4th EDITION

KIDNEY DISEASE CLINICAL TRIALISTS

INI CRCT
CARDIOVASCULAR & RENAL CLINICAL TRIALISTS

FINAL PROGRAM

May 17 & 18, 2019

Washington, DC, USA

www.kdctmeeting.com

Summary

4th EDITION

KIDNEY DISEASE CLINICAL TRIALISTS

www.kdctmeeting.com

Introduction

Dear faculty and participants,

I am pleased to welcome you to the 4th Kidney Disease Clinical Trialists Workshop, previously the INI-CRCT, a high-level think-tank that will give us the opportunity to have an interactive dialog between academia, regulatory representatives, patients and industry to openly discuss the challenges of clinical trials for kidney disease.

Over the next two days, the KDCT Workshop will foster an international exchange of ideas where we will brainstorm on trial design, conduct, ethics, interpretation, approvability and implementation encompassing drugs, devices, biomarkers and therapeutic strategies for kidney disease.

Our objectives are to produce relevant data from controlled kidney disease clinical trials that will contribute to better clinical care and to understand the problems associated with making decisions about what constitutes relevant information, how to improve kidney disease clinical trials, and, as is commonly the case, how to satisfy regulatory authorities and payers.

This year, we are delighted to have a number of distinguished nephrologists, clinical trialists, principal investigators and statisticians from academia coming from Europe, North America and Australia as well as NIH, EMA and FDA representatives, patient advocates and industry attendees representing R&D pharma and device companies.

Moderators have accepted the critical task to keep time (speakers: 10 minutes and discussants: 5 minutes) and give each panelist and attendee a chance to be involved.

I look forward to meeting each and every one of you and I thank you for taking part in this meeting.

With my warmest regards,

Patrick ROSSIGNOL
Workshop Director

General information

WORKSHOP VENUE

Maison Française, Embassy of France
4101 Reservoir Rd NW - Washington, DC, 20007

OFFICIAL HOTEL

Grand Hyatt Washington
1000 H Street NW - Washington, DC, 20001

ON-SITE CONTACTS

Patrick WAHBY & Petra NIEHOFF: +1 415-839-8874

TECHNICAL INFORMATION

To facilitate the progress of the meeting, we would be very grateful if you could give your presentation to the technician in the meeting room at least 30 minutes before the session starts (or during the coffee breaks).

LOGISTICS AND TECHNICAL ORGANIZATION

Overcome
13 – 15 Rue des Sablons
75116 Paris Cedex, France
Tel: +33 (0)1 41 92 01 20
Email: kdct@overcome.eu
Website : www.kdctmeeting.com
Password: WASHINGTON

SCIENTIFIC SECRETARIAT

Patrick ROSSIGNOL
INI-CRCT Coordinator
Email: p.rossignol@chru-nancy.fr

Bénédicte ROSSIGNOL
INI-CRCT Global Project Manager
Email: inicrct@chru-nancy.fr

Jessica WINZENRIETH
INI-CRCT Administrative Assistant
Email: inicrct@chru-nancy.fr

TRANSPORTATION

Attractive discounts, up to -15%, on a wide range of public fares on all AIR FRANCE, KLM and their code-shared flights worldwide.
Event: KDCT Workshop
ID Code: 34995AF
Travel Valid Period: 10/05/2019 to 25/05/2019
Event location: WASHINGTON
Please visit the event website or access directly through http://globalmeetings.airfranceklm.com/Search/promoDefault.aspx?vendor=AFR&promocode=34995AF

4th Kidney Disease Clinical Trialists (KDCT) Workshop
May 17-18, French Embassy, Washington DC

Workshop Director: Patrick Rossignol (Nancy, FRA)

Co-Directors: Rajiv Agarwal (Indianapolis, USA); George Bakris (Chicago, USA); Vlado Perkovic (Sydney, AUS); Prabir Roy-Chaudhury (Chapel Hill, USA); Luis Ruilope (Madrid, ESP), Christoph Wanner (Würzburg, GER)

Day 1 - Friday 17 May 2019

SESSION 1: 12.30-14.00

AKI prevention and treatment neutral trials: TIME FOR AN AUTOPSY
"Designing and conducting AKI trials: If I had to do it again, what would I have done differently/ what I am already doing differently in ongoing trials"

Moderators: Patrick Rossignol (Nancy, FRA); Matthieu Legrand (Paris, FRA)

"Autopsy is performed by anatomists with the principal aim to determine the cause of death, the state of health of the person before he or she died, and whether any medical diagnosis and treatment before death was appropriate."

- *It is crucial, but often difficult, to determine if a clinical outcomes trial did not show a treatment effect because of errors in trial design, adverse effect limitations of intervention, execution or if the treatment was just truly ineffective: these are the key questions presenters will address in this autopsy session.*
- *The objective of this session is to have trial specialists examine neutral trials with the aim of determining causes of failure, the robustness of the trials before they failed, and whether any appropriate early examination or corrective action could have prevented negative/ neutral results.*
- *The aim is ultimately to draw lessons that may inform the design and the conduct of future trials. Future trials may be designed addressing lessons learned from informative but inconclusive trials, applying different patient populations, alternate treatment regimens, or different outcomes. Alternatively, trials should be viewed in the broader context of how the results can inform the field.*

Speakers: (10 min each)

Paul Palevsky (Pittsburgh, USA): Outcomes after Angiography with Sodium Bicarbonate and Acetylcysteine. Randomized controlled trial

Jonathan Himmelfarb (Seattle, USA): Perioperative THR-184 and AKI after Cardiac Surgery

Amit Garg (London, CAN): Curcumin AAA AKI Investigators

Stéphane Gaudry (Paris, FRA): Initiation Strategies for Renal-Replacement Therapy in the Intensive Care Unit

Discussants: (5 min each)

Mathieu Legrand (Paris, FRA)

Marty Lefkowitz (Novartis, USA)

NIDDK, FDA, EMA

SESSION 1: 14.00-15.30

HOT TOPIC SESSION DOWNSTREAM CREDENCE: IMPLICATIONS FOR ONGOING AND FUTURE DKD TRIALS.

Moderator: George Bakris (Chicago, USA)

Must all DKD trials now include background SGLT2i therapy as well as RAAS inhibitors? What is the impact on rates of progression, and therefore power and sample size, as well as other aspects of trial design going forward? To whom do the results of CREDENCE apply? And what are the implications for ongoing trials?

Speaker: (10 min)

Vlado Perkovic (Sydney, AUS)

Discussants: (5 min each)

Christoph Wanner (Würzburg, GER)
Jaime Blais (Janssen, USA)
Richard Nkulikiyinka (Bayer, GER)
Sibylle Hauske (Boehringer Ingelheim, GER)
NIDDK, FDA, EMA

15.30-15.45 COFFEE BREAK

SESSION 2: 15.45-17.30

MONITORING FOR KIDNEY SAFETY IN DRUG DEVELOPMENT PROGRAMS and CONSIDERATIONS RELATED TO THE INCLUSION OF PATIENTS WITH ADVANCED CKD IN CLINICALTRIALS

MONITORING FOR RENAL SAFETY/TOXICITY IN DRUG DEVELOPMENT PROGRAMS IN NON-KIDNEY TRIALS

Moderator: Meg Jardine (Sydney, AUS)

Renal function and other parameters of kidney health are frequently monitored in drug development programs to understand whether the product carries renal-relates risks. What is reasonable monitoring when no signal is suspected? How should changes in creatinine/eGFRs seen in early phases of product development, which may be transient or pharmacodynamic in nature and reversible upon discontinuation of therapy, be interpreted and affect the monitoring strategy and rules for discontinuation of therapy in subsequent larger trials? What is the role of plasma/urinary biomarkers beyond serum creatinine? When is a prospective plan to adjudicate potential cases of renal toxicity warranted?

