

## Meeting Faculty

### Norman M. Goldfarb

Norman Goldfarb is a seasoned executive and leading authority on clinical research best practices. He has authored or presented hundreds of articles and talks on clinical research. He is Managing Director of Elimar Systems, which is working to make the clinical research industry a collaborative, learning enterprise. He is also Executive Director of the Site Council, which is helping study sponsors and CROs build healthier relationships with healthier sites; the Clinical Research Interoperability Standards Initiative (CRISI), which is developing a library of standard APIs under CDISC; and the Clinical Study Diversity Score Project (CSDS), which is developing a methodology to calculate quantitative diversity scores for clinical studies.

His influence in the industry is indicated by his 30,000 LinkedIn clinical research connections — #1 in the industry. PharmaVoice Magazine has honored him as one of the 100 most inspiring people of 2016. In 2017, he won ACRP's award for innovation. He previously founded and led MAGI, which held 28 clinical research conferences that delivered 99% attendee satisfaction and offered the industry's only money-back satisfaction guarantee. (WCG Clinical continues to conduct MAGI conferences.) He also founded and edited the Journal of Clinical Best Practices, which published over 2,500 articles, book reviews, and columns from 2005 – 2022.

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### Saurabh Gombar, MD

Dr. Saurabh Gombar is the Chief Medical Officer and co-founder of Atropos Health. Dr. Gombar is an MD PhD with a specialization in Pathology with a diverse background spanning both academia and industry. He was formerly faculty at the Stanford School of Medicine where he currently holds an adjunct appointment. Dr. Gombar's dedication has been towards refining clinical care by aiding physicians in incorporating precision evidence into their decisions and improving patient outcomes.

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### Lydia Kaoutzani

Dr. Kaoutzani was born in Athens, Greece and then moved to Nicosia, Cyprus where she received her high school diploma from the Pagkyprio Gymnasium. She then moved to the United States where she received her bachelor's degree in Chemistry: Biochemistry from Boston University. She also graduated with a minor in Biology. She subsequently completed a master's degree in Medical Science at Boston University School of Medicine. For the following two years she conducted research at the Department of Gastroenterology at Children's Hospital in Boston, Harvard Medical School. She obtained her medical degree at The University of Sydney, Sydney Medical School. She then completed two years of preliminary

general surgery residency at Beth Israel Deaconess Medical Center, Harvard Medical School. Currently she is in her sixth year of neurosurgery residency at the Medical College of Georgia at Augusta University.

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## **Michael Koren, MD, FACC, FAPCR, CPI**

Michael J. Koren, MD, practices cardiology and serves as the Chief Executive Officer at Jacksonville Center for Clinical Research (JCCR). He founded JCCR which has conducted over 2500 clinical trials at 8 locations in Florida since 1997.

He received his medical degree cum laude at Harvard Medical School, and completed residency in internal medicine, chief residency and fellowship in cardiology at New York Hospital/Memorial Sloan-Kettering Cancer Center/Cornell Medical Center.

Dr. Koren is a fellow of the American College of Cardiology. He is a fellow and two-time past president of the Academy of Physicians in Clinical Research and past president of the regional chapter of the American Heart Association. As an ACRP Certified Principal Investigator, Dr. Koren has led more than 500 clinical trials on hypercholesterolemia, cardiovascular disease, and heart failure. He participates in the Cholesterol Treatment Trialist Collaboration based in Oxford. Dr. Koren's research has been published in peer-reviewed journals including Nature, Journal of the American College of Cardiology, Circulation, New England Journal of Medicine, and The Lancet. He has lectured nationally and internationally on topics such as lipid-lowering therapy and preventive cardiology. Currently, he oversees active protocols developing mRNA vaccines and early-phase research in preventative cardiology.

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## **Chaitanya Mamillapalli, MD, MRCP, FAPCR**

Dr. Mamillapalli is an endocrinologist with a strong interest in harnessing the power of data analytics and machine learning to identify gaps in health care and devise interventions to ensure that patients receive quality medical care. He is intellectually curious and aspires to work at the intersection of technology and health care and to use his expertise in developing innovative health care products and services.

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## **Senthil K. Nachimuthu, MD, PhD, FAMIA**

Senthil Nachimuthu, MD, PhD, FAMIA, is the Chief Medical Officer and lead of Nightingale Open Science at the Center for Applied AI and the University of Chicago Booth School of Business. Previously, Senthil worked in large corporation and start up companies in product management and research leadership roles in medical informatics, analytics, interoperability, and healthcare standards. He has led interoperability efforts at several hospitals, contributed to HL7 and LOINC standards, served as an elected US representative to SNOMED, and as an advisor to a US Congressional committee. Senthil also serves as an Adjunct Assistant Professor of Biomedical Informatics at the University of Utah School of Medicine, where he

teaches and conducts research on clinical decision support and interoperability. He is also a researcher in infectious disease epidemiology at the Salt Lake City VA Medical Center. Senthil trained in family medicine and subsequently earned a PhD in Medical Informatics focusing on machine learning for predictive and prescriptive analytics at the bedside. He is a Fellow of the American Medical Informatics Association.

