Application of Artificial Intelligence and Machine Learning for Precision Medicine

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration
Public Workshop
February 17, 2023 | 10:00 AM – 4:15 PM Eastern Time

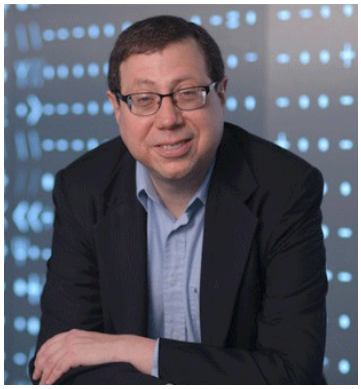
Biographies

Eric Topol, Ph.D.
Founder and Director, Scripps Research Translational Institute
Professor Molecular Medicine
Executive Vice-President, Scripps Research

Dr. Eric Topol is the Founder and Director of the Scripps Research Translational Institute, Professor, Molecular Medicine, and Executive Vice-President of Scripps Research. He has published over 1,200 peer-reviewed articles, with more than 310,000 citations, elected to the National Academy of Medicine, and is one of the top 10 most cited researchers in medicine. His principal scientific focus has been on individualized medicine using genomic, digital, and A.I. tools.

He authored three bestseller books on the future of medicine: The Creative Destruction of Medicine, The Patient Will See You Now, and Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again. Dr. Topol is the principal investigator for two large NIH grants, the All of Us Research Program that supports precision medicine and a Clinical and Translational Science (CTSA) Award that promotes innovation in medicine. He was the founder of a new medical school at Cleveland Clinic (Lerner College of Medicine), was commissioned by the UK to lead a review of their National Health Service, and is active clinically as a cardiologist. Additionally, Dr. Topol is Editor-in-Chief of Medscape, publishes the Substack newsletter “Ground Truths, “and maintains a strong presence on social media on Twitter (@erictopol) with over 675,000 followers.

Alan Edelman Ph.D.
Professor of Applied Mathematics
Computer Science & AI Laboratory
MIT
Chief Scientist
JuliaHub Inc.



Prof. Alan Edelman considers himself to be a pure mathematician and an applied computer scientist. He has consulted for Pixar, IBM, Microsoft, & Thinking Machines, and has cofounded JuliaHub and Interactive Supercomputing. He has won many prestigious prizes including a Gordan Bell Prize, Householder Award, IEEE Fernbach Award, Charles Babbage Award, and was tenth in the nation in the USA Math Olympiad when he was in high school. He is a fellow of ACM, SIAM, IEEE, and the AMS. Most of all he loves the interaction of mathematics and computation.

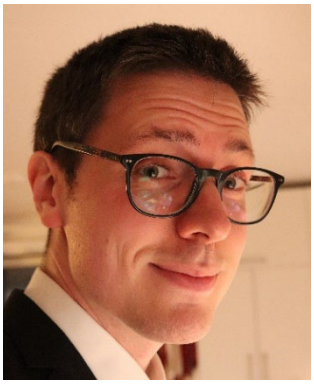
James Lu, Ph.D.
Distinguished AI Scientist in Clinical Pharmacology
Genentech

Dr. James Lu is a Distinguished AI Scientist in Clinical Pharmacology at Genentech, where he currently leads a team of AI/ML scientists. His background is Applied Mathematics and holds a Ph.D. in Computational Fluid Dynamics from MIT, followed by postdoctoral research in mathematical & systems biology and took on modeling roles in the pharma industry. Dr. Lu co-chairs the Innovation & Quality (IQ) Consortium Working Group on AI/ML.

Nadia Terranova, Ph.D.
Head of Advanced Data Analytics in Quantitative Pharmacology
Merck KGaA, Darmstadt

Dr. Nadia Terranova is a Biomedical engineer by training with a Ph.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. Her contributions to the scientific community and to Merck's R&D organization range from impactful systems pharmacology modeling, Pharmacometrics, 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. Nadia is PAGE Lewis Sheiner Awardee, and a member of the CPT Editorial Board, JPKPD Editorial Advisory Board, and ASCPT Pharmacometrics & Pharmacokinetics Steering Committee.