Speaker: (10 min)

Richard Nkulikiyinka (Bayer, GER)

Discussants: (5 min each)

Amit Garg (London, CAN)
Ron Gansevoort (Groningen, NED)
Alain Romero (Relypsa, USA)
Katherine Landschultz (Covance, USA)
NIDDK, FDA, EMA

SESSION 2: continued 17.30-19.15

COMORBIDITIES MANAGEMENT IN TRIALS IN ADVANCED CKD PATIENTS: PRACTICAL IMPLICATIONS FOR ENROLLMENT

Moderator: Christoph Wanner (Würburg, GER)

Most efficacy and safety studies that support drug approval exclude CKD patients with more advanced CKD (i.e. stage 4-5 disease, including those who are on dialysis). Although these patients are at high risk for cardiovascular death, they also suffer from high rates of several other causes of deaths including sepsis and cancer, and suffer a high burden of comorbidities, e.g. hepatitis, infections and depression. How should one practically handle comorbidities, which are generally exclusion criteria, and associated competing risks in these trials? What about including such patients in studies, but excluding them from the primary analyses?

Speaker: (10 min)

Annette Bruchfeld (Stockholm, SWE)

Discussants: (5 min)

Janet Wittes (Statistics Collaborative, USA)

Ron Wald (Toronto, CAN)

Alain Romero (Relypsa, USA)

Patient's perspective: Cynthia Chauhan (Wichita, USA)

NIDDK, FDA, EMA

Day 2 – Saturday 18 May 2019

SESSION 3: 07.30-10.00 **FROM RISK STRATIFICATION TO PRECISION MEDICINE: THE FUTURE OF TRIALS OF PREVENTION OF CKD ONSET AND PROGRESSION, AND AKI**

Moderator: Patrick Rossignol (Nancy, FRA)

Biomarkers may serve to discriminate various substrates in AKI and for CKD onset or progression that could direct individuals to different management strategies. As such, they may stratify patients mechanistically and therapeutically and might help achieve the goal of a more precision management and personalized approach. Oncology has had a number of successes in this space, but they have molecular targets and access to tumor tissue. They may also have a culture compatible with identifying patients and cooperating enough to design and utilize master protocols. What needs to happen in the nephrology space to get there?

- Whether these concepts have gained power and how much are these pertinent to precision and personalized medicine, and how to incorporate in future trials are matters of intense debate (for instance, extent to which we are seeing predictive enrichment used in this space and potential barriers to implementation).
- Lessons learned from the mixed success of biomarkers to define AKI risk versus CKD progression rate and development – guided clinical trials need to be shared with the aim of refining methodology and moving the area forward: current state of risk scores in AKI and CKD space: what's been done and what more needs to be done to support their use as clinical trial entry criteria

Speakers: (10 min each)

Joe Bonventre (Boston, USA)
Chirag Parikh (Baltimore, USA)
George Bakris (Chicago, USA): SONAR trial insights
Bengt Fellström (Uppsala, SWE): IgA nephropathy trials

Discussants: (5 min each)

AnnaLotta Schiller (Olink, SWE)
Wenjun Ju (Ann Arbor, USA)
Matthias Kretzler (Ann Arbor, USA)
Ron Gansevoort (Groningen, NED)
Franck Czerwiec (Goldfinch Bio, USA)
Joachim Struck (Sphingotech, GER)
NIDDK, FDA, EMA

10.00-10.15 COFFEE BREAK

SESSION 3: continued 10.15 -12.00

DEVICE TRIALS (MEMBRANES, WEARABLE, VASCULAR ACCESS) IN CHRONIC HEMODIALYSIS

Moderator: Prabir Roy-Chaudury (Chapel Hill, USA)

>> Part A: Which Endpoints (clinical including PROs – which ones? How to measure fatigue properly? Which biological surrogates e.g. albumin, uremic toxins, inflammation EPO resistant index?)

Speaker: (10 min)

Melissa West (Washington, DC, USA)

Discussants: (5 min each)

Wael Hussein (Satellite Healthcare, USA)
NIDDK, FDA, EMA

>> Part B: When do we need sham controls?

Speakers: (10 min each)

Prabir Roy-Chaudhury (Chapel Hill, USA)
Jeff Lawson (Humacyte, USA)

Discussants: (5 min)

Patrick Rossignol (Nancy, FRA)
NIDDK, FDA, EMA

>> PART C: Specific trial designs and effectiveness endpoints for wearable or implantable renal replacement therapies

Speaker: (10 min)

Jonathan Himmelfarb (Seattle, USA)

Discussants: (5 min)

Patient's perspective: David White (Hillcrest Heights, USA)
NIDDK, FDA, EMA

Patient's perspective on the whole session: Paul Conway (Falls Church, USA)

12.00-12.15 COFFEE BREAK

SESSION 4: 12.15-13.30

PRAGMATIC RANDOMIZED TRIALS IN CKD

Moderator: Vlado Perkovic (Sydney, AUS)

>> Streamlined designs?

Speaker: (10 min)

Amit Garg (London, CAN): Insights from the My TEMP, CKD WIT trials

>> Integrating clinical trials, registries and population health government datasets. Platform trials

Speaker: (10 min)

Meg Jardine (Sydney, AUS)

Discussants: (5 min)

Patient's perspective: Susan Quella (Rochester, USA),
Patient's perspective: Patrick Gee (Chesterfield, USA)

Laura Dember (Philadelphia, USA)

13.30 ADJOURN & LUNCH

Participants

ACADEMIA

George Bakris (Chicago, USA)

Joe Bonventre (Boston, USA)

Annette Bruchfeld (Stockholm, SWE)

Laura Dember (Philadelphia, USA)

Bengt Fellström (Uppsala, SWE)

Ron Gansevoort (Groningen, NED)

Amit Garg (London, CAN)

Stéphane Gaudry (Paris, FRA)

Jonathan Himmelfarb (Seattle, USA)

Meg Jardine (Sydney, AUS)

Wenjun Ju (Detroit, USA)

Matthias Kretzler (Detroit, USA)

Matthieu Legrand (Paris, FRA)

Paul Palevsky (Pittsburgh, USA)

Chirag Parikh (Baltimore, USA)

Vlado Perkovic (Sydney, AUS)

Patrick Rossignol (Nancy, FRA)

Prabir Roy-Chaudhury (Chapel Hill, USA)

Ron Wald (Toronto, CAN)

Christoph Wanner (Würzburg, GER)

Melissa West (Washington DC, USA)

Janet Wittes (Statistics Collaborative, USA)

REGULATORY

Hrefna Guðmundsdóttir (EMA, ISL)

Frank Holtkamp (EMA, NED)

Rekha Kambhampati (FDA, USA)

Robert Lee (FDA, USA)

Krishna Prasad (EMA, GBR)

Brian Pullin (FDA, USA)

Rohini Retarekar (FDA, USA)

Kimberly Smith (FDA, USA)

Norman Stockbridge (FDA, USA)

Winson Tang (FDA, USA)

Aliza Thompson (FDA, USA)

Shen Xiao (FDA, USA)

NIH

Yves Rosenberg (NIH, USA)

Paul Kimmel (NIDDK, USA)

MEDIA

Stuart Spencer (The Lancet, GBR)

Jennifer King (August Editorial, USA)

PATIENT ADVOCACY

David White (Hillcrest Heights, USA)

Cynthia Chauhan (Wichita, USA

Susan Quella (Rochester, USA)

Patrick Gee (Chesterfield, USA)

Paul Conway (Falls Church, USA)

Participants

INDUSTRY

Christian Barnes (Akebia, USA)

Vince Benn (KBP Biosciences, USA)

Masha Berkhin (Novartis, USA)

Patrick Berna (Balmes Transplantation, FRA)

Angelito Bernardo (Baxter, USA)

Erwin Berthier (Tasso, USA)

Nisha Bhatt (Amgen, USA)

Jaime Blais (Janssen, USA)

Geoff Block (Reata, USA)

Jeffrey Connaire (DaVita, USA)

Ansgar Conrad (Relypsa, USA)

Frank Czerwiec (Goldfinch Bio, USA)

Jay Elliott (Bayer, USA)

Jun Fukuda (Kyowa Hakko Kirin, JAP)

Weinong Guo (Novartis, USA)

Nicolas Guzman (AstraZeneca, USA)

Sibylle Hauske (Boehringer Ingelheim, GER)

Guilhem Henrion (CardioRenal, FRA)

Robert Huizinga (Aurinia, CAN)

