SPEAKER BIOGRAPHIES

DAY ONE: Monday, September 18, 2023 - Welcome & Keynote

Jeffrey Siegel, MD | *Office Director* | Office of Drug Evaluation Sciences (ODES) | Office of New Drugs (OND) | CDER | FDA

Previously Dr Siegel was Executive Director, Head - Translational Medicine in the Clinical Research, Inflammation group at Gilead Sciences from March 2019 through December 2020. Before that, Dr Siegel was Senior Group Medical Director, Global Head of Rheumatology & Rare Diseases in Product Development Immunology at Genentech/Roche from 2010-2019. While at Genentech/Roche, his group initiated and completed a Phase 2 and Phase 3 program for tocilizumab (Actemra) for systemic sclerosis, achieved 2 Breakthrough Therapy Designations and filed 2 sBLAs - both approved - and achieved 2 orphan drug designations. Dr Siegel received his medical degree from Yale University School of Medicine, internship and residency training at the University Hospitals of Cleveland, clinical fellowship training in Rheumatology at University Hospitals of Cleveland and basic science research training at the NIH in Immunology and signal transduction. After fellowship he joined the Naval Medical Research Institute for 5 years where he served as Branch Head, Signal Transduction. He then joined the FDA and was there for 14 years, serving as Supervisory Medical Officer, Clinical Team Leader in Rheumatology.

Peter Stein, MD | *Director* | OND | CDER | FDA

Peter Stein, M.D., is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters. A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late-stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience.

Kevin Krudys, PhD | *Associate Director* | Office of Neuroscience (ON) | OND | CDER | FDA

Kevin Krudys is Associate Director for Quantitative Sciences in the Office of Neuroscience at FDA. He worked previously as a Clinical Analyst in the Division of Neurology Products and as a Team Leader in the Office of Clinical Pharmacology. He earned his Ph.D. in Bioengineering from the University of Washington.

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Christina Chang, MD | *Director* | Division of Urology, Obstetrics and Gynecology (DUOG) | Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM) | OND | CDER | FDA

Dr. Christina Chang is the Director of the Division of Urology, Obstetrics and Gynecology (DUOG) in the Office of New Drugs in the Center for Drug Evaluation and Research at U.S. FDA. In this capacity, she oversees a diverse group of drugs and therapeutic biologics for the management of benign urologic, obstetric, and gynecologic conditions. She has led the facilitation and assessment of many development programs in these areas, including products to treat uterine fibroids, pre-malignant dysplasia of the cervix, and to prevent preterm birth. She started her FDA career in 2007 as a clinical reviewer in the Division of Nonprescription Clinical Evaluation and took on the role of clinical team leader in DUOG in 2013. Dr. Chang is a board-certified obstetrician/gynecologist. She obtained her bachelor's degree in Biochemistry from University of California at Berkeley and her medical degree from University of Chicago Pritzker School of Medicine. She also received her Master of Public Health with Honors from the Johns Hopkins University School of Hygiene and Public Health. She completed her obstetrics and gynecology residency at Washington Hospital Center in Washington D.C. Prior to joining the FDA, she provided full-scope obstetric and gynecologic care to adolescent and adult females for seven years and founded her own practice.

George Makar, MD, MSCE | *(Acting) Deputy Director* | Division of Hepatology and Nutrition (DHN) | Office of Immunology and Inflammation (OII) | OND | CDER | FDA

Dr. George Makar is a hepatologist, serving as the Acting Deputy Director in the Division of Hepatology and Nutrition (DHN) at the FDA. He earned his medical degree from the University of Iowa and completed gastroenterology and transplant hepatology fellowships at the University of Pennsylvania, where he joined the faculty in 2007. In 2009 he completed a Master of Science in Clinical Epidemiology (MSCE) at the Center for Clinical Epidemiology and Biostatics (CCEB) at the University of Pennsylvania School of Medicine. He maintained a broad-based transplant and non-transplant hepatology practice for 14 years during which he also served as medical director of the liver transplant program and director of the transplant hepatology fellowship. He joined the FDA in January of 2020 as a medical reviewer.

Laura Lee Johnson, PhD | *Director* | Division of Biometrics III (DBIII) | Office of Biostatistics (OB) | Office of Translational Sciences (OTS) | CDER | FDA

Dr. Johnson is a division director in the Office of Biostatistics at the U.S. Food and Drug Administration Center for Drug Evaluation and Research. Her division supports the Office of New Drug's Office of Immunology and Inflammation (OII) and FDA efforts related to patient experience data including Patient Focused Drug Development (PFDD). Prior to working at the FDA, Dr. Johnson spent over a decade at the U.S. National Institutes of Health (NIH) working on
and overseeing clinical research and research support programs including the CTSAs and the NIH Collaboratory. She co-directs the NIH Principles and Practice of Clinical Research course with annually over 10,000 participants in over 150 countries.

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Don C. Rockey, MD | *Professor of Medicine* | Specialties: Gastroenterology and Hepatology | College of Medicine | Medical University of South Carolina

My basic research has focused on discovering new pathways important in patients with liver disease, particularly focused on translating findings from the bench to the clinic. We study two primary basic research areas including (1) basic mechanisms of liver fibrosis and (2) the molecular basis of portal hypertension. We made several seminal discoveries and contributions to the fibrosis field, including the discovery that hepatic stellate cells transition to hepatic myofibroblasts during liver injury and the wound healing process, and that they express abundant smooth muscle proteins and function as contractile cells in the injured liver. Further, our laboratory has single handedly identified multiple targets in liver fibrosis that have been translated to specific clinical trials (2 large randomized clinical trials) designed to test them as novel therapeutics. The second major focus of our work in the field of molecular portal hypertension, a field that our laboratory has helped create. The work also has a distinct mechanistic focus, specifically in intracellular signaling, including novel protein-protein interactions. In all, our laboratory's basic research has been supported by the National Institutes of Health for over 25 years now.

David E. Kleiner, MD, PhD | *Senior Research Physician* | *Director* | Laboratory Information System | Chief, Post-mortem Section | Laboratory of Pathology | National Cancer Institute (NCI) | National institute for Health (NIH)

Dr. Kleiner obtained an M.D. and Ph.D. (Chemistry) from the University of Chicago. After a residency in Anatomic Pathology at the National Cancer Institute, he joined the faculty of the Laboratory of Pathology in the NCI. He is currently a Senior Research Physician and Chief of the Postmortem Section of the Laboratory of Pathology with expertise in hepatic pathology. His research has focused on liver cancer and chronic liver disease, with particular attention to assessing histological responses to therapy. He played a key role as a pathologist for the NIDDK sponsored clinical networks: the NASH CRN, DILIN and the HBRN. He has authored or co-authored over 400 articles in the medical literature as well as multiple book chapters and review articles on the histopathology of DILI and NASH.

