

THANK YOU to our Speakers, Panelists and Moderators

Marco Schito, PHD, Executive Director of C-Path's CURE Drug Repurposing Collaboratory, the Scientific Director for the Inflammatory Bowel Disease Group, and an Adjunct Professor at the University of Arizona, James E. Rogers College of Law. His work aims to discover potentially safe and effective repurposed therapies for diseases with high unmet medical need by capturing and sharing global, real-world clinical data. Dr. Schito received his PhD from the Ontario Veterinary College at the University of Guelph, Canada in immuno-parasitology.



Heather Stone, MPH is a Health Science Policy Analyst, Office of Medical Policy at U.S. Food and Drug Administration (FDA). Heather Stone is an infectious disease epidemiologist and policy expert focused on global health and, in particular, the cycle between extreme poverty and infectious diseases. Her research focus is on the creation of policies that will encourage drug development for infectious diseases and address the rising challenge of antimicrobial resistance. She applies her policy expertise to issues related to drug repurposing, clinical trial design and antimicrobial drug development. Heather has led the CURE ID program at FDA since 2013 and is the FDA representative for the CDRC, public-private partnership.

Dr. Smith Heavner, PhD, RN (he/they) serves as Senior Scientific Director of the CURE Drug Repurposing Collaboratory. He earned his PhD in Applied Health Research and Evaluation from Clemson University in 2021 and completed a one-year post-graduate training in clinical trial design and analysis at Harvard Medical School in 2023. As a nurse, Dr. Heavner specializes in critical care and emergency medicine with more than ten years of clinical experience and is an active member of the Society for Critical Care Medicine including serving on the core committee of the Discovery Network VIRUS COVID-19 Registry and the Data Outcomes and Definitions Workgroup. Dr. Heavner is a mixed-methods evaluation scientist with expertise in dissemination and implementation science, informatics, real world data, and regulatory science. They hold two adjunct faculty appoints in the Department of Public Health Sciences at Clemson University and the Department of Biomedical Sciences at the University of South Carolina School of Medicine Greenville.





Ruth Kurtycz, PhD will be leading the statistical analysis to identify promising treatments for diseases with inadequate therapy from the data in CURE ID and contributing to the publications of treatments that may merit further study, as well as inform planned clinical trials. Prior to the fellowship, Ruth was a Senior Biostatistician at Blue Cross Blue Shield of Michigan (BCBSM) where they led the evaluation of a multi-state, high-visibility program aimed at helping members with high-cost healthcare needs and high-comorbidity burden reduce their system utilization and spending. Ruth earned a doctorate in Interdisciplinary Health Science with a focus in Biostatistics from Western Michigan University. They also hold a masters in Biostatistics from Grand Valley State University.

Dr. Jagdeep Podichetty, PhD is the Senior Director of Predictive Analytics in the Quantitative Medicine Program at the Critical Path Institute where he is developing quantitative solutions such as disease progression models, survival models, clinical trial simulation, artificial intelligence models to advance the field of drug discovery and development. He is also an Amazon Web Services (AWS) Certified Cloud Practitioner. Prior of joining C-Path, he has worked in academia and pharmaceutical industry in both research and manufacturing of pharmaceutical products. He has received several awards for his research and leadership. He has numerous publications in peer reviewed journal and conference proceedings. He is also an active member of the International Society of Pharmacometrics (ISoP) and American Society for Clinical Pharmacology and Therapeutics (ASCPT). He is currently serving as the Vice Chair of ASCPT Translational Informatics Community. Dr. Podichetty has an MS and PhD in Engineering from Oklahoma State University, and specialized postdoctoral training in Computational Biology and AI/ML from the University of Michigan and Indiana University. He received his Bachelor of Technology in Chemical Engineering from Jawaharlal Nehru Technological University in India.



James C. Robinson, PhD, MPH is Leonard D. Schaeffer Professor of Health Economics at the University of California at Berkeley. He serves on a variety of professional advisory boards and gives numerous invited speeches for pharmaceutical and technology firms, health insurance plans, hospitals, physician organizations, universities, and public agencies. At Berkeley, Professor Robinson's research focuses on the biotechnology, medical device, insurance, and health care delivery sectors. He has published three books and 150 papers in peer-reviewed journals such as the New England Journal of Medicine, JAMA, and Health Affairs. He teaches classes on public policy, health insurance, and the economics of the life sciences industry.



Danielle Boyce is a data scientist, instructor, patient advocate, and researcher. She has served on several patient and caregiver advisory panels for the Patient-Centered Outcomes Research Institute, the US Food and Drug Administration as well as academic institutions, pharmaceutical companies, and nonprofits. She currently advises the Centers for Disease Control and Prevention's National ALS Patient Registry and teaches in the Johns Hopkins Biomedical Informatics and Data Science program. Dr. Boyce is lead technical consultant for the CURE Drug Repurposing Collaboratory (CDRC), a public-private partnership of the Critical Path Institute and the US Food and Drug Administration, where she facilitates implementation of the Edge Tool Suite, a package of resources to aid data harmonization to the OMOP common data model, developed by CDRC partners, including Johns Hopkins University and the OHDSI community.

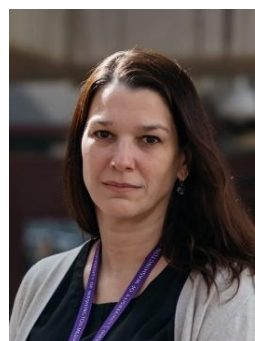
Dr. Boyce is the co-founder of the Johns Hopkins OHDSI Research Community and leads the Grants Accelerator initiative which has been awarded 5.41 million for Hopkins investigators since Oct of 2021 with funding from NSF, NICHD, FDA, and the CDC.