Wael Hussein (Satellite Healthcare, USA)

Julie Ishida (Gilead, USA)

Ashley Johns (Twin City Bio, USA)

Douglas Kling (Corvidia, USA)

Audrey Koitka-Weber (Boehringer Ingelheim, GER)

Katherine Landschulze (Covance, USA)

Jeff Lawson (Humacyte, USA)

Marty Lefkowitz (Novartis, USA)

Eckhard Leifke (Omeros, USA)

Dustin Little (AstraZeneca, USA)

Gabriela Luporini Saraiva (AstraZeneca, USA)

Ciaran McMullan (Merck, USA)

Richard Nkulikiyinka (Bayer, GER)

Mark Ohan (W.L. Gore, USA)

Agata Ptaszynska (Bristol-Myers Squibb, USA)

Natarajan Ranganathan (Kibow Biotech, USA)

Pari Ranganathan (Kibow Biotech, USA)

Alain Romero (Relypsa, USA)

Courtney Rothwell (BD Peripheral Intervention, USA)

AnnaLotta Schiller (Olink, SWE)

Friedrich Schulze (Boehringer Ingelheim, GER)

Deborah Schwartz (Kyowa Hakko Kirin, USA)

Gigi Shafai (Akebia, USA)

Joseph Stavas (Twin City Bio, USA)

Joachim Struck (Sphingotec, USA)

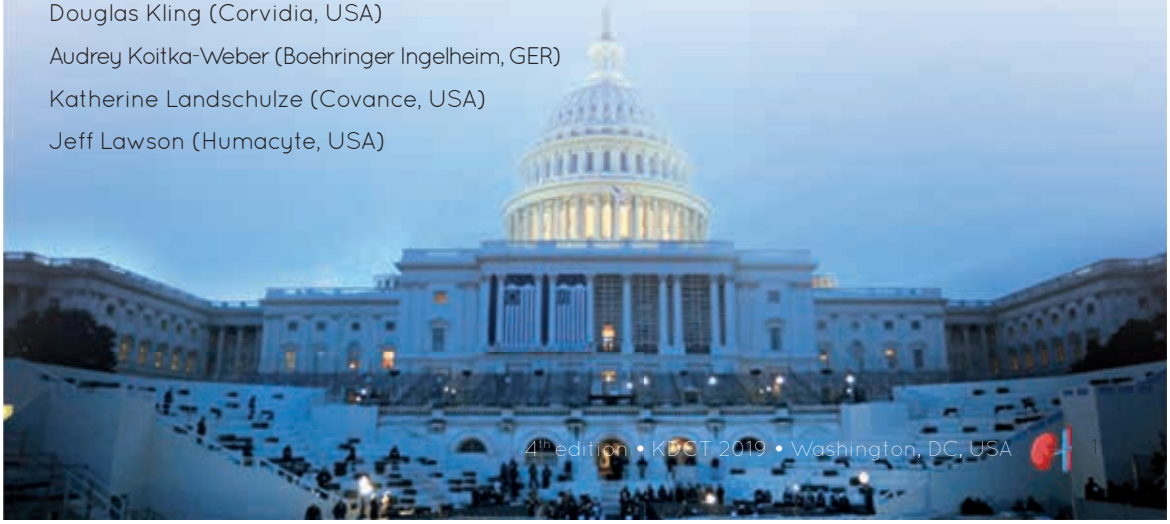
Anna Sundgren (AstraZeneca, USA)

Daniel Wilson (KBP Biosciences, USA)

Melanie Wright (Novartis, SUI)

Fred Yang (KBP Biosciences, USA)

Junichi Yasutke (Kyowa Hakko Kirin, JAP)



Biographies

George Bakris (Chicago, USA)

George Bakris is a tenured Professor of Medicine and Director of the ASH Comprehensive Hypertension Center in the Department of Medicine at the University of Chicago Medicine.
Dr. Bakris has published over 800 peer-reviewed articles and book chapters in the areas of diabetic kidney disease, hypertension and progression of nephropathy. He is the Editor or Co-Editor of 20 books, in the areas of Kidney Disease Progression and Diabetes as well as the new 3rd edition of Hypertension: A Companion to Braunwald's The Heart. He was a member of the NIH National High Blood Pressure Education Program Working Group on Hypertension and Renal Disease (1994). He also served as a special government expert to the Cardio-renal Advisory Board of the FDA and to CMS (1994-2008). He was a co-principal investigator on the NIH Clinical Research training grant for clinical research (K30) (1999-2004). He chaired the first National Kidney Foundation Consensus report on blood pressure and impact on renal disease progression (2000). He has also served on many national guideline committees including: The Joint National Committee Writing Groups VI & 7 (1997, 2003), and the JNC 7 executive committee (2003).

Dr. Bakris is the past-president of the American College of Clinical Pharmacology (2000-2002) and the American Society of Hypertension (ASH). He is the current Editor-in-Chief, Am J Nephrology, Editor-in-Chief- Up-to-Date, Nephrology section, Hypertension Section Editor Up-to-Date and Assoc. Ed of Diabetes Care. He serves on more than 18 editorial boards including Nephrology, Dialysis & Transplant, Hypertension, J Hypertension and J American Soc. Hypertension. Additionally, he is the Hypertension editor of the Merck Manuel.

Christian Barnes (Akebia, USA)

Christian Barnes began his career at the J. Craig Venter Institute in Rockville, MD as a Research Associate in molecular/synthetic biology from 2003 – 2007. He then made a transition to biotech by joining NuPotential, Inc. from 2007-2012 where he helped mold the business around iPS cell development and applications (regenerative medicine, "disease in a dish" cell line creation) and small molecule epigenetic modifier discovery/development. In addition to managing the molecular lab, he maintained responsibility for business development and corporate strategy. Christian then joined Pamlab, the largest oral medical food company in the United States in a role to lead the Company's pipeline and business development. After being acquired by Nestle Health Science within a year, Christian became one of two legacy Pamlab employees asked to join the acquiring company, and eventually moved to Cambridge, MA in 2016 to lead Nestle Health Science's business development efforts for the Brain Health platform. Christian then joined Akebia Therapeutics in January of 2019 as Director, Business Development. Christian holds a BS in Microbiology, a BA in Spanish, and an MPA in Healthcare Technology and Administration from Louisiana State University.

Vincent Benn (KBP Biosciences, USA)

Vincent Benn has more than 35 years of clinical and regulatory affairs management experience from preclinical through all phases of clinical research and life cycle management. He has had management positions at both large (J&J, Merck, Roche) as well as small to midsize biopharmaceutical companies and has

managed or directed more than 125 studies across several therapeutic areas leading to NDA/BLA approvals and new indications. He holds a PhD (Immunology) from Rutgers where he studied under Professor Helen Strausser, an MBA (Marketing, Economics) from Temple, and completed additional training in clinical immunology at University of Texas Medical Center at Houston and at Harvard Medical School.
At KBP Biosciences, Vince oversees all regulatory affairs activity in the US, Latin America, and Europe. He also oversees KBP's medical advisory boards.

Masha Berkhin (Novartis, USA)

Masha Berkhin graduated from Albany College of Pharmacy where she obtained her Pharm.D. She went on to do a 2 year post-doctoral fellowship at Roche, in Regulatory Affairs where she focused on Oncology drug development. After the fellowship she stayed at Roche and worked on the approval of Zelboraf, for the treatment of metastatic melanoma. She then went on to work at Novartis, where she worked on the approval of Entresto, for the treatment of Heart Failure. She is now a Global Program Regulatory Director at Novartis, working in the renal space and focusing on Orphan diseases such as IgAN, C3G, and MN.

Patrick Berna (Balmes Transplantation, FRA)

Patrick Berna founded Balmes Transplantation in 2015 in France; an early-stage pharmaceutical company with fast development timelines focused on ischemia-reperfusion injuries (IRI) in Kidney Transplantation (KTx) and in Acute Kidney Injury (AKI) and its subsequent transition to Chronic Kidney Disease (CKD).