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Naga Chalasani, MD | *David W Crabb Professor of Gastroenterology and Hepatology* | Vice President for Academic Affairs | Indiana University School of Medicine & Indiana University Health

Dr. Chalasani currently serves as David W. Crabb Professor of Medicine and Vice President for Academic Affairs at Indiana University School of Medicine and Indiana University Health. He previously served as the Director of the Division of Gastroenterology and Hepatology (2007-2020) and Chair of the Department of Medicine (2020-2021, interim) at Indiana University School of Medicine. His research is focused on nonalcoholic fatty liver disease (NAFLD) and drug induced liver injury (DILI), two highly significant public health problems. His research has been continuously funded by the National Institutes of Health since 1999. He is a founding principal investigator of the NIDDK funded NASH CRN and is the PI for the HIV NASH CRN. He is the founding PI for the NIDDK funded Drug Induced Liver Injury Network and is the lead author for the ACG Practice Guideline on the Diagnosis and Management of Drug Induced Liver Injury. He published over 550 papers including 375 original papers, 3 Practice Guidelines, 47 book chapters/review articles, 35 editorials/commentaries, 18 symposium proceedings, and more than 600 abstracts (Google Scholar H-index 107, i10 index 389 with ~ 59,219 citations). He is an elected member of the Alpha Omega Alpha, American Society of Clinical Investigation (ASCI) and the American Association of Physicians (AAP).

Cynthia Behling, MD, PhD | *Pathologist* | University of California, San Diego | Pacific Rim Pathology Lab

Dr. Cynthia Behling joined Pacific Rim Pathology in 2005 after previously serving as an Associate Professor of Clinical Pathology at the University of California, San Diego (UCSD). She graduated from Emory University School of Medicine, Atlanta, GA in 1989 and completed her pathology residency at UCSD from 1990 - 1994. Dr. Behling has been board certified in Anatomic and Clinical Pathology since 1994. At Pacific Rim, Dr. Behling serves as the director of the Research department overseeing a variety of clinical trials and studies. Her specialties of expertise include Hepatobiliary and Gastrointestinal pathology. Her professional interests include histologic endpoints for clinical trials, research into fatty liver disease, and pathology education. Dr. Behling serves as a pathology committee lead for the Non-Alcoholic Steatohepatitis Clinical Research Network (NIDDIK) and is a board member of the Sharp Institutional Review.

Theo Heller, MD | *Section Chief: Translational Hepatology Section, Liver Diseases Branch* | Senior Investigator: Clinical Research Section, Liver Diseases Branch | National Institute of Diabetes and Digestive and Kidney Disease (NIKDDK) | National Institute for Health (NIH)

Dr. Theo Heller is the Section Chief of the Translational Hepatology Section of the Liver Diseases Branch of the National Institute of Diabetes and Digestive and Kidney Diseases. His work focuses on rare liver diseases, effects of systemic diseases on the liver, and approaching common problems in liver disease in a multidisciplinary manner.

Q&A Discussion Panel

Naga Chalasani, MD | *David W Crabb Professor of Gastroenterology and Hepatology* | Vice President for Academic Affairs | Indiana University School of Medicine & Indiana University Health - Speaker & Panelist - *(see biography above)*

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Laura Lee Johnson, PhD | *Director* | Division of Biometrics III (DBIII) | Office of Biostatistics (OB) | Office of Translational Sciences (OTS) | CDER | FDA - Speaker & Panelist - *(see biography above)*

Don C. Rockey, MD | *Professor of Medicine* | Specialties: Gastroenterology and Hepatology | College of Medicine | Medical University of South Carolina - Speaker & Panelist - *(see biography above)*

David E. Kleiner, MD, PhD | *Senior Research Physician* | Director, Laboratory Information System | Chief, Post-mortem Section | Laboratory of Pathology | National Cancer Institute (NCI) | National institute for Health (NIH) - Speaker & Panelist - *(see biography above)*

Cynthia Behling, MD, PhD | *Pathologist* | University of California, San Diego | Pacific Rim Pathology Lab - Speaker & Panelist - *(see biography above)*

Scott Friedman, MD | *Dean for Therapeutic Discovery* | Fishberg Professor of Medicine | Professor of Pharmacologic Sciences | Chief, Division of Liver Diseases | Icahn School of Medicine at Mount Sinai

Dr. Scott L. Friedman is the Dean for Therapeutic Discovery and Chief of the Division of Liver Diseases, at the Icahn School of Medicine at Mount Sinai. He has performed pioneering research into the underlying causes of scarring, or fibrosis associated with chronic liver disease, affecting millions worldwide. Dr. Friedman was among the first to isolate and characterize the hepatic stellate cell, the key cell type responsible for scar production in liver. His work has spawned an entire field that is now realizing its translational and therapeutic potential, with new anti-fibrotic therapies for liver disease reaching clinical trials. A 1979 graduate of the Icahn School of Medicine at Mount Sinai, he served as the President of Alpha Omega Alpha Honor Society, then was a Medical Resident at the Beth Israel Hospital, Harvard Medical School, Boston, followed by a Gastroenterology Fellowship at UCSF before assuming a faculty position there which he held for ten years. During a 1995 - 1996 sabbatical from UCSF he was a Senior Fulbright Scholar and Visiting Professor at the Weizmann Institute of Science in Israel, in the laboratory of Professor Moshe Oren. Dr. Friedman has given invited honorary lectures throughout the world and has been a named lecturer or Visiting Professor at over 30 institutions worldwide.

In 2003, Dr. Friedman was honored with the International Hans Popper Award by the Falk Foundation in Freiburg, Germany, in recognition of his outstanding contributions to the understanding of liver disease and its treatment. In 2012 he was awarded the European Association for the Study of Liver Diseases International Recognition Award in Barcelona, Spain, and in 2013 he was awarded the Shanghai Magnolia Gold Award by the Mayor of Shanghai and the China Friendship Award from the Premier of China in 2014 in recognition of his efforts to improve the health of the residents of Shanghai and China through his research achievements.

In 2016 he was awarded the Distinguished Achievement Awards from both the AASLD and the American Liver Foundation. He was elected as a Fellow of the American Gastroenterological Association in 2008, the Am. College of Physicians in 2013, the AASLD in 2014 and the American Association for the Advancement for Science in 2015. As Chief of the Division of Liver Diseases at Mount Sinai since 2001, Dr. Friedman has expanded the faculty from 5 to 40 individuals, increased NIH grant funding more than 5-fold, clinical trials income more than 10-fold, and overseen the creation of the largest liver fellowship in the United States.

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Mary Rinella, MD | *Director of the Metabolic and Fatty Liver Program* | Professor of Medicine at the University of Chicago Pritzker School of Medicine

Dr. Rinella is a Professor of Medicine at the University of Chicago Pritzker School of Medicine and is the Director of the Metabolic and Fatty Liver Program. During the earlier part of her career, she studied basic mechanisms of steatohepatitis with funding from the American Gastroenterological Association and the National Institute of Health (NIH). Currently her focus is on clinical research in non-alcoholic fatty liver disease (NAFLD) / non-alcoholic steatohepatitis (NASH) both before and after liver transplantation. She primarily focuses on the associations between NASH, metabolic co-morbidities and the recurrence of NASH after liver transplantation. Dr. Rinella is actively involved in the American Association for the Study of Liver Diseases (AASLD) where she recently served as Councilor-at-large on the Governing Board. She was an author on the 2018 AASLD Practice Guidance for NAFLD and is the chair of the 2023 AASLD NAFLD Practice Guidance. She has held several national leadership roles in the field of NAFLD including Chair of the AASLD NAFLD Special Interest Group (SIG) and Chair of the AASLD NASH Task Force. As Chair of the NASH Task Force, she was charged with fostering research collaboration and advancing best practice through collaboration with other medical societies, federal agencies and patient advocacy organizations to improve outcomes in patients with NASH. Currently, she is co-leading a pan society global initiative using a Delphi process to identify a more suitable terminology for what we currently refer to as NAFLD. She was recently appointed chair of the Steatotic Liver Disease task force, which will oversee 2 subcommittees focused on national and global strategies, respectively, to increase disease awareness and foster implementation of best practice.