Trevan Locke is an Assistant Research Director at Duke-Margolis working on issues related to biomedical innovation. He oversees Duke-Margolis' involvement as a founding member of the Coalition for Advancing Clinical Trials at the Point of Care as well as workstreams on evidence generation for Duke-Margolis' Real-World Evidence Collaborative. Previously, he worked at the American Association for Cancer Research on regulatory issues impacting cancer care and the development of cancer therapies, including considerations for equitable clinical trial enrollment. Dr. Locke completed a Bachelor of Engineering in Chemical and Biomolecular Engineering at Vanderbilt University and a PhD in Chemical and Biochemical Engineering at Rutgers University.



David A. Simon is a Lecturer on Law at Harvard Law School and a Research Fellow at the Petrie-Flom Center for Health Law Policy, Biotechnology, & Bioethics at Harvard Law School. His scholarship focuses on drugs and devices, innovation, tort law, and intellectual property. He is currently working two multi-year projects: one relating to off-label use; the other relating to in-home digital diagnostics. He also has a special interest in generating innovation directed towards rare diseases. His work has appeared in numerous medical and legal publications, which are listed on his [CV](#). In July, David will join Northeastern University School of Law as an Associate Professor.

Dr. Raghav Tirupathi is the medical Director of Keystone infectious Diseases/HIV as well as Keystone community health services a Chambersburg PA. He also serves as the chair of infection prevention committees of WellSpan Chambersburg and Waynesboro Hospital PA. He has a teaching appointment at Penn State College of medicine, Hershey, PA as clinical assistant professor of medicine. He serves as the clinical consultant at Cure ID/cure drug repurposing Collaboratory, US FDA and NIH joint initiative. He pursued his internal medicine residency at Mount Sinai school of medicine/Morristown Medical Center internal medicine residency program. He pursued infectious disease fellowship at university of medicine and dentistry of New Jersey, Camden PA. He has many peer reviewed publications to his credit. His research interests include antimicrobial drug repurposing, infection prevention, antimicrobial stewardship, COVID-19. He has received several Honorary fellowships including from infectious disease Society of America, royal college of physicians in London and American College of physicians. He has received several prestigious regional and national awards including the clinical practice innovation award from infectious disease society of America.



Dr. Laura Evans is a professor of medicine at the University of Washington and the Medical Director of Critical Care at the University of Washington Medical Center. Her interests focus on sepsis, severe acute respiratory infection as well as preparedness for high consequence infectious diseases. Dr. Evans earned her medical degree at the University of Michigan and did her residency in internal medicine at Columbia University. She completed pulmonary and critical care medicine fellowship training and earned a Master of Science in epidemiology at the University of Washington. She then joined the faculty of NYU and Bellevue Hospital in 2006. In her role there, she led the evacuation of the Bellevue Hospital intensive care units in the aftermath of Hurricane Sandy and was the clinical lead for New York City's only patient with Ebola. After 14 years in NYC, she returned to Seattle in 2019. She co-chaired the 2017 and 2021 Surviving Sepsis Campaign adult sepsis guidelines, and the SSC COVID management guidelines. She is the critical care team lead for the NIH COVID Management Guidelines. She also serves on the Council of the Society of Critical Care Medicine.

Amy Morris has 40+ years' experience in the clinical drug development field. She has held senior management positions (clinical operations, regulatory affairs) within the biopharma industry and non-profit setting. She has spent most of her career working in chronic infectious diseases, immunology disorders, and rare disease. Early in the HIV epidemic she worked to establish community-based research with the Community Programs for Clinical Research on AIDS (CPCRA) and with the American Foundation for AIDS research (AmFAR). Amy has an MBA from Georgia State University, and a BS in Biology from St. Mary's College of Notre Dame.

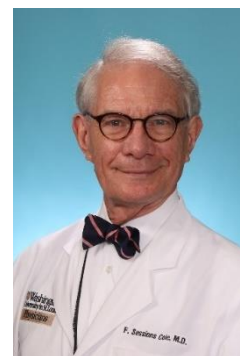


Dr. Kerry Howard (she/her) is the Research Manager for the Center for Public Health Modeling and Response. She has served as a research assistant in the fields of public health and psychology since 2014, accumulating extensive experience with research design, data maintenance and analysis, and scientific writing, as well as an understanding of how these areas can be applied to improve real-world outcomes and disseminate findings to the community. In addition to her role at Clemson University, Dr. Howard serves as a project manager for health disparities research in collaboration with Indiana University. Dr. Howard's research focuses on the elimination of health disparities using data to identify disparities in the community and prevent disease. Her dissertation examined methodological considerations for prevention of Alzheimer's Disease, which is in addition to her research on factors related to optimal delivery of care in disadvantaged populations, prevention and treatment of opioid use disorder, and community factors that affect child safety.



Mark Shapiro is the COO of xCures and principal investigator for XCELSIOR a patient-powered real-world data and outcomes registry in cancer. Prior to joining xCures, Mr. Shapiro was SVP, Operations at a global oncology CRO, where he was responsible for a team of about 500 drug development professionals in 30 countries, and a portfolio of more than 100 active clinical trials. He was previously a management consultant in the Clinical Development and Medical Affairs consulting practice at Syneos Health Consulting. He also managed a pediatric clinical trials network coordinating center at Duke University focused on clinical, pharmacogenomic, and psychometric research. He has published many peer-reviewed articles and patent applications related to clinical research and the use of AI/ML in clinical research and medicine. Mr. Shapiro is a graduate of the Fuqua School of Business at Duke University and holds a master's degree in Pharmacology from the Boston University, School of Medicine.