Niklas Korsbo, Ph.D.
Lead Developer and Scientist
DeepPumas



Dr. Niklas Korsbo joined Pumas-AI as a senior product engineer after a Master's in Theoretical Physics and a Ph.D. in Systems Biology at Cambridge University. He is now the lead developer and scientist of DeepPumas, a role in which he develops and uses innovative modeling methods that seamlessly combines AI with traditional modeling techniques to best inform critical decision-making in the healthcare space. To balance out the theoretical nature of his work, Dr. Korsbo keeps his hands busy with three toddlers and a house under renovation.

Rahul Goyal, M.S.
Pharmaceutical Sciences PhD student
Center for Translational Medicine, University of Maryland School of Pharmacy

Rahul Goyal is a Pharmaceutical Sciences Ph.D. student at the Center for Translational Medicine at the University of Maryland School of Pharmacy. His research is focused on utilizing machine learning and domain models for innovating applications in healthcare, primarily in two areas – medical counter measure development and precision medicine in tuberculosis.

He is also working as a fellow with the US-FDA for developing a guidance on designing pediatric major depressive disorder trials. Before joining the Ph.D. program, Rahul pursued his M.S. in Business Analytics from the University of Texas at Dallas. Through the program, he equipped himself with essential skills in Data Science field such as machine learning, statistics, computer programming, and technical communication. After the M.S. degree, he worked in financial companies as a Data Scientist and Data Engineer. Using his professional training and work experience, Rahul has been working on developing useful artificial intelligence solutions, such as development of a compound screening tool for hematopoietic acute radiation syndrome and antibiotic dose optimization in lung tuberculosis with radiomics applied on computed tomography and positron emission tomography images. He also holds a B.S. in Mechanical Engineering from the National Institute of Technology in India.

Hao Zhu, Ph.D., MStat
Director, Pharmacometrics Division
OCP | OTS | CDER | FDA

Dr. Hao Zhu is the director of the Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Science, Center of Drug Evaluation and Research, U.S. Food and Drug Administration. Dr. Zhu received his Ph.D. in Pharmaceutical Sciences and Master in Statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 16 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than six years and a QT-IRT scientific lead for two years. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.

Michael A. Pacanowski, Pharm.D., M.P.H.
Director, Division of Translational and Precision Medicine
OCP | OTS | CDER | FDA

Dr. Michael Pacanowski is the Director of the Division of Translational and Precision Medicine in FDA's Office of Clinical Pharmacology. He oversees a multidisciplinary team of clinical scientists who lead the Office's regulatory review, research, and policy activities related to pharmacogenomics, biomarkers, targeted therapies, and drugs for rare diseases.

He received his Pharm.D. from the Philadelphia College of Pharmacy and his M.P.H. from the University of Florida. Dr. Pacanowski completed a residency in clinical pharmacology at Bassett Healthcare in Cooperstown, NY, and a clinical research fellowship in cardiovascular pharmacogenomics at the University of Florida.

Luca Foschini, Ph.D.
President and CEO
Sage Bionetworks

Dr. Luca Foschini is the President and CEO of Sage Bionetworks. Prior to this role, he co-founded and served as Chief Data Scientist at Evidation for 10 years. During his time at Evidation, Dr. Foschini led a team of over 50 health data scientists and shaped the role and requirements for the health data scientist profession. He also led Evidation's research and development efforts and worked on projects funded by organizations such as NIH, DARPA, and BARDA. Dr. Foschini collaborated with top biopharma companies to provide technology and methodology for collecting and analyzing person-generated health data (PGHD) from sources such as smartphones and wearables in order to measure human health.

Dr. Foschini's research in the past decade has focused on the emerging field of digital medicine, particularly in the areas of data collection and analysis methodology. He has co-authored more than 70 peer-reviewed articles and given talks at the FDA, NIH, and the National Academies of Sciences, Engineering, and Medicine on topics including machine learning in healthcare, continuous health monitoring, and privacy in high-dimensional data.

Dr. Foschini holds a PhD in Computer Science from the University of California, Santa Barbara and a Master's degree in Computer Engineering from the Sant'Anna School of Pisa. He has also conducted theoretical computer science and cybersecurity research in academia and industry, including research positions at Google and Ask.com.

Dr. Foschini is a retired competitive programmer who represented Italy in the International Olympiads in Informatics and later coached the Italian national team.