Gregory Levin, PhD | *Associate Director for Statistical Science and Policy* | OB | OTS | CDER | FDA

Gregory Levin is the Associate Director for Statistical Science and Policy in the Office of Biostatistics in the FDA's Center for Drug Evaluation and Research. He received a Ph.D. in biostatistics from the University of Washington in 2012. Greg has experience supporting drug review across a wide range of therapeutic areas and has represented CDER on several policy and guidance working groups, including efforts related to adaptive design, master protocols, benefit-risk, and the evaluation of effectiveness.

Nicholas Petrick, PhD | *Deputy Director* | Division of Imaging, Diagnostics, and Software Reliability (DIDSR) | Office of Science and Engineering Laboratories (OSEL) | Center for Devices and Radiological Health (CDRH) | FDA

Nicholas Petrick received his Ph.D. from the University of Michigan in Electrical Engineering-Systems focusing on medical signal and image processing. Dr. Petrick is currently Deputy Director for the Division of Imaging, Diagnostics, and Software Reliability in the Center for Devices and Radiological Health, U.S. Food and Drug Administration. He is also member of the FDA's Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) and is a Fellow of SPIE and the American Institute of Medical and Biomedical Engineering. Dr. Petrick's research is focused on developing robust medical AI/ML, least-burdensome assessment methods for a wide range of medical imaging-based AI/ML devices and quantitative imaging biomarkers.

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Cynthia Guy, MD | *Professor of Pathology* | Liver Pathology Division Chief | Department of Pathology | Duke University Health Systems

Cynthia Guy is a gastrointestinal and liver pathologist with more than 20 years of clinical diagnostic experience, and she is active in many areas of translational research. She has a special interest in Nonalcoholic Fatty Liver Disease (NAFLD) / Nonalcoholic Steatohepatitis (NASH). She is a longstanding member of the NASH Clinical Research Network Pathology Committee, and a member of the International NAFLD Pathology Group. She received her MD degree from the Medical University of South Carolina, completed Anatomic and Clinical Pathology residency training at Emory University, and was fellowship trained at Duke University.

Q&A Discussion Panel

George Makar, MD, MSCE | *(Acting) Deputy Director* | Division of Hepatology and Nutrition (DHN) | Office of Immunology and Inflammation (OII) | OND | CDER | FDA - Speaker & Panelist - *(see biography above)*

Prakash Jha MD, MPH | *Medical Officer* | Division of Molecular Genetics and Pathology (DMPG) | OHT7: Office of In Vitro Diagnostics and Radiological Health | Office of Product Evaluation and Quality (OPEQ) | CDRH | FDA – Panel Only

Prakash Jha is a medical officer in the Division of Molecular Genetics and Pathology. He is responsible for review of molecular genetics and pathology in vitro diagnostics, and companion diagnostics in the Center for Devices and Radiological Health. Prakash is a pathologist with dual fellowships in Gastrointestinal/Liver, and Soft Tissue/Bone from the Armed Forces Institute of Pathology (AFIP). In addition, he has a Master in Public Health from George Washington University.

David E. Kleiner, MD, PhD | *Senior Research Physician* | *Director* |Laboratory Information System | Chief, Post-mortem Section | Laboratory of Pathology | National Cancer Institute (NCI) | National institute for Health (NIH) - Speaker & Panelist - *(see biography above)*

Nicholas Petrick, PhD | *Deputy Director* | Division of Imaging, Diagnostics, and Software Reliability (DIDSR) | Office of Science and Engineering Laboratories (OSEL) | Center for Devices and Radiological Health (CDRH) | FDA - Speaker & Panelist - *(see biography above)*

Cynthia Behling, MD, PhD | *Pathologist* | University of California, San Diego | Pacific Rim Pathology Lab - Speaker & Panelist - *(see biography above)*

Cynthia Guy, MD | *Professor of Pathology* | Liver Pathology Division Chief | Department of Pathology | Duke University Health Systems - Speaker & Panelist - *(see biography above)*

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Zachary Goodman, MD, PhD | *Director* | Liver Pathology Research Center for Liver Diseases | Inova Fairfax Hospital – Panel Only

Zachary Goodman, MD, PhD is currently Director of Liver Pathology Research at Inova Fairfax Hospital, located in the Northern Virginia suburbs of Washington, DC. He attended Vanderbilt University, enrolling in the joint MD-PhD program with PhD work in Experimental Pathology, followed by internship and Pathology residency at the Johns Hopkins Hospital. Since residency he has specialized in liver pathology, first at the Armed Forces Institute of Pathology (AFIP) in Washington, DC, and since 2010 at Inova where he has continued his work in diagnostic liver pathology and teaching, including directing and participating in dozens of CME courses. He has participated in research in nearly all areas of liver disease, including serving as central pathologist for dozens of multicenter clinical trials of new forms of therapy for liver diseases, including 13 trials for treatment of hepatitis B, 32 trials for hepatitis C, one trial for hepatitis D, 24 trials for NAFLD/NASH and 2 trials for primary sclerosing cholangitis. He has authored or co-authored over 260 peer-reviewed papers, over 50 book chapters and invited reviews and over 300 abstracts.

Katy Wack, PhD | *Vice President* | Clinical Development Strategy | PathAI, Inc.| Board of Directors | Digital Pathology Association (DPA) – Panel Only

Katy Wack is the Vice President of Clinical Development, joining the PathAI team in November of 2019. In addition to leading all clinical and regulatory strategy, she designed and led PathAI's Clinical Trial Services Program, spearheaded the AIM- NASH Drug Development Tool qualification effort and led the regulatory submission that resulted in 510k clearance for PathAI's AISight Dx digital pathology platform. She brings clinical and scientific expertise through her decades of work in drug development and digital pathology. Before PathAI, she served as Vice President of Development for an oncolytic virus company in co-development with Pfizer, leading IND-enabling preclinical, assay and process development, and CMC activities. Prior to that, Katy served as Lead Clinical Scientist at a digital pathology company, where she led a 4-site PMA clinical study for primary diagnosis, publishing and patenting novel analytical methodologies. Katy earned her BS in Biological Science and Engineering from Carnegie Mellon, her MS in Liver Tissue Engineering and Toxicology from M.I.T., and her PhD from University of Pittsburgh in Cell Biology and Pathology, using quantitative imaging to study age-related chronic kidney disease.