F. Sessions Cole, M.D., is a neonatologist and the Park J. White, M.D., Professor of Pediatrics at Washington University School of Medicine. His longstanding engagement in the undiagnosed and rare disease space has provided him with opportunities to see the impact of leveraging team science to end diagnostic odysseys and the importance of discovering therapeutic strategies for rare disease patients, families, biomedical discovery, and society. Most recently, he served as the Principal Investigator for the Undiagnosed Diseases Network (UDN) Clinical Site at Washington University (2018-2021) and currently serves as a leader of UDN's Therapeutic Matching Committee, the Co-Chair of the UDN's Sustainability Working Group, and a Co-Principal Investigator of the Clinical Research Support Core in the UDN's Data Management Coordinating Center.

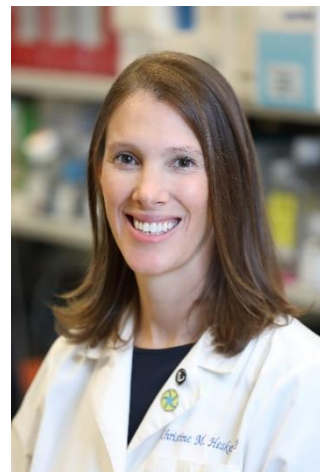




John Liddicoat works on empirical methods and doctrinal aspects of IP law, often melding these approaches together to answer legal questions. He is generally interested in whether patent law meets its welfare-enhancing goal of accelerating the creation of new technology. His research has been funded by the Novo Nordisk Foundation, the Wellcome Trust and Cancer Research UK, amongst others. John publishes in a range of scientific and law journals, including *Nature Biotechnology*, *International Review of Intellectual Property & Competition Law*, and *Intellectual Property Quarterly*. Over the past five years, John has been focusing on IP issues surrounding repurposing. He has empirically studied whether extra commercial incentives for repurposing have been effective, and whether clinical

trials for repurposing stop when generics are authorized. He sits on the CDRC Policy Working Group and is currently studying the different approaches from around the world that are aimed at overcoming the challenges facing repurposing.

Dr. Christine Heske is a clinician and physician-scientist with an active translational and clinical research program focused on sarcoma treatments. Her goal is to improve outcomes for patients with pediatric sarcomas by understanding mechanisms of resistance and identifying and evaluating new therapeutic targets. After completing her undergraduate work at Harvard University, Dr. Heske received her M.D. from The George Washington University School of Medicine and Health Sciences. She completed her pediatric internship and residency at Brown University/Hasbro Children's Hospital, followed by her fellowship training at the combined National Cancer Institute-Johns Hopkins University Pediatric Hematology and Oncology program, where she served as Chief Fellow. In 2016, Dr. Heske began her own group as a Physician-Scientist Early Investigator in the Pediatric Oncology Branch. She was promoted to Investigator in 2021 and currently leads the Translational Sarcoma Biology Group. Dr. Heske holds board certifications in General Pediatrics and Pediatric Hematology/Oncology.



Patricia Vandamme is Policy Officer at the Anticancer Fund. She has been working more than 20 years in the pharmaceutical industry, both in Belgian and global roles, before joining ACF in 2022. She is highly skilled in regulatory affairs, pharmacovigilance and quality assurance. As a pharmacist she is fully committed to the health and wellbeing of patients. She plays an important role in connecting with peer organizations, clinical investigators, drug developers and policymakers to make sure drug repurposing makes a leap forward in oncology, as cancer patients urgently need more costly-effective

treatments options.



Perdita Taylor-Zapata, M.D., is a Physician with the Obstetric and Pediatric Pharmacology and Therapeutics Branch at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), where leads the effort for the implementation of the Best Pharmaceuticals for Children Act (BPCA) at the NICHD. She is a pediatrician from the Washington Metropolitan area. She graduated from Howard University Medical School in 1994, and completed her pediatric residency training at the Children's National Medical Center in Washington, D.C. After her residency, she worked at the National Institutes of Health Clinical Center as a clinic physician in the Pediatric HIV Working Group of the National Cancer Institute. There she spent 7 years taking care of the

outpatient and inpatient medical needs of the HIV-positive pediatric patients enrolled in phase I/II clinical treatment trials. In addition to her role as a staff physician, she was also involved in medical research, writing parts of clinical protocols and conducting retrospective and prospective research projects. Since 2004, she has worked in OPPTB, starting as the primary outreach liaison for the BPCA Program, then as the Program official for the BPCA Data Coordinating Center (DCC), and now as the primary program lead for the entire BPCA Program, including the Pediatric Trials Network, the DCC and the logistics contract team. In addition to pediatric drug development, Dr. Taylor-Zapata also has research interests in pharmacoepidemiology, workforce diversity, and adverse effects of medications used in children.

Eva Spin is a final year master's student in Pharmacy (PharmD) at Utrecht University, the Netherlands. In a collaborative project between the Dutch Medicines Evaluation Board (MEB) and the US Food and Drug Administration (FDA), she is researching regulatory initiatives to advance drug repurposing. By analyzing regulator's experiences within these efforts, Eva aims to deduce recommendations for future undertakings in the field. She works under the guidance of Marjon Pasmooij (MEB), and Heather Stone (FDA).

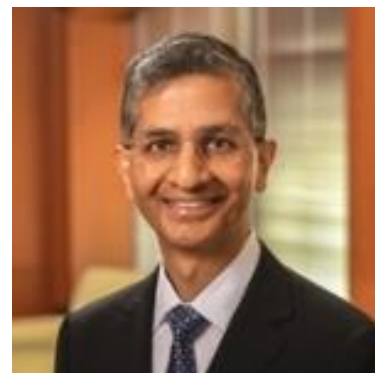


Rosie Lovett is a health service leader with expertise in clinical research and health technology assessment. She leads the Medicines Repurposing Program for England, a multi-agency initiative to use existing medicines in new ways, outside the current licence. She previously worked in the science policy and research program and technology appraisals program at the National Institute for Health and Care Excellence (NICE) and as a researcher at University College London. Rosie will be speaking at the CDRC Annual Meeting about the Medicines Repurposing Program in England.