Elham Tabassi, Ph.D.
Senior Research Scientist
NIST

Dr. Elham Tabassi is a Senior Research Scientist at the National Institute of Standards and Technology (NIST). She leads NIST Trustworthy and Responsible AI program that aims to cultivate trust in the design, development, and use of AI technologies by improving measurement science, standards, and related tools in ways that enhance economic security and improve quality of life. She has been working on various machine learning and computer vision research projects with applications in biometrics evaluation and standards since she joined NIST in 1999. Dr. Tabassi is a member of the National AI Resource Research Task Force, a senior member of IEEE, and a fellow of Washington Academy of Sciences.

Joseph Lehar, Ph.D.
Senior Vice President of Strategy
Owkin

Dr. Joseph Lehár is SVP of Strategy at Owkin, and also advises multiple biotechs, incubators, and venture funds. Before his current activities, Dr. Lehar led cross-functional teams and drove scientific projects at J&J/Janssen, Google/Verily, Novartis, and CombinatoRx. His first career in astrophysics focused on gravitational lensing; at Harvard, Cambridge Univ, and MIT. For more information, see Dr. Lehar's LinkedIn and gScholar profiles.

Tala Fakhouri, B.Sc., Ph.D., M.P.H.
Associate Director for Policy Analysis
OMP | CDER | FDA

Dr. Tala Fakhouri is the Associate Director for Policy Analysis in the Office of Medical Policy (OMP), Center for Drug Evaluation and Research (CDER), FDA. Her responsibilities are focused on developing policies for drug development and regulatory decision making with emphasis on data science, artificial intelligence (AI) and machine learning (ML), real-world data and real-world evidence (RWD/RWE), and digital health technologies.

Prior to joining FDA in October of 2020, Dr. Fakhouri served as a Senior Health Scientist and Chief Statistician for the CDC's flagship population survey, the National Health and Nutrition Examination Survey (NHANES). Additionally, she served on the CDC's National Center for Health Statistics Disclosure Review Board, the Cancer Moonshot Data Science Workgroup, and co-led the Federal Committee for Statistical Methodology (FCSM) Nonresponse Bias Subcommittee. Prior to joining NHANES, Dr. Fakhouri served as an Epidemic Intelligence Service Officer with the CDC. She earned a Ph.D. in Oncological Sciences from The Huntsman Cancer Institute at the University of Utah, an MPH in Epidemiologic and Biostatistical Methods from the Johns Hopkins University School of Public Health, a postdoctoral fellowship in molecular biology and genetics from Harvard University, and holds a BSc Medical Technology from the Jordan University of Science and Technology.

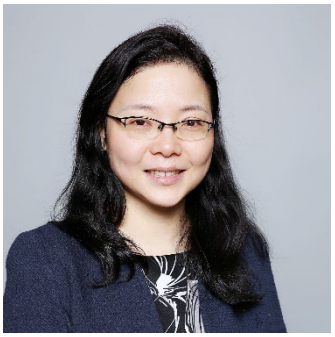
Paul Schuette, Ph.D.
Scientific Computing Coordinator
OB | CDER | FDA

Dr. Paul Schuette is the Scientific Computing Coordinator for the Office of Biostatistics in the Center for Drug Evaluation and Research at the FDA and is a member of OB's Division of Analytics and Informatics. He joined the FDA in 2008 after previously working in academia and as a government contractor. Dr. Schuette is the PI for a Cooperative Research and Development Agreement (CRADA) for detecting data anomalies in clinical trial data using unsupervised machine learning, and is a member of FDA's Scientific Computing Board, the High Performance Computing Governing Advisory Board, FDA's Modeling and Simulation working group, and CDER's AI working group. He received his Ph.D. and Master's degrees from the University of Wisconsin-Madison, with a specialization in probability theory, and his undergraduate degree in Mathematics from Kansas State University.