Dean Tai, PhD | *Managing Director & Chief Scientific Officer* | HistoIndex Pte Ltd – Panel Only

Dr. Dean Tai is the co-founder and Chief Scientific Officer (CSO) at HistoIndex, where he leads the R&D team and collaborates with key opinion leaders on a global scale. He plays a pivotal role in the successful development and launch of the Company's innovative platform technology, revolutionizing stain-free, fully automated imaging solutions for visualizing and AI/ML-based analysis of fibrosis and other biomarkers in biological tissues. Within HistoIndex, Dr. Tai oversees multi-center clinical trials and validations worldwide, ensuring the seamless implementation of the Company's proprietary imaging and analysis technology. Moreover, he established the world's first stain-free imaging database for studying fibrosis in chronic liver diseases, extending its reach across US, Europe and Asia-Pacific countries. His research interests are in cutting-edge imaging technologies and AI/ML-based methodologies.

Day One Wrap Up

Frank Anania, MD | *(Acting) Director* | DHN | OII | OND | CDER | FDA

Frank Anania, MD, is currently the Acting Director of the Division of Hepatology and Nutrition (DHN) in the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration (FDA). He joined the FDA in early 2018 after which he served as a primary medical reviewer until September 2019 when he was promoted to clinical team leader, a position that became permanent in spring 2020. In addition to serving in leadership in liver disease product development at the FDA, Dr. Anania has given multiple lectures as a regulatory scientist at the Center for Drug Evaluation and Research (CDER) since joining the FDA due to his expertise in non-alcoholic fatty liver disease (NAFLD), non-alcoholic steatohepatitis (NASH), and liver fibrosis. He also has a courtesy staff appoint in the Liver Diseases Branch of the National Institutes of Diabetes, Digestive, and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) in Bethesda, MD; as well as an adjunct faculty appointment at Georgetown University School of Medicine where is he (clinical) Professor of Medicine. Prior to coming to the FDA, Dr. Anania was a physician-scientist who conducted basic research focused on NASH and hepatic fibrosis.

DAY TWO: Tuesday, September 19, 2023

Insook Kim, PhD | *Master Scientist* | Division of Inflammation and Immune Pharmacology (DIIP) | Office of Clinical Pharmacology (OCP) | Office of Translational Sciences (OTS) | CDER | FDA

Insook Kim, Ph.D. is a master scientist in the Division of Inflammation and Immune Pharmacology of the Office of Clinical Pharmacology leading the clinical pharmacology reviews of INDs, NDAs, and BLAs for the Division of Hepatology and Nutrition and the Division of Gastroenterology (DG) in the Center for Drug Evaluation and Research (CDER) at FDA. Dr. Kim also has review experience in inborn errors of metabolism and has participated in the Guidance Working Groups on the hepatic impairment study, drug interactions with gastric acid reducers, labeling for organ impairment, and pediatric inflammatory bowel diseases. Prior to joining FDA, Dr. Kim conducted post-doctoral research on nuclear receptors including FXR at the National Cancer Institute. She graduated with a PhD in Pharmaceutics from the University of Michigan, a master's degree in Pharmaceutics from Seoul National University. Dr. Kim is interested in optimizing drug development by leveraging clinical pharmacology.

Rebecca Hager, PhD | *Lead Mathematical Statistician* | Division of Biometrics III (DBIII)| Office of Biostatistics (OB) | OTS | CDER | FDA

Rebecca Hager is a lead mathematical statistician in the Division of Biometrics III supporting the Division of Hepatology and Nutrition (DHN) in the Center for Drug Evaluation and Research (CDER) at FDA. Rebecca additionally has review experience in other therapeutic areas including COVID-19, dermatology and dentistry, and rare disease and is on the CDER Office of Biostatistics Master Protocols Working Group. She graduated with a PhD in Statistics from North Carolina State University.

Abbas Bandukwala, MS | *Lieutenant Commander, United States Public Health Service* (*USPHS)* | Science Policy Analyst Biomarker Qualification Program (BQP) | OND | CDER | FDA

Abbas Bandukwala graduated from Vanderbilt University as a Biomedical Engineer. He then served 5 years as a United States Naval Officer. He completed his master's degree in chemical engineering from University of Maryland. He joined the FDA in 2009 in the Center of Devices and Radiological Health (CDRH) and reviewed pre-market applications for light-based devices. In 2017, he moved from CDRH and became part of the Center Drug Evaluation and Research (CDER) Biomarker Qualification Program (BQP).

Phil Newsome, MD, PhD | *Director of Centre for Liver & GI Research* | University of Birmingham

Professor Newsome runs the metabolic services at the Liver Unit at the Queen Elizabeth Hospital Birmingham which includes a large multi-disciplinary clinic for patients with NAFLD. He was Chief Investigator on a randomised controlled trial of Glucagon-like peptide-1 (GLP-1) therapies in NAFLD published in the Lancet and the NEJM. He is the Co-ordinating Investigator for several global NAFLD studies. He chaired the national guidelines for liver transplantation in
NAFLD and sat on the NICE Guideline Development Group for NAFLD. He led the recent UK multi-stakeholder guideline group on the management of abnormal liver blood tests and led on NAFLD for the recent EASL Lancet Liver Commission. He recently completed his term as Secretary General (President) of EASL.

DAY TWO: Tuesday, September 19, 2023

Claude Sirlin, MD | *Professor of Radiology* | Liver Imaging Group | University of California

Claude B. Sirlin, MD, Professor of Radiology at UC San Diego in the United States, is a clinician scientist who specializes in liver imaging, metabolic imaging, quantitative imaging, and imaging of abdominal cancers. Dr Sirlin directs UC San Diego Health's Liver Imaging Group, which seeks to advance screening, diagnosis, treatment, and outcomes of individuals with liver disease. He is academic co-chair of the Imaging Workstream for the Foundation of the NIH's Non-Invasive BioMarkers for MetaBolic Liver DiseasE (NIMBLE) project. He is the founder of the Liver Imaging Reporting and Data System, which is now used worldwide for radiologic imaging of liver cancer. Dr. Sirlin mentors medical students, residents, fellows, visiting scholars, and junior faculty.

Scott Reeder, MD, PhD | *Professor and Senior Vice Chair (Research)* | Chief of Magnetic Resonance Imaging | Departments of Radiology, Medical Physics, Biomedical Engineering, Medicine, and Emergency Medicine | University of Wisconsin-Madison

Scott Reeder MD, PhD is a Professor, Vice Chair of Research and Chief of MRI in the Department of Radiology at the University of Wisconsin, Madison. He joined UW-Madison in 2005 from Stanford University where he completed his radiology residency, and a fellowship in abdominal and cardiovascular imaging. In addition to his clinical and administrative duties, Dr. Reeder is also the Director of the UW Liver Imaging Research Program, an internationally recognized and active NIH-funded group that performs research in technical development and translation of new imaging methods, particularly quantitative imaging biomarkers, to assess liver disease. Specific areas of research interests include development of new MRI methods for quantification of abdominal adiposity, liver fat, liver iron overload and other features of diffuse liver disease, quantification of perfusion in liver tumors, hemodynamics of portal hypertension and the use of new contrast agents in liver and biliary diseases.