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## **Prashant Natarajan, BE, MTPC, SCPM**

Prashant Natarajan is a global healthcare leader, industry expert, and best-selling author and keynote speaker. He is VP of Strategy and Products at H2O.ai Health and is responsible for AI products and solutions used by life sciences companies, health systems, and insurers.

Prashant is an inventor with patents in medical imaging and health data management. He has several “firsts” to his credit - cloud-based EHRs at Siemens/Cerner; disease management solutions for Medicare/Medicaid at McKesson/Optum; and the first healthcare-specific data & analytics platform at Oracle. Prashant is a best-selling author of books on big data, applied machine learning/AI, and cancer informatics. His latest book is “Demystifying AI for the Enterprise - A Playbook for Business Value & Digital Transformation.” Prashant serves as Co-Faculty Instructor at Stanford University School of Medicine and as Distinguished Fellow at Health Innovation Alliance.

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## **Harry Nyanteh, MD, MPH, MSc, CRCP**

Dr. Nyanteh’s dedication to advancing healthcare through clinical research is evident in the success of Omega Research Group, LLC. With over 15 years of experience at the forefront of medical advancements, the facility continues to make significant contributions to the field. As a passionate advocate for ethical standards in research, Dr. Nyanteh ensures that Omega Research Group conducts its studies with the utmost integrity and compliance. His expertise as a Certified Regulatory and Compliance Professional has solidified the facility’s reputation as a trusted and reliable partner for clinical research.

Beyond his impressive credentials, Dr. Nyanteh’s multicultural background has shaped his unique perspective on global healthcare. Having been born and raised in Ghana and pursuing his Medical Degree in Hungary, he brings a wealth of knowledge and understanding to his work. His fluency in Hungarian not only allows him to communicate effectively with diverse patients and colleagues but also fosters an environment of inclusiveness within the facility.

In addition to his professional achievements, Dr. Nyanteh is known for his compassionate approach to patient care. He believes in treating each individual with empathy and respect, ensuring that their voices are heard throughout the research process. This patient-centric philosophy not only enhances the quality of the studies conducted at Omega Research Group but also contributes to the overall well-being of the participants. With a remarkable blend of medical expertise, research acumen, and a profound commitment to improving healthcare outcomes, Dr. Harry Nyanteh continues to make significant contributions to the field of clinical

research. His unwavering dedication to advancing medical knowledge and improving patient care serves as an inspiration to both his peers and aspiring healthcare professionals around the world.

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## **Amy Price, PhD**

Dr. Amy Price worked as a Neurocognitive Rehabilitation consultant and in International Missions before sustaining serious injury and years of rehabilitation. She emerged with a goal to build a bridge between research methodology, research involvement and public engagement where the public is trained and empowered to be equal partners in health research. She earned her DPhil at Oxford where Amy's professional expertise and lived experience have shown her that shared knowledge, interdisciplinary collaboration, and evidence-based research will shape and develop the future. She serves as a BMJ Research Editor (Patient and Public Partnership) and is a senior research scientist at Stanford University. She is a member of the FDA Medical Devices Dispute Resolution Committee and is researching the links between generative AI, shared decision-making and empathy.

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## **Peter H. Rheinstein, MD, JD, MS**

Peter Rheinstein joined APCR a year before he retired from FDA as Director of the Medicine Staff in the Office of the Commissioner. He is a Past President of APCR and currently serves as our Treasurer and AMA Delegate. From 1974-99, as a senior manager at FDA, Peter oversaw FDA's implementation of the Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act as well as the development of the Agency's regulations governing prescription drug promotion.

Peter is a researcher and a consultant on medical law and regulation. Since 2012, Peter has been Chairman of the United States Adopted Names (USAN) Council which assigns the generic names for all drugs marketed in the US. He represents the Maryland State Medical Society at the USP. From 2001 through 2022, he was the publisher of Discovery Medicine, an internet-based journal. He is a Past President of the Drug Information Association (DIA) and the Academy of Medicine of Washington, DC.

Peter earned his BA and MS in math at Michigan State; MD at Johns Hopkins; and JD at U of Maryland, where he serves on the Alumni Board. He is licensed to practice medicine in MD, DC and CA and admitted to the practice of law in MD, DC and before the Supreme Court of the US. He is board certified in family medicine, geriatrics, and legal medicine. He is the current Chairman of the American Board of Legal Medicine.