Matthew Diamond, M.D., Ph.D.
Chief Medical Officer for Digital Health Center of Excellence
CDRH | CDER | FDA

Dr. Matthew Diamond is the Chief Medical Officer at FDA's Digital Health Center of Excellence. Serving as the senior clinical expert for digital health medical devices at FDA's Center for Devices and Radiological Health (CDRH), Dr. Diamond provides clinical leadership for digital health policy development for emerging technologies including artificial intelligence. Dr. Diamond represents FDA for national and international digital health initiatives including the International Medical Device Regulators Forum (IMDRF) Artificial Intelligence Working Group. Prior to joining the Agency, Dr. Diamond served on leadership teams of large and small technology companies, including as Chief Medical Officer at Nokia, and as Medical Director at Fossil Group and the startup Misfit Wearables. Dr. Diamond served on numerous advisory boards including at the Center for Personalized Health Monitoring at UMass Amherst and for the venture firm NGP Capital. As Vice Chair of the Consumer Technology Association (CTA) Health & Fitness Technology Board of Directors, he promoted public health applications of mobile technology and established an ANSI-accredited standardization committee to develop standards in digital health for wellness-related hardware and mobile applications. Dr. Diamond earned his MD and PhD (biophysics) from the Mount Sinai School of Medicine, and he is board certified in rehabilitation medicine and certified in medical acupuncture. A faculty member at NYU, Dr. Diamond is passionate about helping people improve their mobility and performance through a holistic approach to rehabilitation and technology that promotes wellness.

Qi Liu, Ph.D., MStat., FCP
Associate Director for Innovation and Partnership
OCP | OTS | CDER | FDA



Dr. Qi Liu is currently the Associate Director for Innovation & Partnership in the Office of Clinical Pharmacology (OCP) at the U.S. FDA. She leads OCP's innovative initiatives through strategic partnership. She helped develop 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. Dr. Liu leads OCP's Innovative Data Analytics program and Machine Learning Review Team. 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. Dr. Liu worked on several working groups for FDA guidance documents and Manual of Policies & Procedures development. She had experience leading/co-leading OCP's Physiological Based Pharmacokinetic Modeling and Simulation Oversight Board and Biologics Oversight Board. She was a co-lead of the Real-Time Oncology Review and Assessment Aid Pilot Programs.

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 Clinical and Translational Science.

Before joining the 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.

Joga Gobburu, Ph.D.
Professor, School of Pharmacy and School of Medicine
Director, Center for Translational Medicine
University of Maryland

Dr. Joga Gobburu is Professor with the School of Pharmacy and the School of Medicine, University of Maryland, Baltimore, MD, USA. He held various positions at the U.S. FDA between 1998 and 2011. He has experience with overseeing the review of 1000s of Investigational New Drug Applications (INDs),over 250 New Drug and Biological Licensing Applications, numerous FDA Guidances, and policies pertaining to drug approval and labeling. At the FDA, he was part of the committee responsible for 21st Review Process and provided input into PDUFA planning.

He received numerous FDA awards such as the Outstanding Achievement Award and was recognized with the Senior Biomedical Research Scientist appointment. He also received the Outstanding Leadership Award from the American Conference on Pharmacometrics (2008), the Tanabe's Young Investigator Award from the American College of Clinical Pharmacology (2008), and Sheiner-Beal Pharmacometrics Award from the American Society of Clinical Pharmacology and Therapeutics (2019). He is also a Fellow of AAPS and ACCP. Dr. Gobburu is on the Editorial Boards of several journals. He has published over 100 papers and book chapters.

Kunal Naik, Pharm.D.
Pharmacist
OCP |OTS | CDER | FDA

Dr. Kunal Naik is part of the Executive Program and Project Management team within the Office of Clinical Pharmacology at FDA. He graduated from pharmacy school at Northeastern University. Dr. Naik worked in drug safety and pharmacovigilance before joining FDA in 2018.

Neha Mehta, M.S.
Regulatory Health Project Manager
OCP | OTS | CDER | FDA

Neha Mehta graduated from the University of Maryland with a BA in Anthropology and the University of Maryland, Baltimore with an MS in Pharmacometrics. She currently is a Project Manager within the Office of Clinical Pharmacology at the FDA.

James Polli, Ph.D.
Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, University of Maryland School of Pharmacy

James Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption. His two main research interests are 1) maximizing oral bioavailability through formulation and chemical approaches and 2) developing public quality standards for oral dosage forms. He has served as advisor to 24 Ph.D. graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; www.cersi.umd.edu) and the Center for Research on Complex Generics (CRCG; www.complexgenerics.org), each an FDA-funded collaborative agreement with the Agency. He is Director of the online M.S. in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

He is a fellow of the American Association for Pharmaceutical Scientists and until recently served as an editor of its flagship journal Pharmaceutical Research for 12 years. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB). He is a member of the Scientific Advisory Board of Simulations Plus.