Q&A Discussion Panel

Abbas Bandukwala, MS | *Lieutenant Commander, USPHS* | Science Policy Analyst Biomarker Qualification Program (BQP) | OND | CDER | FDA – Panel Only

Dan Krainak, PhD | *Assistant Director* | Division of Radiological Imaging & Radiation Therapy Devices | Office of Radiological Health (OHT8) | Office of Product Quality and Evaluation (OPEQ) | CDRH | FDA – Panel Only

Dan Krainak, Ph.D., is the Assistant Director for the Magnetic Resonance and Nuclear Medicine devices team in CDRH. Dan joined the FDA in 2011 and has participated in the review of radiological devices, imaging biomarkers, and radiological imaging in therapeutic medical product clinical trials. He is a former co-chair of the Biomarker Working Group at FDA and member of the NIH-FDA Biomarker Working Group that maintains the BEST (**B**iomarkers, **E**ndpoint**S**, and other **T**ools) Resource.

Phil Newsome, MD, PhD | *Director of Centre for Liver & GI Research* | University of Birmingham - Speaker & Panelist - *(see biography above)*

Claude Sirlin, MD | *Professor of Radiology* | Liver Imaging Group | University of California - Speaker & Panelist - *(see biography above)*

DAY TWO: Tuesday, September 19, 2023

Scott Reeder, MD, PhD | *Professor and Senior Vice Chair (Research)* | Chief of Magnetic Resonance Imaging | Departments of Radiology, Medical Physics, Biomedical Engineering, Medicine, and Emergency Medicine | University of Wisconsin-Madison - Speaker & Panelist - *(see biography above)*

Rajarshi Banerjee, PhD | *CEO* | Perspectum Ltd | Honorary Consultant Physician | Oxford University Hospitals NHS Trust – Panel Only

Rajarshi Banerjee, Ph.D. is Chief Executive Officer of Perspectum. Prior to co-founding Perspectum in 2012, Dr. Banerjee was a research fellow at the University of Oxford and developed the magnetic resonance imaging techniques for rapid non-invasive liver assessment and commercialized the method as LiverMultiScan, which has received 510(k) clearance from the FDA and is used in over 250 sites. Dr. Banerjee continues to work as a consultant physician with the Oxford University Hospitals NHS Foundation Trust, with research into the phenotyping of liver disease at an individual and population level in adults and children. Dr. Banerjee has many years of experience in running clinical trials and working in multidisciplinary scientific teams to develop applications for cutting-edge imaging technology and is a keen advocate of smart trial design. Dr. Banerjee received a BM. BCh. in Medicine and a Ph.D. in Cardiovascular Health from the University of Oxford, as well as a MSc. in Public Health from the London School of Hygiene and Tropical Medicine.

Richard Ehman, MD | *Professor of Radiology* | Blanche & Richard Erlanger Endowed Professor of Medical Research | Mayo Clinic – Panel Only

Richard L. Ehman, M.D., is Professor of Radiology and the Erlanger Endowed Professor of Medical Research at the Mayo Clinic. He led the Body MRI practice at the Mayo Clinic through years of rapid growth. His NIH-funded research program is focused on developing new imaging technologies. He holds more than 45 US patents and many of these inventions are widely used in clinical practice. As part of his duties at Mayo. Dr. Ehman serves as CEO
of Resoundant Inc., a Mayo Clinic-owned company, founded to provide patients everywhere with access to *magnetic resonance elastography*, an imaging technology invented at Mayo and now deployed at more than 2200 locations globally. He has served on the Advisory Council of the National Institute of Biomedical Imaging and Bioengineering of the NIH and as a member of the NIH Council of Councils. Dr. Ehman has been awarded Gold Medals by the International Society for Magnetic Resonance in Medicine, the Society of Advanced Body Imaging, and the Radiological Society of North America. He is a Fellow of the National Academy of Inventors and an elected member of the US National Academy of Medicine. Dr. Ehman has served as president of the International Society for Magnetic Resonance in Medicine, the Academy of Radiology Research, the Society for Advanced Body Imaging, and the Radiological Society of North America.

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David T. Fetzer, MD | *Assistant Professor* | Abdominal Imaging Division | Medical Director | Ultrasound | Department of Radiology | UT Southwestern Medical Center (UTSW) – Panel Only

Dr. Fetzer is an abdominal radiologist at UT Southwestern Medical Center, specializing in ultrasound, with a particular interest in hepatobiliary and quantitative imaging. Dr. Fetzer is Medical Director of Ultrasound at UTSW University Hospital and Clinics, and Parkland Health and Hospital System, within the Department of Radiology. He is also the director of the clinical and translational research lab CACTUS (Collaborative for Advanced Clinical Techniques in UltraSound Lab). His research and education efforts include ultrasound and CEUS use in HCC surveillance and diagnosis, and in quantitative biomarkers of chronic liver disease. Dr. Fetzer is the co-chair of the American Institute of Ultrasound in Medicine (AIUM) Liver Fat Quantification Task Force, and the chair of the Elastography Community. For the AIUM/RSNA Quantitative Imaging Biomarker Alliance (QIBA), Dr. Fetzer servers as co-chair of the Shear Wave Speed biomarker committee, and a working group co-chair of the Pulse-Echo Quantitative UltraSound (PEQUS) biomarker committee for liver fat quantification. He is frequently asked to speak, review, and write on the topics of chronic liver disease and ultrasound quantification.

Céline Fournier, PhD | *Chief Medical Officer* | Echosens – Panel Only

Céline Fournier, as Chief Medical Officer, globally leads Medical Affairs, Clinical Operations and Clinical Application at Echosens (Paris, France). Since 2002, she oversees the clinical development of the FibroScan medical devices and associated composite scores as non-invasive aids for the clinical management, diagnosis, and monitoring of patients with confirmed or suspected liver disease. She graduated with a PhD in Bioengineering from the Paris XII University.

Lori E. Dodd, PhD | *Section Chief Clinical Trials Research Section* | Biostatistics Research Branch | Division of Clinical Research | National Institute for Allergy and Infectious Diseases (NIAID) | National Institute for Health (NIH) – Panel Only

Lori Dodd is a biostatistician and section chief for the Clinical Trials Research Section within the Biostatistics Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, where she primarily collaborates on infectious disease clinical trials. Lori served as principal statistician for the Pamoja Tulinde Maisha (PALM; "Together, Save Lives") randomized controlled trial of Ebola virus disease therapies and the Adaptive COVID-19 Treatment Trial (ACTT) series of randomized controlled trials. Prior to joining NIAID, she worked as a mathematical statistician at the National Cancer Institute. Dr Dodd earned her PhD from the Department of Biostatistics at the University of Washington.

Tram T. Tran MD, FAASLD, FACG | *Physician Medical Officer* | DHN | OII | OND | FDA

Dr. Tram Tran is a Medical Officer in the Division of Hepatology and Nutrition in the Center for Drug Evaluation and Research (CDER) at the FDA. Her former roles were as the Medical Director of Liver Transplant at Cedars Sinai Medical Center and Professor of Medicine at Geffen UCLA School of Medicine and Global Vice President of Medical Affairs, Liver Diseases and Covid-19 at Gilead Sciences. She obtained her MD at New York Medical College and completed her fellowships in Gastroenterology and Transplant Hepatology at the UCLA School of Medicine and Cedars Sinai.