Prior to founding Balmes Transplantation, Berna was Chief Development Officer (2006-2015) and a member of the Management Board (2010-2015) of Trophos, a biotech startup acquired by Roche Pharmaceuticals. Patrick was previously Director of R&D Projects at Boehringer Ingelheim (2003-2005), Team Leader Projects Early Clinical Development at Parke-Davis (1999-2000) and Pfizer (2000-2003) and Project Team Leader Preclinical at Jouveinal (1996-1999).

Mr. Berna wrote or co-authored twenty-three peer-reviewed publications and published seven patents. He holds a PhD in Biochemistry from UTC, Compiègne, France and has been trained in the management of innovative companies at the Institut Français de Gestion.

Angelito Bernardo (Baxter, USA)

Angelito Bernardo is currently the Global Medical Affairs Head Renal Care at Baxter Healthcare Corporation. Previously he held the position of Chief of Nephrology and Director of Renal and Hypertension Clinic at Chicago VA Healthcare System. His interests include Kidney Care Innovation, Renal Replacement Therapy and Products, Clinical Trials, Product Development.

Erwin Berthier (Tasso, USA)

Erwin Berthier is the co-founder and CTO of Tasso Inc, a Seattle-based company developing patient-centric, distributed, health technologies. Tasso is providing solutions to connect anyone, anywhere, with a blood testing solution, whether it is a centralized laboratory or point-of-care systems. He is also an Affiliate Assistant Professor in the department of chemistry at the University of Washington in Seattle. He received a Diplôme Ingénieur in Fluid Mechanics from ENSTA (Ecole Nationale Supérieure des Technologies Avancées) in Paris, a Masters of Electrical Engineering from the University of Canterbury (New Zealand), and a PhD in Biomedical Engineering from the University of Wisconsin in Madison. He is the author of over 50 publications in peer-reviewed scientific journals, 12 patents, and a co-author of the book "Open Microfluidics".

Nisha Bhatt (Amgen, USA)

Nisha Bhatt, MD is a Clinical Research Medical Director at Amgen, Inc. She is the US Medical Lead for the Nephrology Franchise and is responsible for the programs overall US strategy and clinical research activities in secondary hyperparathyroidism and anemia of chronic kidney disease. Before joining Amgen, Dr. Bhatt was a practicing nephrologist for several years in South Florida, with an extensive practice of End Stage Renal disease patients on dialysis, as well as outpatient and inpatient nephrology patients. Nisha completed her Internal Medicine at Weill-Cornell/New York Presbyterian in New York City, and her fellowship in Harvard-Beth Israel Deaconess Medical Center. She obtained her M.D from Tufts University and a B.S of Finance from Rutgers School of Business.

Geoff Block (Reata, USA)

Geoff Block currently serves as Vice President, Nephrology at Reata Pharmaceuticals, Inc. Geoff previously served as the Medical Director of the DaVita-Lowry Hemodialysis Unit and as Director of Clinical Research in the Denver Nephrology Research Division at Colorado Kidney Care/Denver Nephrologists. Earlier in his career, Geoff served as an associate clinical professor in Medicine at the University of Colorado Health Sciences Center, and as an attending physician at St. Joseph's Hospital. Geoff was previously a member of the Executive Steering Committee for KDIGO and served on 2 KDIGO Guideline workgroups. He has had a long-standing interest in translational and clinical research having been involved as Principal Investigator in designing and conducting over 100 clinical trials. Geoff received his medical degree from the University of Cincinnati, College of Medicine and completed his fellowship in nephrology at the University of Michigan at Ann Arbor.

Jaime Blais (Janssen, USA)

Jaime Blais is a graduate of the University of Ottawa with a PhD in human molecular genetics and completed her post doctorate education at the NYU School of medicine. More recently, Jaime was the global medical director of the Cardio-renal and Oncology Divisions at Otsuka Pharmaceuticals where she worked on the clinical development of tolvaptan for the treatment of ADPKD.

Today she is the scientific director at Janssen in the Metabolism franchise where she works on INVOKANA in the treatment of type 2 diabetes and chronic kidney disease.

Joe Bonventre (Boston, USA)

Joseph (Joe) Bonventre is the Samuel A. Levine Professor of Medicine at Harvard Medical School and Professor of Health Sciences and Technology at the Massachusetts Institute of Technology. He is Chief of the Renal Division and Founding Chief of the Engineering in Medicine Division of the Brigham and Women's Hospital. In addition to his B.S. with distinction in Engineering Physics from Cornell, Dr. Bonventre holds M.D. and Ph.D. degrees in biophysics from Harvard University. He has honorary doctorate degrees from Mt. Saint Mary's College and from the Norwegian Institute of Science and Technology in Norway.

Bonventre's research focuses primarily on the

study of kidney injury and repair and signal transduction, with a special emphasis on the role of inflammation, biomarkers and stem cells. His recent work involves the generation of kidney organoids from stem cells and their use in kidney disease modeling. He has more than 350 original research publications, 150 reviews/chapters and editorials and 3 books. His work has been referenced more than 60,000 times and he has an h-index of 129. He has been elected to the American Society of Clinical Investigation (ASCI), the Association of American Physicians (AAP), the American Clinical and Climatological Association (ACCA) and the American Institute for Medical and Biological Engineering (AMBIE). He has been awarded the Osler Medal of the Royal Society of Physicians and the Bywaters Award of the International Society of Nephrology.

Bonventre is past-president of the American Society of Nephrology and founding member of the Board of Directors of the National Space Biology Research Institute. He has served as a member of the Advisory Council of the NIH National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). He is currently on the Council of the International Society of Nephrology and is Editor of Seminars in Nephrology.

Annette Bruchfeld (Stockholm, SWE)

Associate Professor Annette Bruchfeld received her MD degree in 1988 at Karolinska Institutet Stockholm, Sweden. She is currently a Senior Consultant at the Renal Medicine Department at Karolinska University Hospital in Stockholm, Sweden. Her clinical and research interest has mainly been in inflammatory kidney diseases, ANCA-vasculitis, and hepatitis C in CKD and transplantation. Professor Bruchfeld has an extensive experience in conducting academic and sponsored clinical trials, and currently heads the Clinical Trial Unit at Renal Medicine. Recent publications include the C-SURFER trial (Elbasvir/Grazoprevir DAA treatment for HCV in CKD 4 and 5), and the CLEAR trial (Randomized Trial of C5a Receptor Inhibitor Avacopan in ANCA-Associated Vasculitis) Professor Bruchfeld is a long-standing member of EUVAS, the European Vasculitis Society, and is currently a member of the ERA-EDTA Council and the ERA-EDTA Scientific Advisory Board.

Cynthia Chauhan (Wichita, USA)

Cynthia Chauhan has stage IV kidney failure complicated by the presence of only one kidney subsequent to a total right nephrectomy for RCC, stage IB as well as multiple, significant comorbidities including HFpEF; pulmonary hypertension; a history of breast cancer and three forms of arthritis. Due to these issues, Cynthia now takes twice as long to do things half as well but she remains an active, engaged, contributing member of society including working to bring the patient perspective to the research table and to professional discussions. She regularly enters clinical trials as a participant.

Jeffrey Connaire (DaVita, USA)

Jeffrey Connaire MD, Director, Nephrology Services at DaVita Clinical Research has been a nephrologist since 2002, beginning his career in academic medicine. In 2015 he joined DCR where he provides insights in the design, feasibility and execution of clinical trials carried out at DCR's nationwide network of nephrology research sites. Also an active clinical investigator, Dr. Connaire has served as an investigator in over 50 clinical trials spanning Phase I through post-marketing. For enjoyment outside of work, he spends time with his wife and five children and plays music with a motley cover band. In an effort to keep up with all those kids, Dr. Connaire keeps fit by practicing the Kenpo style of karate.

Ansgar Conrad (Relypsa, USA)

Ansgar Conrad, PhD, is an Executive Director of Medical Affairs at Relypsa, a Vifor Pharma Group Company, in Redwood City, CA. Dr Conrad leads a team of Medical Directors and Health Outcomes Directors at Relypsa. He oversees data generation at Relypsa (Investigator initiated and partnered research activities in the fields of hyperkalemia, chronic kidney disease, and heart failure) and leads the health economics and outcomes research (HEOR) function.