Dr. Wes Anderson, PhD is a Postdoctoral Fellow in the Quantitative Medicine Program at the Critical Path Institute, where he is developing quantitative solutions such through machine learning and artificial intelligence to advance the field of drug discovery and development. He is also an Amazon Web Services (AWS) Certified Cloud Practitioner. Prior to joining C-Path, he completed his PhD Biomedical Engineering at Colorado State University, where he was a multi-year Walter J. Scott Fellow. He received his B.A. in Physics from Hastings College.

Vikas P. Sukhatme, MD, ScD, was the Dean of Emory University School of Medicine and Chief Academic Officer of Emory Healthcare from 2017 to 2023. He continues to serve as the Woodruff Professor of Medicine at Emory. Prior to coming to Emory, Sukhatme was Chief Academic Officer and Harvard Faculty Dean for Academic Programs at Beth Israel Deaconess Medical Center in Boston and the Victor J. Aresty Professor of Medicine at Harvard Medical School. Sukhatme completed a bachelor's degree and then a doctorate (ScD) in theoretical physics at Massachusetts Institute of Technology. In 1979, he received an MD from Harvard Medical School in the Harvard-MIT program in Health Sciences and Technology. Following his residency in medicine and a clinical fellowship in nephrology at Massachusetts General Hospital, he spent two years at Stanford in immunology research. His first faculty appointment was at the University of Chicago, where he was also appointed an assistant investigator of the Howard Hughes Medical Institute. Sukhatme's research spans numerous areas of medicine in both fundamental science and clinical care. He has over 200 scientific publications that have been cited more than 50,000 times. His longstanding interest in cancer currently centers around tumor metabolism and tumor immunology and on "outside-of-the-box" approaches for treating advanced cancer. He has conducted studies on genes important in kidney cancer and polycystic kidney disease. Sukhatme's laboratory played a key role in the discovery of the cause of preeclampsia, a blood vessel disorder, and a major cause of morbidity in pregnant women. His research has provided insights into how blood vessels leak in patients with severe infections, and on how new vessels form to feed growing tumors. He has elucidated mechanisms by which statins can cause muscle damage. Along with his wife, Vidula Sukhatme, he is co-founder of a not-for-profit organization, GlobalCures, to conduct clinical trials on promising therapies for cancer not being pursued for lack of profitability. The GlobalCures vision has been expanded at Emory, leading to the creation of the Center for Innovative and Affordable Medicine, in which Sukhatme is founding director.



Marjon Pasmooij, is head of the Science Department at the Dutch Medicines Evaluation Board (MEB) and co-chair of the Regulatory Science Network Netherlands (RSNN). Marjon has been employed by the MEB in various roles since 2007. She worked as a clinical assessor for 10 years in the field of gynaecology and dermatology. During this time she combined her work at the MEB, with a position as a principal investigator on the rare skin disease epidermolysis bullosa at the University Medical Center Groningen in the Netherlands. Since 2018 she is heading the Science Department, and coordinating the Regulatory Science activities where the MEB is involved in (about 15 PhD projects, and 20-25 Master students yearly). Together with Anneliëne Jonker, she is co-

chairing the IRDIRC (International Rare Diseases Research Consortium) Task Force on the Drug Repurposing Guidebook.

Clare Thibodeaux, PhD is the Vice President, Scientific Affairs with Cures Within Reach and has over 20 years of scientific research and philanthropic experience. Clare joined the Cures Within Reach team in November 2015, and collaborates with key opinion leaders, research institution partners, industry representatives and patient advocates from any disease area globally to identify, centralize and vet clinical repurposing research for funding. She is responsible for leading scientific initiatives at Cures Within Reach, managing Cures Within Reach's scientific grant outreach and review process, leading the Science Advisory Board and developing research and patient education events. Clare also serves on the Advisory Board for the Critical Path Institute's CURE Drug Repurposing Collaboratory. She holds a PhD in Tumor Biology from Georgetown University and an MBA from George Mason University.



Denise Robinson is the Director of Research at The EHE Foundation, a non-profit patient advocacy organization that seeks to find effective treatments and a cure for epithelioid hemangioendothelioma (EHE) through collaboration with patients, researchers, and clinicians. Ms. Robinson directs the Foundation's patient-led research initiatives comprising of the EHE Biobank and the EHE Global Patient Registry. Additionally, Ms. Robinson leads the Foundation's strategic research initiatives including the EHE Research Grants Program and collaborations with national consortia such as NCI MyPart, the National Organization for Rare Disorders, the Rare Cancer Dependency Map at the Broad Institute, and the Cure Drug Repurposing Collaboratory (CDRC). Ms. Robinson joined The EHE Foundation as a volunteer advocate in 2018 and has worked to build infrastructure that enables

robust patient-led research, while raising awareness and interest in EHE research worldwide. She brings over 20 years of operations experience in life sciences and clinical research, leading and executing strategies across global studies to advance clinician, patient, and advocacy engagement and participation.

Jacqueline Corrigan-Curay, J.D., M.D., is the Principal Deputy Center Director in the FDA's Center for Drug Evaluation and Research (CDER) where she provides executive leadership on strategic initiatives that advance CDER's mission to deliver safe, effective and high-quality medications to the public. Prior to taking on this role, Dr. Corrigan-Curay was the director of CDER's Office of Medical Policy leading the development, coordination, and implementation of medical policy programs and strategic initiatives, including on real-world evidence, use of technology in drug development and prescription drug promotion.