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Richard K. Sterling, MD, MSc, FACP, FACG, FAASLD, AGAF | *Professor of Medicine and Chief of Hepatology* | Chief Clinical Officer | Stravitz-Sanyal Institute for Liver Disease and Metabolic Health | Virginia Commonwealth University

Dr. Sterling received his BS in Chemistry and Natural Science from Muhlenberg College in Allentown Pa in 1982, a Master in Biochemistry from the University of Texas in Austin in 1984, an MD from Jefferson Medical College in Philadelphia in 1988 and a Master in Biostatistics and Clinic Research from Virginia Commonwealth University (VCU) in 2007. He completed his residency in Internal Medicine in 1991 and Fellowship in Gastroenterology and Transplant Hepatology from VCU in 1994. He is currently the VCU Hepatology Professor of Medicine (promoted to tenure June 2011) in the Divisions of Gastroenterology, Hepatology, and Nutrition and Infectious Diseases and Section Chief of Hepatology, Medical Director of Viral Hepatitis at VCUHS, Associate Program Director for Scholarship and Research for the core Internal Medicine Residency, and Assistant Chair for Research in the Department of Medicine. His research interest is in HIV-liver disease (HCV, HBV, and/or NAFLD) which is supported by several U01 and R01 NIH grants. Other research interests include noninvasive assessment of liver disease, biomarkers for hepatocellular carcinoma, viral hepatitis, and liver transplantation. He has published over 250 manuscripts, several book chapters and serves on several prominent committees of national associations such as the ABIM, AGA, AASLD, and ACG and has served on several study sections of the NIH. He has won numerous awards for teaching and leadership and was voted “Top Doc” in 2012, 2013, 2022, and 2023 in Richmond magazine.

Keyur Patel, MD, PhD | *Professor of Medicine* | University of Toronto | Staff Hepatologist | UHN Division of Gastroenterology

Dr. Patel received his Medical degree from the University of Southampton, United Kingdom. He completed his Gastroenterology/Hepatology training in Western Australia, and his post-doctoral clinical and translational research fellowships in viral hepatitis at Scripps Clinic and Research Foundation, San Diego, CA and Duke Clinical Research Institute, Durham, NC. His research interests include early phase clinical therapeutic development of antifibrotic therapy and non-invasive biomarkers of fibrosis progression.

Q&A Discussion Panel

Tram T. Tran MD, FAASLD, FACG | *Physician Medical Officer* | DHN | OII | OND | FDA
- Speaker & Panelist - *(see biography above)*

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Paula V. Caposino, PhD | *Acting Deputy Director* | Division of Chemistry and Toxicology Devices (DCTD) | Office of Health Technology 7 (OHT7) | Office of In Vitro Diagnostics | OPEQ | CDRH | FDA – Panel Only

Paula Velasco Caposino was born in Cali, Colombia. She received a B.A. in Biology from Boston University in 1996 and received her Ph.D. in Cell Biology from the University of Kiel, Germany in 2005. After completing a three-year Fellowship at the HIV and AIDS Malignancy Branch, in the Center for Cancer Research (National Cancer Institute, National Institutes of Health), she joined the Division of Chemistry and Toxicology Devices (DCTD) in OHT7 | Office of In Vitro Diagnostics (Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration) in 2008 as a Reviewer. In 2017 she became the Chief of the Cardio-Renal Diagnostics Branch in DCTD and is currently the Acting Deputy Division Director of DCTD.

Richard K. Sterling, MD, MSc, FACP, FACG, FAASLD, AGAF | *Professor of Medicine and Chief of Hepatology* | Chief Clinical Officer | Stravitz-Sanyal Institute for Liver Disease and Metabolic Health | Virginia Commonwealth University - Speaker & Panelist - *(see biography above)*

Keyur Patel, MD, PhD | *Professor of Medicine* | University of Toronto | Staff Hepatologist | UHN Division of Gastroenterology - Speaker & Panelist - *(see biography above)*

Insook Kim, PhD | *Master Scientist* | Division of Inflammation and Immune Pharmacology (DIIP) | Office of Clinical Pharmacology (OCP) | Office of Translational Sciences (OTS) | CDER | FDA - Speaker & Panelist - *(see biography above)*

Naim Alkouri, MD, FAALD | *Chief Medical Officer (CMO)* | Director of the Fatty Liver Program Hepatology | Arizona Liver Health (ALH) – Panel Only

Prior to joining ALH, Dr. Alkhouri served as the director of the Metabolic Health Center at the Texas Liver Institute and Associate Professor of Medicine and Pediatric at the University of Texas (UT) Health in San Antonio, TX. He completed his Gastroenterology and Transplant Hepatology training at the Cleveland Clinic in Cleveland, OH where he was also appointed Assistant Professor of Medicine and Director of the Metabolic Liver Disease Clinic at the Cleveland Clinic Digestive Disease and Surgery Institute. Dr. Alkhouri is a key opinion leader in the field of NASH therapeutics and an advisor/ consultant to many pharmaceutical and biomarker development companies. He is Principal Investigator on several multicenter global NASH trials and a member of the AASLD NASH Special Interest Group (NASH SIG). Dr. Alkhouri is published in over 230 publications to include publications in the New England Journal of Medicine, Lancet, JAMA, Gastroenterology, Hepatology, and Journal of Hepatology. He presents his work at both national and international medical conferences.

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Matthew Gee, MSc | *Director* | Regulatory Affairs | Siemens Healthcare Diagnostics Inc.– Panel Only

With over 25 years of experience in the in vitro diagnostics industry, Matt is currently Director of Regulatory Affairs at Siemens Healthineers, supporting development of the company's immunoassay products. Since 2012, Matt has been leading the regulatory strategy for the ELF Test, which was granted De Novo marketing authorization by the FDA in 2021, a highlight of his career. Matt has a Master of Science from the University of Toronto.

Rohit Loomba, MD, MHSc | *Chief, Division of Gastroenterology and Hepatology* | Director | NAFLD Research Center |University of California San Diego – Panel Only

Dr. Rohit Loomba is a Professor of Medicine (with tenure), Director of Hepatology, at the University of California at San Diego. He is an internationally recognized thought leader in nonalcoholic steatohepatitis (NASH), and non-invasive assessment of liver disease using advanced imaging modalities. He is the founding director of the UCSD NAFLD Research Center which is one of the most well-funded clinical and translational research programs at UCSD. The NAFLD Research Center fosters collaborative team science where a multi-disciplinary team of researchers are conducting cutting edge research in all aspects of NAFLD including non-invasive biomarkers, genetics, epidemiology, clinical trial design, imaging end-points, and integrated OMICs using microbiome, metabolome and lipidome. This integrated approach has led to several innovative applications such as establishment of MRI-PDFF as a non-invasive biomarker of treatment response in early phase trials in NASH, which has now been adopted in more than a hundred clinical trials conducted worldwide. He holds several patents on non-invasive biomarkers of NASH and fibrosis. His research is funded by the National Institutes of Health as a Principal Investigator including two R01s, three U01 (two NIDDK and one from NIAAA), clinical core director of P30 (NIDDK) and project director P01 (NHLBI) grant mechanisms, Foundation of NIH, as well as several large multicenter, multimillion-dollar investigator-initiated research projects funded by the industry. He is the Principal Investigator, UCSD, for the NIDDK-sponsored NASH Clinical Research Network and the Liver Cirrhosis Network.