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## **Raj Shah, MD, FAPCR**

Raj C. Shah, MD, has been a geriatrician at Rush University Medical Center in Chicago, Illinois, for over 20 years. Currently, he is a Professor in the Department of Family & Preventive

Medicine and the Rush Alzheimer's Disease Center. He completed his bachelor of science in chemical engineering at Northwestern University and then attended the University of Illinois at Chicago College of Medicine. After completing a family practice residency at West Suburban Hospital and Medical Center in Oak Park, Illinois, he received further geriatrics training at Rush.

Dr. Shah's academic career interest is the design and conduct of community-based clinical trials for the prevention and treatment of age-related conditions including, but not limited to, memory loss. He is a principal investigator for clinical trials in Alzheimer's disease and disability-free survival. Dr. Shah also serves as the Assistant Vice Provost, Clinical Research, for Rush University. He is a current board member of the Academy of Physicians in Clinical Research (APCR) and is an active Fellow of the APCR.

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## **Monish A. Sheth, MD, FHM**

Dr. Sheth completed his medical school at Smt. N.H.L Munciple Medical College in India and went to the University of Pittsburgh Medical Center (UPMC-Mercy) for Internal Medicine Residency. After the residency training, he moved to Temple-Texas to join as Hospitalist at Baylor Scott & White Medical Center and took Assistant Professorship with Texas A&M University Medical School. He has applied to be promoted as Clinical Associate Professor with Baylor College of Medicine. He is actively involved in medical student mentorship and training future healthcare providers. He has participated in multiple clinical trials for COVID-19 and is active in peer-reviewed article publication and presenting abstracts at national conferences. He is Inquiry Project Mentor for Baylor College of Medicine Medical students and facilitates problem-based learning. He is passionate about reducing readmission for complex patients including heart failure and COPD, and sits on a committee for inpatient pain management. His primary aim is to reduce polypharmacy associated with opiate use and works with Anesthesia department to work on Ketamine project for Hospitalized patients. He is focused on improving communication between multidisciplinary teams and sub-specialty teams to improve patient understanding and satisfaction thus improving patient outcomes.

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## **Jeymi Tambiah, MBChB, FRCS, FAPCR**

Dr Jeymi Tambiah qualified in medicine from the Universities of St. Andrews and Manchester, UK. He completed a Doctorate degree in vascular biology from Imperial College London then becoming a specialist registrar in cardiothoracic surgery at Guys and St. Thomas's Hospitals. He joined the pharmaceutical industry in 2008, progressing to lead Medical Affairs teams through numerous immunology drug launches, initially in the UK and from 2011 in the USA. Through his industry career his professional interests have moved towards translational medicine and clinical trial design, encompassing innovative technologies such as genomics research and artificial intelligence. He is currently Senior Vice President of Clinical Development and External Innovation for Biosplice Therapeutics based in San Diego, developing drugs across a range of diseases including osteoarthritis, oncology, and Alzheimer's Disease. He regularly presents data at academic congresses and has published

several research papers. He is a Fellow of the Royal College of Surgeons of England and Edinburgh, a Member of Faculty of Pharmaceutical Physicians UK by Distinction, and Fellow of the Academy of Physicians in Clinical Research.

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## **Leonard Weather, Jr., MD, RPh, FAPCR**

Leonard Weather Jr., RPh, MD, FAPCR is an obstetrician/gynecologist. He received his BS in Pharmacy from Howard University and his MD from Rush Medical College in Chicago, Illinois. He completed his internship, residency and fellowship in gynecology and obstetrics at the Johns Hopkins University Hospital in Baltimore, Maryland.

Dr. Weather is a health educator and professor, ordained minister, artist, author and photographer. He has authored three inspirational poetry books and an infertility handbook. He is an active gynecological clinical trials researcher, has presented over 200 peer review presentations and papers on pelviscopic surgical treatment of infertility, endometriosis, pelvic pain and fibroids. He invented the surgical procedure Optical Dissection Pelviscopy, to assist in the prevention of organ injury during laparoscopy. Dr. Weather is Past President of the National Medical Association, the New Orleans Medical Association and the Louisiana Medical Association. He currently serves as the President of the North Louisiana Medical Association. Additionally, he is a member of the Board of Scientific Advisors to the Endometriosis Association, World Endometriosis Society, a Fellow of the Academy of Physicians in Clinical Research, National President of the Chi Delta Mu Medical Fraternity, Fellow of the Federation of State Medical Boards, Board Member of the Louisiana State Board of Examiners and a Board Member of the Academy of Physicians in Clinical Research Board of Trustees.