Frank Czerwiec (Goldfinch Bio, USA)

Frank Czerwiec is Chief Medical Officer of Goldfinch Bio, "The Kidney Company" based in Cambridge MA. In this role, he is responsible for leading all aspects of clinical development and partners with the CMO, CSO and CBO/COO in driving the overall strategy for the company's current and future R&D pipeline. Dr. Czerwiec comes to Goldfinch Bio from Otsuka Pharmaceutical Development & Commercialization, Inc, where as VP Global Clinical Development he co-led a department of physicians and scientists in the strategic development of CNS, Oncologic and Renal products. Most notably, Dr. Czerwiec's team was responsible for the approval of tolvaptan (Jynarque TM), the first treatment approved to delay chronic kidney disease progression in autosomal dominant polycystic kidney disease (ADPKD) and the first US-FDA approved drug for treating an important form of CKD in the past decade. Dr. Czerwiec trained in Adult Endocrinology and Metabolism at the NIH – NICHD/NIDDK and the University of Miami School of Medicine.

Laura Dember (Philadelphia, USA)

Laura Dember is a Professor of Medicine and Epidemiology at the University of Pennsylvania Perelman School of Medicine where she is a practicing nephrologist and clinical investigator with a major focus on improving outcomes in end-stage renal disease. She is a national leader for multicenter clinical trials and observational cohort studies funded by the National Institutes of Health including the Dialysis Access Consortium trials, the Hemodialysis Fistula Maturation Study, and the Hemodialysis Novel Therapies Consortium, and is the Principal Investigator for the Time to Reduce Mortality in End-Stage Renal Disease Trial (TiME), a large, cluster-randomized pragmatic trial conducted in partnership with two large dialysis provider organizations. Dr. Dember has led projects for the Kidney Health Initiative, a public-private partnership spearheaded by the American Society of Nephrology and the FDA, to facilitate innovation in kidney disease treatments, and is a Deputy Editor for the American Journal of Kidney Diseases. Dr. Dember is a graduate of Yale University School of Medicine and completed her internal medicine residency training at the University of Pennsylvania and nephrology fellowship training at both Penn and Brigham and Women's Hospital.

Jay Elliott (Bayer, USA)

Jay Elliott is a Senior Scientist in Bayer's U.S. Medical Affairs organization supporting clinical-stage renal and cardiovascular assets. In this role, he manages strategic medical planning and execution including data generation, scientific communication and collaboration with external stakeholders. Jay has over 12 years of diverse pharmaceutical industry experience as a Medical Science Liaison, Field Medical Director and Clinical

Trial Manager of Phase II-IV clinical trials. He is currently based in Cincinnati Ohio and holds a PhD from the University of North Carolina at Chapel Hill with a postdoctoral fellowship at the Medical University of South Carolina.

Bengt Fellström (Uppsala, SWE)

Bengt Fellström, MD, PhD, Professor of Nephrology at Uppsala University Hospital, Uppsala, Sweden, has been active in experimental and clinical research for 35 years. He is leading a research group with focus on immune driven glomerular disease and cardiovascular diseases in combination with renal failure and following transplantation. Several PhD students have successfully completed their theses in his research group. Multiple clinical trials targeting atherosclerotic disease in renal patients have been performed, where he has served on steering committees. An extensive network of scientific collaboration has been established worldwide and many close relations within the pharmaceutical industry. He has been author or co-author of 240 original peer-reviewed scientific articles, over 100 review articles and hundreds of abstracts. He is frequently engaged in medical conferences with presentation of data and has also organized several such conferences. Numerous commissions of trust, such as being a member of the board of medicine and health of the Swedish Scientific Council (MRC). He is also a member of several national and international reputable associations in the medical field.

Jun Fukuda (Kyowa Hakko Kirin, JAP)

Jun Fukuda, Ph.D. works in the Product Strategy Group, Corporate Strategy & Planning Department in Kyowa Hakko Kirin, based in Tokyo. He graduated from the Division of Applied Life Sciences in Kyoto University, where he also obtained his master's and doctoral degree.

Ron Gansevoort (Groningen, NED)

Ron Gansevoort, professor of Medicine and nephrologist, works at the Dept. of Nephrology at the University Medical Center Groningen, the Netherlands. He has two lines of research: the epidemiology of chronic kidney disease (CKD) and prevention of renal function loss in patients with heritable polycystic kidney disease (PKD). He is coordinator of the PREVEND study, an observational general population based study, investigating the association between albuminuria and health outcomes, and member of the Steering Committee of the international CKD Prognosis Consortium. He was instrumental in the work that led to the new KDIGO classification of CKD, for which he was awarded the United States Kidney Foundation Distinguished International Medal. Prof. Gansevoort also is head of the Groningen Expertise Centre for PKD. He was/is member of the Steering Committee of several international randomised controlled clinical trials in the field of PKD (TEMPO 3:4, TEMPO 4:4, REPRISE, DIPAK-1, STAGED-PKD), as well as diabetic nephropathy (ARTS-DN, FIDELIO, FIGARO). Prof. Gansevoort is associate editor for 5 international nephrological journals, published over 500 peer-reviewed papers and supervised over 20 PhD theses.

Amit Garg (London, CAN)

Amit Garg practices nephrology at the London Health Sciences Centre where he provides care in the outpatient, inpatient and hemodialysis unit setting. He is also a Professor of Medicine, Epidemiology and Biostatistics at Western University.
Dr. Garg has participated in the design, analysis and / or recruitment of 30+ randomized clinical trials (RCT). His first RCT conducted 20 years ago tested the effects of different computer anatomical

models on medical student spatial learning (Lancet 2001). A current interest is the conduct of cluster RCTs in hemodialysis facilities, done with patients as full partners with altered methods of patient consent, where interventions are delivered by routine healthcare staff (not research coordinators), with baseline and follow-up information obtained through routinely available healthcare data sources. Dr. Garg has held several leadership positions including President of the Canadian Society of Nephrology, and Lead for the Ontario Institute for Clinical Evaluative Sciences Kidney, Dialysis and Transplantation Program (ICES-KDT). He is also a Professor of Medicine, Epidemiology and Biostatistics at Western University, in London, Ontario, Canada.

Stéphane Gaudry (Paris, FRA)

Stéphane Gaudry is intensivist in Paris area. He is working in the field of acute kidney injury in the context of multi-organ failure. He is the lead author of the Artificial Kidney Initiation in Kidney Injury (AKIKI) trial.

Patrick Gee (Chesterfield, USA)

Patrick Gee had been a peritoneal dialysis patient since December 2013. In 2017, he received a kidney transplant at the Hume-Lee Transplant Center at the Medical College of Virginia. After spending 33 days in the hospital, 4 surgeries and a 47 days wait until his kidney began to function, Patrick is back to advocating for a more comprehensive healthcare, patient engagement, community educational resources and a better quality of live for kidney patients. Patrick serves in several capacities including member of the National Advisory Council for the Agency on Health Care Policy, Research and Evaluation, Quality Insights Renal Network 5 Chair, Patient Advisory Committee & Member of Medical Review Board of Directors, UNOS Ambassador, Chronic Disease Coalition Ambassador, among many others.
Gee retired from the Virginia Department of Corrections as a Major/Chief of Security. Patrick has a Bachelor's and Master's in Criminal Justice from the University of Richmond, VA. He also has a Doctorate of Philosophy in Justice, Law and Criminology from American University, Washington, DC. Patrick is also a licensed Associate Minister at Mountain Movers Ministry Church, Richmond, VA. His ministry is working with those suffering from kidney disease. Patrick is a husband, father of 5 and a grandfather of 9. Patrick's motto is, "I am the Voice for the Voiceless and the Face of the Faceless in the fight against kidney disease."

Hrefna Guðmundsdóttir (EMA, ISL)

Hrefna Gudmundsdóttir is a nephrologist and a doctorate in immunology. Currently she works for the Icelandic Medicines Agency and serves as a member of CHMP (Committee for Medicinal Products for Human Use) of the European Medicines Agency and both the Scientific Advice Working Party (SAWP) and Rheumatology Immunology Working Party (RIWP). She also holds a part time (20%) position at Landspitali, The National University Hospital of Iceland.