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Meena B. Bansal, MD, FAASLD | *Professor of Medicine* | *Director* | NASH Center of Excellence Director of Translational Research | Liver Diseases Icahn School of Medicine at Mount Sinai – Panel Only

Dr. Bansal joined the faculty at Mount Sinai in 2001 after completing Gastroenterology Fellowship at the University of Pennsylvania. In 2002 she became the Transplant Hepatology Fellowship Director, leading one of the largest transplant hepatology fellowships in the United States. While remaining clinically active, she had also developed an NIH-funded basic research program focusing on understanding underlying molecular mechanisms of liver fibrosis/cirrhosis to develop novel anti-fibrotic therapies. Her current research interests focus on how HIV may promote hepatic inflammation and fibrosis as well as novel therapeutic strategies for Non-Alcoholic Steatohepatitis (NASH). She became the Director of Translational Research in the Division of Liver Diseases in 2013 and is the principal investigator in several clinical trials for the treatment of NASH. From 2015-2021 Dr. Bansal served as the Chief Medical Officer of Mount Sinai Care LLC (2015-2018), Deputy Chief Medical Officer for Mount Sinai Health Partners (2015-2021), and Vice-President in Pop Health for Quality and Efficiency (2017-2021). In these roles, Dr. Bansal had the opportunity to translate findings from research/clinical trials to address population health needs and understand payor relations in an ever-changing healthcare landscape. In 2022, she became the Director of the newly formed NASH Center of Excellence at Mount Sinai where she is focused on developing a longitudinal registry for predictive algorithms of fibrosis progression and regression, sub-phenotyping of the heterogenous NASH population, non-invasive assessments of liver fibrosis, and novel population screening and therapeutic approaches.

Anup Amatya, PhD | *Lead Mathematical Statistician* | Division of Biostatistics V (DBV) | OB | OTS | CDER | FDA – Panel Only

Anup Amatya, PhD, is a lead mathematical statistician in the Division of Biostatistics V supporting Division of Oncology (DO2) in the Center for Drug Evaluation and Research (CDER) at FDA. He is a member of various working groups and committees within the Office of Biostatistics and Oncology Center of Excellence. Prior to He received his PhD in Biostatistics from the University of Illinois at Chicago.

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Arun Sanyal, MD | *Director* | Stravitz-Sanyal Institute for Liver Disease and Metabolic Health | Professor of Medicine, Physiology, and Molecular Pathology | Virginia Commonwealth University School of Medicine

Arun J. Sanyal, M.D., is a Professor of Medicine, Physiology, and Molecular Pathology in the Division of Gastroenterology at Virginia Commonwealth University (VCU) Medical Center in Richmond, Virginia. At VCU, he is currently the Director of the Stravitz-Sanyal Institute for Liver Disease and Metabolic Health and the Interim Chair of the Division of GI, Hepatology and Nutrition. Dr. Sanyal serves as Chairman of the NIH NASH Clinical Research Network, the NIMBLE consortium, and the Liver Forum for NASH and fibrosis. His research interests include all aspects of NAFLD and NASH as well as complications of end-stage liver disease. He served on numerous advisory boards to pharmaceutical companies and the liver center at Yale University. He chaired the hepatobiliary pathophysiology study section of the NIH and was a founding member of the Hepatology committee of the American Board of Internal Medicine. He also served as Secretary as well as President of the American Association for the Study of Liver Diseases. Dr. Sanyal has authored more than 350 articles in publications such as Cell Metabolism, Nature Medicine, New England Journal of Medicine, Lancet, Gastroenterology, Hepatology, and the Journal of Infectious Diseases has an H-index of 102. He has been continuously funded by the NIH since 1995 and is the principal investigator of four active NIH grants. He is the recipient of the Distinguished Mentorship Award from the American Gastroenterological Association and the Distinguished Scientific Achievement Award from the American Liver Foundation in 2017 and the Distinguished Achievement Award from the AASLD in 2018.

Professor Quentin M. Anstee BSc (Hons), MB BS, PhD, MRCP (UK), FRCP | *Deputy-Dean of Research & Innovation* | Faculty of Medical Sciences | Professor of Experimental Hepatology & Consultant Hepatologist | Translational & Clinical Research Institute | Newcastle University

Prof Quentin M. Anstee is the Chair of Experimental Hepatology and the Deputy-Dean of Research & Innovation in the Faculty of Medical Sciences, Newcastle University, UK. A practicing clinician, he is also an Honorary Consultant Hepatologist in the Liver Transplant Unit at Newcastle's Freeman Hospital, where he leads one of the largest Non-Alcoholic Fatty Liver Disease (NAFLD) clinical services in the U.K. He trained in medicine at University College London where he was awarded a First Class Honours degree and won First Prize in Medicine in the final MB BS examination. Prof Anstee's translational research has made major contributions across the pathophysiology, natural history, diagnosis and treatment of NAFLD. His work has provided key insights into temporal changes in steatohepatitis during disease evolution, identified genetic and epigenetic modifiers of liver disease progression and hepatocellular carcinoma risk and has substantially advanced the field of biomarker development in liver disease. He coordinates two major international research consortia that are studying NAFLD pathogenesis and developing/validating accurate biomarkers to assist the diagnosis, risk-stratification and monitoring of patients with NAFLD: 'EPoS' Elucidating Pathways of Steatohepatitis (EU H2020 funded €6 million, 2015-2019) and 'LITMUS' Liver Investigation: Testing Marker Utility in Steatohepatitis (EU IMI2 funded €47.3 million, 2017-2023). He leads the European NAFLD Registry and is the chief investigator of multiple ongoing clinical trials assessing new medical therapies for NAFLD. He is an Associate Editor of the Journal of Hepatology.

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Mazen Noureddin, MD, MHSc | *Professor of Medicine* | Lynda K. and David M. Underwood Center for Digestive Disorders J.C. Walter Jr. Transplant Center

Mazen Noureddin, MD, MHSc, did his internal medicine residency at the University of Southern California (USC) and then moved to the National Institutes of Health (NIH), where he enrolled in a three-year hepatology fellowship at the Liver Diseases Branch of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). There, he finished the NIH/Duke University Master of Health Sciences in Clinical Research program. After completing his NIH fellowship, he completed a gastroenterology fellowship at the University of California, San Diego (UCSD), where he was a T32 NIH fellow. He joined the University of Southern California (USC) as an Assistant Professor of Clinical Medicine in 2013. He was then recruited to Cedars-Sinai Medical Center in 2015 and was appointed as the founding director of Fatty Liver Program.

