Development Quantitative Systems Pharmacology (ECD-QSP) group where she supports the oncology research unit. She obtained her Ph.D. in biostatistics from Harvard in 2022. Her dissertation focused on building tumor evolution models to identify optimal drug dosing schedules in combinational therapy. After her Ph.D., she joined Pfizer ECD-QSP as a post-doc where she was able to refine her skills with mechanistic models of cancer and drug response. Using her training in statistics, she has been able to employ more data-driven approaches when building or calibrating mechanistic models at Pfizer. Her interests primarily lie in refining her knowledge in machine learning and combining ML methods with QSP, or mechanistic, models for oncology research.

Dr. Joifung Poon

Senior Director, Microsoft Health Futures

Hoifung Poon is Senior Director at Microsoft Health Futures and an affiliated professor at the University of Washington Medical School. At Microsoft, he leads research on biomedical AI, with the overarching goal of structuring medical data for precision medicine. He has given tutorials on this topic at top conferences such as the Association for Computational Linguistics (ACL) and the Association for the Advancement of Artificial Intelligence (AAAI). His research spans a wide range of problems in machine learning and natural language processing (NLP), and his prior work has been recognized with Best Paper Awards from premier venues such as the North American Chapter of the Association for Computational Linguistics (NAACL), Empirical Methods in Natural Language Processing (EMNLP), and Uncertainty in AI (UAI). He received his Ph.D. in Computer Science and Engineering from University of Washington, specializing in machine learning and NLP.

Dr. Didier Renard

Modeling & Simulation Novartis Pharma AG

Didier Renard is a statistician by training and spent the first part of his career as project statistician in the pharma industry. He has been in the Pharmacometrics/Modeling & Simulation group at Novartis for 13 years, operating in various roles. He is currently overseeing Pharmacometrics contributions in the Immunology and Global Health areas, and in Global Medical Affairs. More recently he has been interested by the rapid adoption of AI/ML techniques in pharma and how they can be bridged with traditional pharmacometrics approaches to enhance decision making in drug development.

Dr. John Sanders

Senior Director, Merck & Co., Inc.

John Sanders received a B.A. in Chemistry from Colgate University and completed a Ph.D. in Physical Chemistry at the University of Illinois at Urbana-Champaign. At UIUC, John worked with Eric Oldfield and used molecular modeling to characterize and design novel bisphosphonates for their potential use as antiparasitic agents. He joined Merck in 2006 as a computational chemist in West Point, PA where he has primarily worked on neuroscience and infectious disease discovery programs. In recent years John has been a champion of the prospective application of machine learning for decision-making in various discovery contexts, particularly in ADMET properties. Beginning in late 2020, he has also partnered with colleagues in development and worked to bridge the computational efforts in the discovery and development organizations.

Dr. Mohamed Shahin

Clinical Pharmacology Lead in Global Product Development, Pfizer Inc.

Dr. Mohamed Shahin is a Clinical Pharmacology Lead in Global Product Development at Pfizer. He is a pharmacist by training with extensive training in the field of Clinical Pharmacology, Precision Medicine, and Biomedical Informatics. He received his Ph.D. from the University of Florida, followed by a master's degree in biomedical informatics and a 2-year fellowship in informatics at the University of Florida Informatics Institute. Over the past ten years, he led several research projects, both in academia and the pharmaceutical industry, to optimize drug response for patients with complex diseases and support drug development in different therapeutic areas. He has contributed to the field of Clinical Pharmacology, Precision Medicine, and Biomedical Informatics by

publishing several research articles in high-impact journals like The Lancet, Clinical Pharmacology and Therapeutics, and Hypertension as well as chairing several workshops and symposiums in national and international scientific meetings. He currently serves as an Associate Editor for the Clinical and Translational Science Journal and as an Editorial Board member for the Clinical Pharmacology and Therapeutics journal. He also serves as the Chair of the Translational Informatics Community at the American Society for Clinical Pharmacology and Therapeutics.

Dr. Thomas Tensfeldt

Senior Director of Clinical Pharmacology and Pharmacometrics, Pfizer Inc.

Tom has over 39 years of experience with Pfizer in pre-clinical and clinical research and development. Tom developed and managed the original Pfizer US Pharmacometrics group, the Pharmacometrics Clinical PK teams, and the Model-Based Meta-Analysis team responsible for the delivery of drug disease and indication databases supporting quantitative and systematic reviews of data deriving from the scientific and medical literature.