Weinong Guo (Novartis, USA)

Weinong Guo, MD, PhD, is currently a Senior Global Program Clinical Head with Novartis, based in New Jersey, US. He has been taking on increasing responsibilities since joining Novartis in 2006, working across multiple indications and submissions within the CardioMetabolic therapeutic area. Dr. Guo received his MD from Soochow University School of Medicine, PR China, and a PhD in Physiology from Nagoya University School

of Medicine, Japan. He also completed a post-doctoral fellowship in cardiac electrophysiology at Washington University in St. Louis before joining the industry. Dr. Guo has been a Fellow of American College of Cardiology since 2005.

Nicolas Guzman (AstraZeneca, USA)

Nicolas Guzman is Senior Medical Director in the Cardiovascular Renal Metabolic group at AstraZeneca and Clinical Associate Professor of Medicine at The George Washington University Division of Renal Diseases and Hypertension in Washington, DC. After more than 25 years of academic experience and clinical nephrology practice, Dr. Guzman joined AstraZeneca clinical development to work on Late Stage Drug Development of the company's renal portfolio. The latter encompasses a variety of assets that are currently undergoing clinical trials for the treatment of complications of chronic kidney disease and kidney disease progression, as well as studies focused on CV outcomes in chronic kidney disease. Dr. Guzman is based at AstraZeneca's Research & Development campus in Gaithersburg, MD.

Sibylle Hauske (Boehringer Ingelheim, GER)

Sibylle Hauske is a nephrologist and Global Medical Director leading the Global Clinical Development Program for Empagliflozin in CKD at Boehringer Ingelheim. She is a passionate clinical scientist who is constantly striving to improve outcomes of people living with chronic kidney disease.
Her strategic mind-set and multifaceted experience across the spectrum of patient care, academic research, clinical development and regulatory submissions allows her a holistic view on unmet needs of various stakeholders to ultimately driving innovation to fill treatment gaps with the patient at its core. As such, she is currently leading a pragmatic clinical registrations programme in CKD, the EMPA-KIDNEY study, a unique academic collaboration with world-leading partners from the University of Oxford.
She has nearly a decade of experience in clinical practice and academic research with a major focus on diabetic kidney disease at the University of Heidelberg (Medical Center Mannheim) where she headed the clinical research group. Her industry experience spans across identifying novel drug candidates for the treatment of diabetic nephropathy (Sanofi), and driving device development in the area of CGM and closed-loop systems (Roche).

Guilhem Henrion (CardioRenal, FRA)

Guilhem Henrion is the CTO of CardioRenal, a French-based company developing a home-base device for monitoring Cardio and renal valuable blood biomarkers. This medical device integrates a cloud application and a proprietary software for the analysis of vital signs.

Jonathan Himmelfarb (Seattle, USA)

Jonathan Himmelfarb is the Director of the Kidney Research Institute, Professor of Medicine, and holds the Joseph W. Eschbach M.D. Endowed Chair in Kidney Research at the University of Washington. He is also co-Director of the University of Washington Center for Dialysis Innovation. Dr. Himmelfarb has served on numerous study sections and grant review committees, scientific advisory boards and has held leadership positions in many national and international nephrology societies, including serving as President of the American Society of Nephrology in 2014-2015. He has served on expert panels for the U.S. Food and Drug Administration, Veterans Health Administration, Centers for Medicare & Medicaid Services and

other organizations. Dr. Himmelfarb has served on numerous editorial boards including the Journal of the American Society of Nephrology (JASN), Clinical Journal of the American Society of Nephrology (CJASN), Kidney International, BMC Medicine, the Faculty of 1000 in Medicine, and the Faculty of 1000 in Research. His current research interests include developing a wearable artificial kidney; development of a human 'kidney-on-a-chip', development and evaluation of risk biomarkers in acute and chronic kidney disease; and studies of Kidney Precision Medicine. Dr Himmelfarb leads numerous investigator-initiated clinical trials and cohort studies, as well as multicenter collaborative studies. He is the author of more than 270 peer-reviewed publications, including original research, reviews, and editorials.

Frank Holtkamp (EMA, NED)

Frank Holtkamp is a scientific clinical expert at CBG for new registrations or modification of existing registrations of medicinal products intended for use for the European market (EMA). He is also a member of Rheumatology and Immunology Working Party (RIWP) EMA (Nephrology expert). In particular, experience involves drugs for kidney disease, cardiovascular management, cardiometabolic disease (lipid disorders), pediatric registration procedures, fixed dose combinations, QT prolongation in clinical development, among others.

Robert Huizinga (Aurinia, CAN)

Robert Huizinga has more than 24 years of clinical research experience. He has managed the global clinical development of voclosporin since 2002 with Aurinia in 2013. Before joining industry, Rob was an Investigator in nephrology and transplantation clinical trials where he was involved in more than 60 clinical trials from Phase I through Phase IV and the successful development of numerous compounds. He has acted as a consultant to nephrology and transplantation pharmaceutical companies and has lectured extensively. Rob has numerous articles published in leading medical journals, including the New England Journal of Medicine, Lancet and the American Journal of Transplantation.
He holds a M.Sc. in Medicine (Epidemiology) from the University of Alberta, a doctorate in Organizational Leadership, is certified in Nephrology and a member of Sigma Theta Tau (Honor Society of Nursing).

Wael Hussein (Satellite Healthcare, USA)

Wael Hussein is Director of Clinical Research at Satellite Healthcare, California. He obtained his primary medical degree from University of Khartoum before moving to Ireland for his higher specialty training. He subsequently finished a fellowship in nephrology at Stanford, California. Dr Hussein has interest in computer programming, informatics and analytics. He obtained a Master's degree in Healthcare Informatics from University of Bath, UK. At Satellite Healthcare, Dr Hussein oversees a very active team working on Applied Pragmatic Clinical Research (APCR), with a focused interest in research that involves improving the patient experience and clinical outcomes.

Julie Ishida (Gilead, USA)

Julie Ishida is a graduate of UC Berkeley (BA), Stanford University (MD), and UCSF (Master of Advanced Study in Clinical Research). She completed her internal medicine residency and nephrology fellowship at UCSF. She has performed research and provided consultation on drug development programs for Genentech/Roche. Dr. Ishida's research focuses on improving the quality of medication prescribing for patients with kidney disease, and her long-term goal is

to develop and implement strategies to promote appropriate medication use in this population. Her interests include the persistent under-representation of patients with kidney disease in cardiovascular trials. She has authored an invited commentary for JAMA Internal Medicine on this topic and is co-chair of a Kidney Health Initiative project aimed at understanding and overcoming the challenges to involving patients with kidney disease in cardiovascular trials.

Meg Jardine (Sydney, AUS)

Associate Professor Meg Jardine is a clinical researcher at The George Institute for Global Health. She is currently supported by a Next Generation Clinical Researchers Program - Career Development Fellowship Funded from the Australian government Medical Research Future Fund. She is Head of George Clinical Renal Trials, a Conjoint A/Professor of Medicine at The University of UNSW and a practising nephrologist. Jardine is the current Deputy Chair (Chair Elect) of the Scientific Committee of the Australasian Kidney Trials Network (AKTN) and the immediate past Chair of the Haemodialysis Working Group, AKTN. She is a Member of the ISN Advancing Clinical Trials Committee and a member of the national nephrology association (ANZSN) Research Advisory Committee as well as a Can-SOLVE CKD International Research Advisory Committee member. She has contributed to Working Groups and Conferences of the International Society of Nephrology and the international KDIGO guidelines group and is on the Editorial Board for CJASN.
Jardine's research interests centre on the use of innovative and cost-effective methodologies to investigate the impact of pharmaceutical, device and health service interventions on outcomes for people with chronic disease. Her research has focussed on investigating the progression and complications of kidney disease and diabetes through epidemiological analyses of large scale datasets and the development and implementation of randomised clinical trials.