Cynthia Adinig is from Vienna, Virginia and developed Long Covid in March 2020. Cynthia has had a long career in community service and marketing, including work with nonprofits, small businesses, and tech companies. She is also the co-founder of BIPOC Equity Agency, a multidisciplinary consulting agency specializing in promoting racial equity in healthcare and scientific research. Cynthia is an advocate for ME/CFS and Long Covid and has been featured in multiple national news media including TIME, Bloomberg, USA Today, NBC and more. She has spoken at the Milken Institute 2022 Future of Health Summit as well. Cynthia was part of the team that helped guide legislative language for the Covid-19 Long Haulers Act and met with Rep. Ayanna Pressley and Senator Tim Kaine's teams as they drafted Long COVID legislation. She has also given sworn testimony on Capitol Hill, as a patient advocate at the Coronavirus Committee hearing. Cynthia has a son who became a member of Mensa at 5 years old, who also has intermittent struggles with Long Covid.

Anup Challa is an Associate Director at AstraZeneca, supporting global pediatric vaccines and immunotherapies development as a pharmacovigilance scientist. While very early in his career, he is a content expert in the management and evaluation of RWE, with particular interest in its use for benefit/risk contextualization of pharmaceuticals and associated regulatory interactions. Before joining AZ, Anup was a Principal Investigator at Vanderbilt University Medical Center, where he led Modeling Adverse Drug Reactions in Embryos (MADRE), a federally and privately funded research network that harnessed methods of team science, data science, advanced clinical trial design, and digital process engineering to innovatively assess therapeutic indices in underrepresented minorities (e.g., pregnant women and young children) using RWE, across all phases of drug development. Anup has broadly published and presented academic and public interest pieces on these topics, including on drug repurposing applications. He has also supported the US Government's efforts to develop best practices in this space—some of his associated roles include Co-Chair of CDRC's Special Populations Coordinating Committee; advisor to the Pregnancy Domain Team of NIH's National COVID Cohort Collaborative, to guide on therapeutic study design within a distributed network of EHRs; collaborator with FDA's Sentinel Initiative, to guide on special populations research in a distributed network of health insurance claims; supporter of NIH's Accelerating COVID-19 Therapeutic Interventions and Vaccines program, in evidence discovery for clinical trial investment decisions; advisor to NIH's Lifespan Enterprise Research Committee, in research agenda setting and prioritization; and consultant on the State of Tennessee's use of unstructured patient data in the public health response to Lyme disease. Anup is a chemical engineer by training, providing him with a uniquely analytical and procedural lens when engaging with clinical colleagues. Given his experience navigating industry, academic, and government value propositions for the use of RWE in infectious diseases therapy development, as well as his zeal for cross-functional partnership, he is respected for his breadth of knowledge in pharmaceuticals R&D and for his science policy skills.



Sundeep Agrawal, MD, is a board-certified medical oncologist and currently serves as a lead physician in the Division of Oncology 1 in the FDA's Office of Oncologic Diseases. He is also the clinical director for Project Renewal within the Oncology Center of Excellence (OCE), evaluating evidence and providing clinical input for this public health initiative that aims to update the safety and efficacy labeling information for older oncology products. He completed his internal medicine residency training at Drexel University College of Medicine in Philadelphia, PA and completed fellowship in hematology and oncology at Washington Hospital Center/Georgetown University Hospital in Washington, DC. His research interests include novel clinical trial designs and methods to expedite drug development and the treatment of genitourinary malignancies. He still sees patients on a part-time basis.

Stacey Coe, MS, CCRP, is a Senior Clinical Research Coordinator at the Critical Path Institute, CURE Drug Repurposing Collaboratory (CDRC). She has over 10 years of experience conducting complex inpatient and outpatient drug trials and post-market device trials in the therapeutic areas of trauma and critical care, neurology, orthopedics, nephrology and podiatric wound care. She has expertise in regulatory operations, good clinical practice, project management, participant outreach, epidemiology and research design and analysis. Ms. Coe has been a co-author on several articles in peer-reviewed journals and industry publications as well as award winning abstracts and posters presented at national and international conferences. In her current role she applies her clinical trial expertise to advance drug repurposing efforts and to innovate clinical trial design to improve efficiency.



Jonathan Sevransky, M.D., MHS, FCCM is Professor of Medicine and Associate Division Director for Critical Care in the division of Pulmonary, Allergy, Critical Care and Sleep Medicine at Emory University. He also serves as the Director of Critical Care for Emory University Hospital. His research, clinical, mentoring and administrative responsibilities are centered on improving the care of patients with life threatening medical illness, including sepsis. He has led single center and multicenter clinical trials in sepsis and successfully mentored other investigators to do the same, and has been participant in the first 5 Surviving Sepsis Campaign Guideline groups. He

serves as an associate editor of the journal Critical Care Medicine, and additionally served chair of the Discovery Research Network of the Society of Critical Care Medicine, and the founding director of the Emory Critical Illness Research Center (E-CIRC).

Dr Charlotte Asker Hagelberg is serving as a Medical Strategist at the Director General's Office of the Swedish Medical Products Agency (MPA) in Uppsala, Sweden. She holds a Ph D in molecular Tumor Biology and is Associate Professor in Clinical Pharmacology at Karolinska Institutet, Stockholm, Sweden. Her previous work experience includes Clinical Pharmacology services, tutoring in Pharmaceutical Medicine, heading of a Phase I Clinical Trial Unit, and the Stockholm Regional Adverse Drug Reaction Center. Since 2011 she has held different positions within the MPA and represents the Swedish MPA in the Repurposing Observatory Group (RePOG), a multistakeholder steering group led jointly by European Medicines Agency (EMA) and the AEMPS, the Spanish Medicines Agency.