Dr. Noureddin is internationally known for his research in NAFLD/NASH and NASH related cirrhosis. He conducted more than 50 investigational clinical studies of novel treatments for NASH. He is an expert in non-invasive testing and biomarkers of NASH and cirrhosis. He has published in all these areas and has been invited to consensus panels on these topics by multiple international societies including the American Association for the Study of Liver Diseases (AASLD), European Association for the Study of Liver Diseases (EASL), Asian Pacific Association for the Study of the Liver (APASL) and Latin American Association for the Study of the Liver (ALEH). He has given invited lectures on NAFLD/NASH at national and international society meetings and serves on several steering committees/advisory boards for industry. He is the vice chair of the AASLD NASH special interest group and has served on the editorial board for major GI journals including “Gastroenterology”, “Hepatology” and “Clinical Gastroenterology and Hepatology (CGH)”. He is an Associate Editor for “Clinical Gastroenterology and Hepatology (CGH)”. Dr. Noureddin has been funded by the National Cancer Institute and has served as a reviewer on NIH study sections. He has published >200 papers in many journals including: The Lancet, Nature Medicine, Lancet Gastroenterology and Hepatology, Science Translational Medicine, Journal of Hepatology, Journal of Clinical Investigation, Gastroenterology, Hepatology, Clinical Gastroenterology and Hepatology and others. In May 2022, Dr. Noureddin moved to Houston, He is currently a Professor of Medicine at the Lynda K. and David M. Underwood Center for Digestive Disorders J.C. Walter Jr. Transplant Center Sherrie & Alan Conover Center for Liver Disease & Transplantation at Houston Methodist Hospital (currently ranked #8 in GI and GI surgery by US News). He has also established the Houston Research Institute which is State of the Art facility that offers patients with liver disease access to new innovative non-invasive diagnostic tests and breakthrough therapies.

Vlad Ratziu, MD, PhD | *Professor of Hepatology* | Sorbonne University | Pitié-Salpêtrière Hospital – Paris, France

Vlad Ratziu is a Professor of Hepatology at Sorbonne University and performs his hospital work at the Pitié-Salpêtrière Hospital and research work at the Institute for Cardiometabolism and Nutrition (ICAN) all in Paris, France. His main research interests are in the field of fatty liver disease in particular clinical trials, mechanisms, risk factors, and progression of liver fibrosis, non-invasive biomarkers and digital pathology and the determinants of hepatocarcinogenesis in patients with metabolic dysfunction. He is a Senior Editor for the Journal of Hepatology and a member of the organizing committee of the NASH–TAG meetings.

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Laurent Castera, MD, PhD | *Professor of Hepatology* | Université Paris Cité | Head of the NASH program | Department of Hepatology | Hôpital Beaujon, Assistance Publique | Hôpitaux de Paris, Clichy, France

Laurent Castera is Professor of Hepatology at the University of Paris Cité (Department of Hepatology, Hôpital Beaujon, Clichy, France) and Visiting Professor of Medicine in University College of London (Institute of Liver and Digestive Health, Royal Free Hospital London, UK). He received his medical degree from the University of Paris-VI and his PhD from the University of Paris-XII. His research interests focus on non-invasive methods for liver fibrosis assessment and NAFLD. He has published more than 200 papers in international peer reviewed journals and serves as Associate Editor for Clinical Gastroenterology and Hepatology, as well as on the editorial boards of the Journal of Hepatology, Gut and Liver International. He has been the chairman of the first international guidelines on the use of non-invasive tests (EASL-ALEH Clinical Practice Guidelines J Hepatol 2015). He has served on the Scientific Committee of the United European Gastroenterology (UEG) from 2011 to 2013 and on the UEG Council from 2017 to 2021. In addition, he has served on the Governing Board of the European Association for the Study of the Liver (EASL) from 2012 to 2017, as EASL Vice Secretary from 2013 to 2015 and as EASL Secretary General from 2015 to 2017.

Timothy R. Morgan, MD | *Director* | VA National Liver Disease Program | *Deputy Director* | VA National Gastroenterology and Hepatology Program | Veterans Health Administration (VHA) | Professor of Medicine | University of California

Timothy Morgan is Director of the VA National Liver Disease Program, which oversees the policies and practice of liver disease care in the Veterans Healthcare System. He is responsible for management of NAFLD in the VA, including criteria the VA can use to identify patients with NAFLD, the education of VA providers on identifying and evaluating patients with NAFLD risk factors, evaluating tests for the diagnosis and monitoring of NASH, and developing criteria for pharmacotherapy of NASH. He was the chair of the VA multidisciplinary group that released guidelines for the management of NAFLD in the VA healthcare system in 2021. He has participated in pharma, VA, and NIH sponsored clinical trials in liver disease for the past 30 years and has been the chair of DSMBs for multiple clinical trials.

Frank Anania, MD | *(Acting) Director* | DHN | OII | OND | CDER | FDA - Speaker & Panelist - *(see biography above)*

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Veronica Miller, MD | *Director* | Forum for Collaborative Research | Adjunct Professor Division of Infectious Diseases and Vaccinology | School of Public Health | University of California Berkeley – Panel Only

Veronica Miller is the Director of the Forum for Collaborative Research (the Forum), a public/private partnership addressing cutting edge science and policy issues through a process of stakeholder engagement and deliberation at the UC Berkeley School of Public Health, and Adjunct Professor at the UC Berkeley School of Public Health. Under her leadership the Forum's deliberative process to advance regulatory science applied successfully to HIV was extended to drug development for hepatitis C infection in 2007, and starting in 2014, to the treatment of liver diseases (NASH, PSC and other cholestatic liver diseases), Hepatitis B and D infection, Transplantation Associated Viral Infections, and Ocular Diseases. The Forum's most recent addition is the collaborative Data & Analysis Center to support drug development with disease specific placebo arm cohorts, development of innovative analytics to explore randomized clinical trial and real-world-date contributions to assessment of clinical efficacy. As professor, she developed and teaches courses on regulatory science and drug development, and on development and regulation of diagnostics. She mentors interns and fellows pursuing regulatory, biotech and translational medicine careers. She has published more than 120 peer-reviewed publications. She joined the Forum in 2001 after directing the interdisciplinary HIV Research Group at the HIV Outpatient Clinic of the JW Goethe University in Frankfurt, Germany. Together with Joep Lange, she co-founded and chaired the Euro-Guidelines Group on HIV Drug Resistance, the first pan-European group established for the purpose of assuring a common standard-of-care for patients in all European states.

Arun Sanyal, MD | *Director* | Stravitz-Sanyal Institute for Liver Disease and Metabolic Health Professor of Medicine, Physiology, and Molecular Pathology | Virginia Commonwealth University School of Medicine - Speaker & Panelist - *(see biography above)*

Professor Quentin M. Anstee BSc (Hons), MB BS, PhD, MRCP (UK), FRCP | *Deputy-Dean of Research & Innovation* | Faculty of Medical Sciences | Professor of Experimental Hepatology & Consultant Hepatologist | Translational & Clinical Research Institute | Newcastle University - Speaker & Panelist - *(see biography above)*

Mazen Noureddin, MD, MHSc | *Professor of Medicine* | Lynda K. and David M. Underwood Center for Digestive Disorders J.C. Walter Jr. Transplant Center - Speaker & Panelist - *(see biography above)*

Laurent Castera, MD, PhD | *Professor of Hepatology* | Université Paris Cité | Head of the NASH program | Department of Hepatology | Hôpital Beaujon, Assistance Publique | Hôpitaux de Paris, Clichy, France - Speaker & Panelist - *(see biography above)*

Timothy R. Morgan, MD | *Director* | VA National Liver Disease Program | *Deputy Director* | VA National Gastroenterology and Hepatology Program | Veterans Health Administration (VHA) | Professor of Medicine | University of California - Speaker & Panelist - *(see biography above)*

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