Tom has contributed to the Model Informed Drug Development (MIDD) contributions for numerous clinical development programs and regulatory submissions across numerous disease indications. Additionally, he is responsible for the design, development, delivery, and management of the Clinical Pharmacology technical infrastructure environments used to accelerate the delivery of MIDD contributions to the clinical development portfolio.

In his current role, he supports the design and delivery of pharmacometric environments, automations, tools, and methods to advance MIDD remit across the company.
Tom also currently serves as the co-chair of the Technology Committee for the International Society of Pharmacometrics.

Dr. Nadia Terranova

Scientific Director, Head Quantitative Pharmacology Advanced Data Analytics, Merck KGaA

Dr. Nadia Terranova is a Biomedical engineer by training with a PPh.D.in Bioengineering and Bioinformatics, currently serving as the Head of Advanced Data Analytics in Quantitative Pharmacology at Merck KGaA, Darmstadt (EMD Serono, US), which she joined in 2013. Dr. Terranova's contributions to the scientific community and to Merck's R&D organization range from impactful systems pharmacology modeling, Pharmacometrics,

and applications of advanced Machine Learning techniques to complex and multivariate drug development problems, across oncology, immuno-oncology, and multiple sclerosis programs. Dr. Terranova is the leading author of several papers in selected journals and in international conference proceedings. She is a PAGE Lewis Sheiner Awardee, and a member of the CPT Editorial Board, JPKPD Editorial Advisory Board, and ASCPT Pharmacometrics & Pharmacokinetics Steering Committee.

Dr. Yaning Wang

Chief Executive Officer, Createrna Science & Technology

Dr. Yaning Wang is the CEO of Createrna Science & Technology. He was the Director of the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA until September 2021 and oversaw reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. Before joining FDA in 2003, Dr. Wang received his Ph.D. in Pharmaceutics and master's degree in Statistics from the University of Florida in 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. He served as a board member of the International Society of Pharmacometrics (ISoP) and is a fellow of ISoP. He is a member of the Advisory Committee for the Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and the Clinical Research Institute at Beijing University. Dr. Wang has published over 110 papers and given over 320 presentations at various national and international meetings as an expert in new drug development and regulation.

Dr. Pavan Vaddady

Senior Director and Head of Advanced Pharmacometrics, Daiichi Sankyo, Inc.

Pavan Vaddady currently serves as the Head of Advanced Pharmacometrics within the Quantitative Clinical Pharmacology Department at Daiichi Sankyo, Inc. During his career, he led several early and late-stage development programs across multiple therapeutic areas both as a clinical pharmacologist and a pharmacometrician and applied model informed approaches to impact key drug development decisions. His current role involves developing a team of scientists for advanced pharmacometrics aspects including complex pharmacometrics modeling and simulation, disease progression, AI/ML, Bayesian approaches, MBMA across a portfolio of compounds. He is passionate about teaching and mentoring colleagues and has delivered comprehensive courses and tutorials

on NONMEM, R, and Shiny for pharmacometricians. He obtained his B. Pharm. (Hons.), and M. Pharm. from BITS Pilani, India and his Ph.D. in pharmaceutical sciences from the University of Tennessee Health Science Center, Memphis, USA.

Dr. Jinfeng Zhang

CEO, Insilicom LLC and Professor, Department of Statistics, Florida State University

Dr. Jinfeng Zhang obtained his Bachelor's degree from Peking University in Beijing, China in 1997. He then came to the US to pursue graduate studies at the University of Illinois at Chicago, where he obtained a master's degree in chemistry (2001), a master's degree in mathematics and computer science (2002), and a Ph.D. in bioinformatics (2004). He then received postdoctoral training in the department of statistics at Harvard University during 2004-2007. He joined the department of statistics at Florida State University as a faculty member in 2007.

Dr. Zhang's research lies in three major areas: biological information extraction, integration, and mining; genomics data analysis; and computational structural biology.

Dr. Zhang began a leave of absence from FSU in the summer of 2022 and now working full-time on his startup company, Insilicom LLC. Insilicom provides solutions enabled by advanced AI techniques to harness the power of Big Data to accelerate research and development efforts in both industry and academia. It specializes in document retrieval, information extraction, knowledge management, and knowledge discovery using knowledge graph-based AI algorithms. It is working with pharmaceutical companies to accelerate their drug discovery processes using modern AI techniques.