Dr. Chris Lindsell is director of data science and biostatistics at the Duke Clinical Research Institute, Professor of Biostatistics and Bioinformatics at Duke University, and Professor of Biomedical Informatics at Vanderbilt University Medical Center. His research portfolio includes clinical trials, health systems and services, and biomarker discovery and validation. His primary focus is on optimizing the data generation process, including the development of decentralized and pragmatic trial features, regulatory-enabling study designs, and generation of clinical research data in real-time data for study decision-making and rapid reporting of results. He has published over 350 peer-reviewed papers and has led the statistical and data coordinating centers for numerous studies including ACTIV6 and the IVY Network. He has deep experience running clinical research operations across a range of therapeutic domains with a heavy emphasis on acute and critical care. He holds patents for data-informed prognosis and prediction in sepsis and septic shock and is working towards precision approaches to improve the care of critically ill patients, as well as trial innovations that will enhance our ability to learn from data.

Saco de Visser is the scientific director of FAST (Centre for Future Affordable and Sustainable Therapy development). He is a pharmacochemist, board certified Clinical pharmacologist and holds a PhD in medicine with his thesis; “A Question Based Approach to Drug Development” (Leiden University). He has 12 years’ experience in management, execution and funding of international clinical drug development studies at the Centre for Human Drug Research (CHDR), Netherland Organisation for Health Research and Development (ZonMw) and Nycomed (currently Takeda). In 2009 he initiated the ZonMw funding programme (>220 M Euro) rational use of pharmacotherapy that focusses on improving (cost)effective, safe and effective use of medication (including stimulating drug repurposing). From 2014 he combined his position at ZonMw with positions as Director cluster development at Leiden Bioscience Park and Head of Education at Paul Janssen Futurelab Leiden (Leiden University Medical Centre). From 2020 he initiated the centre for Future Affordable and Sustainable Therapy development commissioned by both the Ministry of Economic affairs and the Ministry of Healthcare of the Dutch government. He is also member of the Platform Medicines for Society (Amsterdam University Medical Centre) supervising PhD projects in the field of rare diseases and drug repurposing. He represents the Netherlands in the Board of Governors of the European infrastructure for translational medicine (EATRIS) and active in the funders network of its repurposing platform REMEDI4ALL. Saco takes part in several (inter)national committees and working groups advising government, public and/or private parties on drug development and/or funding opportunities.





Amit Aggarwal has over 14 years' experience in the pharmaceutical industry, most recently at LEO Pharma as Medical Director for the UK and Ireland. Prior to that he spent over a decade at Bayer where he held various roles including pharmacovigilance, Global medical affairs, and latterly as Director of Medical Affairs UK for General Medicine. His background is as a medic, spending 5 years working clinically in the NHS, mainly in secondary care. Amit has worked on both innovative and established product launches, spanning a range of therapy areas including oncology, women's health, cardiovascular medicine, dermatology, and thrombosis in the UK and globally. Amit holds a MA in Neuroscience from the University of Cambridge, and a MBBS from Guy's, King's & St Thomas' School of Medicine.

Leonard Sacks, MD received his medical education in South Africa, moving to the USA in 1987, where he completed fellowships in immunopathology and Infectious Diseases. He worked as an attending physician in Washington DC and South Africa and he joined the FDA in 1998 as medical reviewer in the Office of New Drugs. Subsequent positions included acting director of the Office of Critical Path Programs and associate director for clinical methodology in the Office of Medical Policy in the Center for Drug Evaluation and Research. In this capacity he has led efforts to support novel approaches to clinical trials including the use of electronic technology. Besides his involvement in the design and analysis of clinical trials, he maintains a special interest in tuberculosis and other tropical diseases and has published and presented on these topics. He holds academic appointments as Associate Clinical Professor of Medicine at George Washington University, and at the Uniformed Services University of the Health Sciences.



Matthew Robinson, MD, is Assistant Professor in the Division of Infectious Diseases at Johns Hopkins University School of Medicine. He is interested in leveraging diagnostic innovation and precision medicine to reduce diagnostic and prognostic uncertainty for infectious diseases. His current projects include applications in global health, antimicrobial resistance, antibiotic stewardship, infection control, COVID-19, acute febrile illness, and tuberculosis. His work with the Johns Hopkins Precision Medicine Center of Excellence for COVID-19 has examined the individual contributions of specific therapeutics for COVID-19 and used

novel machine learning techniques to develop a tool that reports the probability of developing severe disease or death among patients admitted with COVID-19 which is now available as a web tool and integrated into the electronic medical record at 5 hospitals. Supported by CDRC/C-Path/FDA, he is working collaboratively to lower the barrier to adoption of the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) by partner institutions.

David Fajgenbaum, MD, MBA, MSc, is a physician-scientist at the University of Pennsylvania, co-Founder & President of the Castleman Disease Collaborative Network, co-founder of Every Cure, and national bestselling author of 'Chasing My Cure: A Doctor's Race to Turn Hope Into Action'. He is also a patient battling a deadly disease called idiopathic multicentric Castleman disease (iMCD), which he discovered a treatment for that is saving his life and others. Through his work at the University of Pennsylvania's Center for Cytokine Storm Treatment & Laboratory, he has also identified and advanced 9 other treatment approaches for iMCD and cancer. Dr. Fajgenbaum applies business-inspired solutions to drive forward iMCD research and works to turn this innovative model into a blueprint for accelerating rare disease research and drug repurposing.



Lennie Woods is executive director and co-founder of the Clear Cell Sarcoma Foundation (formerly Sara's Cure) along with her husband of 30 years, Denny. As a Charleston native and college of Charleston graduate, she was able to build a successful career in Real Estate until life's direction took a drastic change in when her daughter, Sara, was diagnosed with Clear Cell Sarcoma during a church mission trip to Guatemala. After flying home Lennie and Denny were told Sara was metastatic and there was no treatment or cure, they immediately decided that this was not acceptable for their daughter or anyone suffering from this ultra-rare cancer. Lennie is blessed with a drive to get answers and make the connections needed for success. The CCSF was established for the purpose of finding the right treatment for clear cell sarcoma by bringing the patients and their experiences together, so CCS has a bigger voice within the

cancer research community. Thanks to some amazing doctors and aggressive surgery, Sara has been NED since 2018.