Ashley Johns (Twin City Bio, USA)

Ashley Johns is currently Vice President of Clinical Operations at Twin City Bio/inRegen and President of Johns Clinical Consulting. She has experience in the clinical research field having worked as a research coordinator and project manager at the site and sponsor levels. Prior to joining Twin City BIO/inRegen team in 2015, Ashley worked as a Clinical Project Manager at Tengion, Inc. and Director of Clinical Operations at RegenmedTX managing an inter-disciplinary product development team with domestic and international trial sites. Mrs. Johns has managed multiple programs for inRegen over the past few years and has done extensive work with FDA and MPA regulatory authorities to gain approvals for clinical trials. Mrs. Johns received her B.S. in Clinical Research from the University of North Carolina at Wilmington and her Masters of Health Science from George Washington University.

Wenjun Ju (Ann Arbor, USA)

Wenjun Ju is an associate research scientist in the Department of Medicine and Department of Computational Medicine and Bioinformatics at the University of Michigan. Dr. Ju has extensive experience on integration of patients' kidney biopsy transcriptomics, plasma and urinary proteomics, highly granular morphometrics data, cross-sectional and longitudinal clinical data to determine critical molecular networks and pathways for risk stratification, molecular subgrouping, and targeted therapy followed by identification of non-invasive surrogates and final validation in the global research network. Her long term goal is to translate these molecular markers into clinically implementable tools for kidney precision medicine.

Rekha Kambhampati (FDA, USA)

Rekha Kambhampati, MD, MHS is a Medical Officer in the Office of New Drugs, Division of Cardiovascular and Renal Products at the Food and Drug Administration. She was awarded her Doctor of Medicine from Drexel University College of Medicine in Philadelphia, PA.

She completed her residency in Internal Medicine at Rutgers-Robert Wood Johnson School of Medicine in New Brunswick, NJ and her Nephrology fellowship at Johns Hopkins University School of Medicine in Baltimore, MD. Given her strong interest in public health, she pursued a Master of Health Sciences in Clinical Epidemiology at the Johns Hopkins Bloomberg School of Public Health during which she studied health disparities in chronic kidney disease.

Paul Kimmel (NIDDK, USA)

Paul Kimmel directs three programs under the Division of Kidney, Urologic, and Hematologic Diseases. As director of the Acute Kidney Injury program, my responsibilities include managing clinical studies on the pathogenesis, prevention, and treatment of acute kidney injury. He oversees a research portfolio that uses genetic and genomics approaches to study such topics as the susceptibility to development of kidney disease in different populations. He also directs the Kidney HIV/AIDS program, which supports basic and clinical studies on renal structure and function in individuals with HIV infection.

Douglas Kling (Corvidia, USA)

Douglas Kling is a clinical development executive with over 20-years of experience. Kling has been involved with the successful filing of numerous NDAs during his career for products such as Humira, Lovaza, and Epanova. Doug has helped develop the clinical and regulatory strategies for products and lead the day-to-day execution of study trial execution. Doug's experience spans the globe as he has managed trials in India, South America, Europe, Asia and Russia. Doug has a BS in Biology from Duke University and an MBA for Rutgers Business School.

Audrey Koitka-Weber (Boehringer Ingelheim, GER)

Audrey Koitka-Weber received her PhD in Human Physiology and Physiopathology at the Faculty of Medicine of Angers, France. She continued her research on vascular diabetic complications at the Baker Heart & Diabetes Institute in Melbourne, Australia using animal models of diabetes. After joining the industry, Dr Koitka-Weber has been or is involved in the design and analysis of cardiovascular and kidney outcome trials, including EMPA-REG OUTCOME and EMPA-KIDNEY. She is currently the Global Medical Director in Medical Affairs at Boehringer Ingelheim for empagliflozin in CKD.

Matthias Kretzler (Ann Arbor, USA)

Matthias Kretzler is the Warner-Lambert/ Parke-Davis Professor of Internal Medicine/

Nephrology and Computational Medicine and Bioinformatics. The overarching goal of his research is to define chronic organ dysfunction in mechanistic terms and use this knowledge for targeted therapeutic interventions. To reach this goal he has developed a translational research pipeline centered on integrated systems biology analysis of renal disease.

He leads the NIH U54 Nephrotic Syndrome Research Network (Neptune) in the Rare Disease Clinical Research Network II. He co-leads the Coordinating center of the Kidney Precision Medicine Program (KPMP) and the CureGN research network, is the Director of the Applied Systems Biology Core, a principle investigator in the R24 "Integrated Systems Biology Approach to Diabetic Microvascular Complications" and in the NIH Acceleration of Medicine (AMP) program in autoimmunity.

He has 20 years of experience in integration of bioinformatics, molecular and clinical approaches in more than 250 papers. He has a tract record on interdisciplinary data integration of large-scale data sets in international multi-disciplinary research networks in the US, Europe, China and sub-Saharan Africa.

These studies enable precision medicine across the genotype-phenotype continuum using carefully monitored environmental exposures, genetic predispositions, epi-genetic markers, transcriptional networks, proteomic profiles, metabolic fingerprints, digital histological biopsy archive and prospective clinical disease characterization. The molecular mechanism identified have result in new disease predictors and clinical trials of a novel therapeutic modality in glomerular diseases.

Katherine Landschulz (Covance, USA)

Katherine Landschulz, PhD, is the Cardiovascular / Metabolic Disease Therapeutic Area Lead for the Biomarker Solution Center at Covance. She is responsible for biomarker selection / strategy development and feasibility study design for Covance drug development clients. Dr. Landschulz provides guidance for translational and exploratory biomarker data analysis, and delivers therapeutic expertise for diabetes, metabolic disease and cardiovascular and rare diseases.

Her expertise include drug discovery and development, target validation, in vitro screening, in vivo pharmacology, biomarker data for Phase I-III submissions and translational biomarkers in preclinical disease, safety models, among others.

Dr. Landschulz joined Covance in 2010, after more than a decade as a scientist in Discovery through Translational Medicine roles at Pfizer, Abbott and Eli Lilly. She received a PhD in Human Genetics/Biology from Johns Hopkins University and a BSc in Genetics from University of California-Davis.

Jeff Lawson (Humacyte, USA)

Jeffrey Lawson is the President and CEO of Humacyte. He is an innovator, scientist and vascular surgeon has been involved in the development of Humacyte's vascular technologies, in collaboration with his career-long research partner and Humacyte founder Laura Niklason, over the past 20 years.

Prior to joining Humacyte, Lawson served in leadership roles at Duke University Medical Center, including Professor of Surgery and Pathology, vice chair for Research in Surgery, and director of Clinical Trials for the Department of Surgery. Lawson earned his medical degree and his Ph.D. in Cell and Molecular Biology from the University of Vermont and completed his residency in General and Thoracic Surgery and his fellowship in Vascular Surgery at Duke University Medical Center. Lawson is also an American Board of Surgery certified Vascular Surgeon, a Fellow of the American Surgical Association and the current President of the Vascular Access Society of the Americas (VASA).

Robert Lee (FDA, USA)

Robert Lee, MD is a medical officer from the Vascular and Endovascular Devices Team in the Office of Cardiovascular Devices, Office of Product Evaluation and Quality, Center for Devices & Radiologic Health, US Food and Drug Administration, in Silver Spring, Maryland. The Vascular and Endovascular Devices Team has the responsibility over the total product life cycle for many of the devices used either to create dialysis access with fistulas or prosthetic grafts, or to treat the venous stenosis that is the bane of angioaccess providers and patients. Dr. Lee is a native of Detroit and a graduate of the University of Michigan Medical School. He completed a general surgery residency and a vascular surgery fellowship at Henry Ford Hospital in Detroit. Dr. Lee is certified by the American Board of Surgery in both general surgery and vascular surgery. Prior to joining the FDA in 2015, he practiced vascular and endovascular surgery in southeast Michigan for three decades, where providing access for hemodialysis was a significant component of his clinical activity. Dr. Lee is a coauthor of the paper "FDA Regulatory Perspectives for Studies on Hemodialysis Vascular Access" recently published in the Clinical Journal of the American Society of Nephrology.