Suanna Bruinooge, MPH, is the Division Director of Research Strategy and Operations in ASCO's Center for Research and Analytics (CENTRA). CENTRA generates, integrates, analyzes, and shares oncology data to foster innovation in research and patient care and help develop and evaluate ASCO's policy positions. CENTRA develops and implements ASCO's research priorities, including the Targeted Agent Profiling and Utilization (TAPUR) clinical trial and projects to advance clinical trial design and methodology. CENTRA also staffs ASCO's Cancer Research Committee and Research Community Forum. Prior to joining ASCO, Suanna worked for seven and a half years in the U.S. House of Representatives, working for Congresswoman Nancy Johnson (R-CT) and Congressman Vernon Ehlers (R-MI). Ms. Bruinooge earned a Master of Public Health in Health Policy at The George Washington University's Milken Institute School of Public Health in 2015. Suanna also has a B.A. in political science from Calvin College in Grand Rapids, MI.





Dr. Żaneta Zemła - Pacud is Assistant Professor at the Institute of Law Studies at the Polish Academy of Sciences (ILS PAS). She graduated from Adam Mickiewicz University, Poznan, in both law and European studies. In 2012 she obtained her PhD at Cracow's Jagiellonian University with a dissertation on patent protection for medicines, awarded by the Ministry of Science and Higher Education. Żaneta has published and presented extensively on technology protection, especially in the life sciences. She also has led and participated in several domestic and international research projects in the field of biotechnological inventions, AI in patent judiciary, IP in the health sector in Poland, and others. As an external expert, she served WIPO and PPO projects. As a visiting researcher, she carried out her research at the MPI for Innovation and Competition in Munich and at the LML Centre at the University of Cambridge. She has taught intellectual property law, patent law, and new technologies at several prominent Polish universities. Since 2021 she has led a Life Science Legal Lab at the ILS PAS. Her present research is centered around protection of regulatory data. Żaneta has also gained expertise in the Life Science practice as an Of Counsel in Trapple Konarski Podrecki, one of the leading Polish law firms.

William D. Tap, MD is the Chief of the Sarcoma Medical Oncology Service at Memorial Sloan Kettering Cancer Center in New York. Bill has extensive experience in translational medicine and is currently in charge of the clinical, basic science, and translational aspects of the Sarcoma Medical Oncology Program at MSKCC. He is also helping to develop a comprehensive Adolescent and Young Adult Cancer Program at MSKCC. Bill received his Medical Degree from Jefferson Medical College in Philadelphia, PA and performed his residency in Internal Medicine at the Vanderbilt University Medical Center in Nashville, TN and his fellowship in Hematology and Medical Oncology at the UCLA Medical Center in Los Angeles, CA. Bill also has a tremendous interest in global health care initiatives and effecting health disparities in underserved areas in the US and abroad.



Ms. Vidula Sukhatme is the Co-founder and CEO of GlobalCures, Inc. Additionally, she played a role in founding the Morningside Center for Innovative and Affordable Medicine at Emory University. She has earned two master of science degrees: one in mathematics from Northeastern University and another in epidemiology from the Harvard T.H. Chan School of Public Health. She also has two decades of experience working with information systems in healthcare settings.

Sabine Grimm (PhD) is a senior health economist at the Maastricht University Medical Center and an associate editor for Value in Health. Sabine acts as a health economic lead for an evidence assessment group for the England & Wales, NICE. She has a keen interest in health economic modelling methods and handling uncertainty in health technology assessment (HTA). As part of REPO4EU, a European funded project to build a European / global drug repurposing platform, Sabine co-leads the HTA work package. The team develops recommendations for innovative HTA and regulatory methods and policies that can facilitate drug repurposing.



Dr. Andrea Gross is a board-certified pediatrician and pediatric oncologist who earned her medical degree at the University of Connecticut and completed pediatric residency at Cincinnati Children's Hospital Medical Center. She completed a pediatric hematology/oncology fellowship at Children's National Medical Center and is currently an Assistant Research Physician working in the Pediatric Oncology Branch at the National Cancer Institute in the lab of Dr. Brigitte Widemann. Dr. Gross has been the lead associate investigator on the phase 2 trial of selumetinib for patients with neurofibromatosis type 1 (NF1) and inoperable plexiform neurofibromas since 2015, which led to the first FDA approved medication for NF1 in 2020. Her research focuses on clinical trials for tumor predisposition syndromes. Her areas of interest include developing and utilizing functional outcome measures to define clinical benefit of therapies for tumor predisposition syndromes like

NF1, designing and running clinical trials for rare disease populations and working with patient advocates to increase patient engagement in clinical trial design.

Donald Lo is the Director for Medicines Development at EATRIS, the European Infrastructure for Translational Medicine, and Scientific Lead of REMEDI4ALL, the newly launched European Platform for Medicines Repurposing. Before joining EATRIS last year, Don headed the Therapeutic Development Branch at the National Center for Advancing Translational Sciences (NCATS) at the US National Institutes of Health (NIH). Don came to NIH following a 25-year academic career at Duke University Medical Center. Along the way he also co-founded and led 2 biotechnology companies and a nonprofit patient care organization for Huntington's disease and served as science lead for a venture philanthropy organization focused on brain cancer drug discovery and development. Don is a graduate of the California Institute of Technology, received his PhD from Yale University, and conducted postdoctoral research at University College London.





Brandi Felsner joined the Sarcoma Foundation of America (SFA) as the Chief Executive Officer in December 2019. She has more than 20 years' non-profit senior leadership experience, most recently serving as the Chief Operating Officer – Chief of Staff at the National Breast Cancer Coalition. Brandi has a strong background in patient advocacy and education, as well as advancing cancer research and public policy initiatives. Having lost both of her parents to cancer, Brandi uses her passion and personal experience to elevate the voices of sarcoma patients and family members and to fund meaningful research that will ultimately lead to better outcomes for people diagnosed with sarcoma. She has a Master of Business Administration (MBA) from The George Washington University, and is completing a Master in Liberal Arts, Clinical Psychology, from the Harvard University Extension School.

Savva Kerdelmelidis is a Commercial/IP Consultant Legal Counsel and Patent Attorney with 20 years experience advising in relation to IP and commercial law. He graduated with a LLM (1:1, Hons) and BSc (2:1, Hons) from the University of Canterbury, New Zealand. He is admitted as a Barrister and Solicitor of the High Court of New Zealand and lawyer in the Supreme Court of Queensland, Australia. He also is a New Zealand and Australian Patent and Trade Mark Attorney. Savva conducted his LLM thesis in 2014 on alternatives to the patent system for developing medicines. He founded Crowd Funded Cures as a NZ charity in 2013 to implement the idea of using pay-for-success contracts as an incentive to find new uses for off-patent drugs and other unmonopolisable therapies.



Dr. Ewy Mathé is the Director of Informatics in the Division of Preclinical Innovation at NCATS. She received a Bachelor's degree in Biochemistry (minor in Sociology) from Mount Saint Mary's University, MD in 2000 and a PhD in Bioinformatics from George Mason University, VA in 2006. She leads a diverse team of experts in bioinformatics, cheminformatics, data science, and software development that empower translational scientists to make meaningful data-driven decisions in their research. Her team is currently developing computational resources, methods and tools that optimize the use of large scale molecular (high throughput screening, multi-omics, etc.) and knowledge-driven datasets that draw from various sources of information on drugs, drug targets, and diseases.

Oved Amitay is a pharmacologist by training, a drug-developer by trade, and a patient-advocate by choice. He serves as President and Chief Executive Officer at the Solve ME/CFS Initiative- a national organization devoted to making Myalgic Encephalomyelitis (also known as chronic fatigue syndrome or ME/CFS) and other infection-associated diseases such as Long-Covid, understood, diagnosed and treatable. Oved is has dedicated most of his professional career to the development of life-changing therapeutic options for people affected by rare genetic diseases, that resulted in eight Orphan Drugs approved by the FDA. Oved is using his extensive biotech experience to help bring a change to this space. Oved and his organization were early to recognize the emerging concern that some people with COVID who were infected by SARS-CoV-2 may continue to struggle and develop a post infection condition, that we now call Long COVID. In the summer of 2020 Oved co-authored an op-ed calling for an immediate research effort to be initiated, and later co-founded the Long Covid Alliance, building a network of patient-advocates, scientists and disease experts to collaborate and share their collective knowledge to transform our understanding and treatment of Long COVID and associated diseases. Together, their advocacy led to Congress directing \$1.15B to the NIH for funding of Long Covid research. As the pandemic continues, Solve is pushing for more comprehensive solutions to address this mass-disabling disease, and its report on the economic, social and workplace impact of Long Covid was recently featured in the Milken institute's Review. Throughout his career, Oved has had extensive engagements with healthcare systems and patient advocacy organizations around the world, forging collaborations for patient registries and natural history studies for drug development. One of Solve M.E.'s flagship programs is the You+ME Registry and Biobank, an online clinical study of individuals living with ME/CFS, people with long COVID, and control volunteers. Oved uses his extensive R&D background that to advance research initiatives, and foster public-private partnerships. Oved's leadership and expertise are recognized by government agencies, researchers and the community, and he is invited often to speak about these topics. Prior to joining Solve M.E., Oved served as Chief Business Officer at CENTOGENE (NASDAQ: CNTG), a global leader in the diagnostics of rare hereditary disorders. He held the position of President and Chief Operating Officer at Arrett Neuroscience, where he led the company's efforts to develop therapies for Rett syndrome. Prior to that, Oved had senior executive positions at top-tier biotech companies- Alnylam Pharmaceuticals (NASDAQ: ALNY) and Genzyme Corporation (now Sanofi Genzyme).



Dr Nathalie Strub-Wourgaft joined Drugs for Neglected Diseases *Initiative* (DNDi) in 2009 and is member of the Global Executive Team as COVID 19 and preparedness Director. She holds over 30 years' experience in R&D. As Director of NTDs since 2018, Dr Strub-Wourgaft provided strategic and technical oversight to a wide portfolio of R&D and access plans for therapeutic areas covering Sleeping Sickness, Chagas disease, Cutaneous and Visceral Leishmaniasis, Filariasis, & Mycetoma. In 2018, through an international public and private partnership including scientific platform from Africa, DNDi developed Fexinidazole, its first new chemical entity registered from its portfolio. Since March 2020, Nathalie leads DNDi's response to COVID-19, as Coordinator of the ANTICOV study Consortium and one of the initiators of the COVID 19 clinical research coalition. She is involved in several working groups dedicated to therapeutics for COVID, with a specific focus on LMIC needs and settings. She has been appointed as General Delegate for PANTHER (PANdemic preparedness plATform for Health Emerging infections Response) since August 2022. Prior to her current appointment, Dr Strub-Wourgaft created and held the Medical Director position at DNDi, where she notably developed the organisation's quality, pharmacovigilance and regulatory activities. Prior to DNDi, Dr Strub-Wourgaft served as Clinical Development Director at Trophos, and held many related roles within Pfizer, Lundbeck and Aspreva. Dr Strub-Wourgaft graduated as Medical Doctor from Necker Hospital, Université René Descartes in Paris in 1983. She co-authored several scientific publications in peer review journals.