Marty Lefkowitz (Novartis, USA)

Martin (Marty) Lefkowitz, MD, is the CardioRenal Therapeutic Area Head at Novartis Pharmaceuticals Corporation. Over his 20-year career, Dr. Lefkowitz has focused on the clinical development of compounds for heart failure, hypertension, thrombosis and renal disease. He was closely involved in the design and execution of major outcome trials including ACCOMPLISH, PARADIGM-HF, PARAGON-HF and PARADISE-MI. Dr. Lefkowitz received a medical degree from New York University and did his internal medicine training at the University of Michigan. Subsequently, he completed a fellowship in nephrology at the University of Pennsylvania. Prior to joining the pharmaceutical industry, Dr. Lefkowitz was in the clinical practice of nephrology.

Matthieu Legrand (Paris, FRA)

Matthieu Legrand is Professor in Anesthesiology and Critical care medicine and holds a PhD in physiology. He works in the Department of anesthesiology, Critical care and burn unit of St-Louis hospital, (university Paris Diderot), in Paris, France. He has carried preclinical and clinical research in the field of critical care medicine with a special interest in the pathophysiology and treatment of acute kidney injury and shock in critical care and peri-operative and settings. He has served as a reviewer for several peer-review journals and expert in the field of critical care for several committees and task forces.

Eckhard Leifke (Omeros, USA)

Eckhard Leifke, MD, assumed the role as Omeros' Chief Medical Officer in August 2018. With more than 20 years of drug development experience, he has built and headed global teams at leading pharmaceutical companies that include Bayer, Takeda and, most recently, Sanofi, where he was global head/vice president of early project & external opportunities–cardiovascular and metabolism and global head/vice president of late-stage development diabetes. Dr Leifke has led the global development of multiple early- and late-stage small-molecule and biologic drug candidates to successful market authorizations in the US, Europe, Japan, and other countries. Dr Leifke holds a Medical Doctorate from the University of Freiburg, Germany, and is board-certified in internal medicine and endocrinology.

Dustin Little (AstraZeneca, USA)

Dustin Little is a nephrology clinical research physician at AstraZeneca in Gaithersburg, MD; where he works predominately on phase III clinical trials being conducted in patients with chronic kidney disease. He is a graduate of the University of Washington School of Medicine in Seattle, WA; and was an active duty US Army officer and nephrologist at Walter Reed National Military Medical Center, before joining AstraZeneca in 2016.

Gabriela Luporini Saraiva (AstraZeneca, USA)

Gabriela Luporini Saraiva is the Global Medical Affairs - Dapagliflozin Heart Failure Physician Director at AstraZeneca.

Ciaran McMullan (Merck, USA)

Ciaran McMullan is a Clinical Director in cardiovascular disease at Merck Research Laboratories (MRL). Dr. McMullan works on several early and late stage development programs on the design and implementation of clinical trials in cardiovascular and renal disease. Prior to working at MRL, he was faculty at Harvard Medical School and at Brigham and Women's Hospital (BWH) in Boston where he conducted clinical research in hypertension and diabetes.
McMullan is a board-certified nephrologist. He completed undergraduate education at the University of Cambridge in the UK and medical school at Trinity College in Ireland. He was a resident in internal medicine at Massachusetts General Hospital (MGH) in Boston and a nephrology fellow in the combined BWH-MGH nephrology program.

Richard Nkulikiyinka (Bayer, GER)

Richard Nkulikiyinka holds a Medical Degree from the University of Cambridge in the UK. He received his Membership of the Royal College of Physicians (MRCP) of London after completing his post-graduate training in general internal medicine at the Royal London and the Northwest London NHS Trusts, with a focus on emergency medicine and intensive care. He also holds a M.Sc. in Epidemiology from the London School of Hygiene and Tropical Medicine. He joined Bayer Pharmaceuticals in 2008, where he has held positions in Pharmacovigilance and Clinical Development, with responsibility for the planning and oversight of Phase 2-3 clinical studies, leading to NDA/MAA submissions in several indications. He is currently focused on new therapies for Heart Failure and Diabetic Kidney Disease, with a special interest for HFpEF and the cardio-renal axis.

Mark Ohan (W.L. Gore, USA)

Mark Ohan obtained his Biology degree from the University of Colorado, followed up with an MS and PhD degrees in Biomedical Engineering from Rutgers/ Robert Wood Johnson Medical School.

He has worked for over 20 years in the medical device industry, with an emphasis on market assessment and product development related to Dialysis Access and End Stage Renal Disease. He is currently employed at W.L. Gore and Associates in Flagstaff, Arizona.

Paul Palevsky (Pittsburgh, USA)

Paul Palevsky, MD, is Professor of Medicine and Clinical and Translational Science in the Renal-Electrolyte Division at the University of Pittsburgh School of Medicine and is Chief of the Renal Section at the VA Pittsburgh Healthcare System. Dr. Palevsky completed his undergraduate and medical education at Northwestern University followed by internship and residency training in internal medicine and fellowship training in nephrology at the University of Pennsylvania. Dr. Palevsky joined the faculty at the University of Pittsburgh in 1989, where he has remained since. Palevsky's research has primarily focused on acute kidney injury and critical care nephrology. He was the study chair of the VA/NIH Acute Renal Failure Trial Network (ATN) study evaluating intensity of renal replacement therapy in critically ill patients with acute kidney injury and the co-chair of the PRESERVE trial, which evaluated the comparative effectiveness of saline and bicarbonate and the efficacy of N-acetylcysteine in preventing kidney damage following angiography.

Chirag Parikh (Baltimore, USA)

Chirag Parikh is a Professor of Medicine and the Division Director of Nephrology at Johns Hopkins University. He received his medical degree from Seth G.S. Medical College and KEM Hospital in Mumbai, India and subsequently completed his Nephrology fellowship and a PhD in Clinical Investigation at the University of Colorado Health Sciences Center.

Dr. Parikh's research focuses on the translation and validation of novel biomarkers for the diagnosis and prognosis of acute kidney injury. Progress in kidney diseases has been hamstrung by significant heterogeneity within the current disease definitions, which are largely based on serum creatinine. Dr. Parikh's research has addressed this critical challenge by developing biomarkers of renal tubular injury, repair, and inflammation to dissect this heterogeneity. He has assembled multicenter longitudinal prospective cohorts for translational research studies across several clinical settings of acute kidney injury and chronic kidney disease for the efficient translation of novel biomarkers.

Dr. Parikh has published over 250 original articles, which are cited over 25000 times in the literature. His studies have refined the clinical definitions of perioperative acute kidney injury and hepatorenal syndrome, have developed strategies to reduce kidney discard in deceased donor transplantation, and have advanced regulatory approvals of kidney injury biomarkers. He has also developed biomarkers to identify rapid progressors of early diabetic kidney disease before derangements in serum creatinine. Dr. Parikh's research goal is to translate our understanding of pathophysiological mechanisms into clinical practice and to improve outcomes in patients with kidney disease.

Dr. Parikh also conducts a successful mentoring program for fellows interested in patient-oriented research in AKI and kidney diseases, with a focus on translational research. He has over 150 publications with his mentees and nine of them are pursuing careers as physician scientists. He has been the recipient of numerous honors and awards, including the 2017 Young Investigator Award from the American Society of Nephrology. He also was elected to the prestigious American Society of Clinical Investigation in 2018.

Vlado Perkovic (Sydney, AUS)

Vlado Perkovic is Executive Director of The George Institute, Australia, Scientia Professor with the Faculty of Medicine at UNSW Sydney, and a Staff Specialist in Nephrology at the Royal North Shore Hospital. His research focus is in clinical trials and epidemiology, in particular in preventing the progression of kidney disease and its complications. He leads several international clinical trials, and has been involved in developing Australian and global treatment guidelines. He has played a central role in the development of

an affordable dialysis system, which was a Eureka Prize finalist in 2017. Perkovic is the President of the Association of Australian Medical Research Institute and a member of the National Health and Medical Research Council Principal Committee on Research Translation, and is on the Board of the Australian Clinical Trials Alliance. He is Chair of the International Society of Nephrology Advancing Clinical Trials (ISN-ACT) group; and is a Fellow of the Royal Australasian College of Physicians, and the Australian Academy of Health and Medical Sciences. He serves on the Editorial Boards of a number of leading specialist and general journals, including the Journal of the American Society of Nephrology, Circulation, and the New England Journal of Medicine

Krishna Prasad (EMA, GBR)

Krishna Prasad is a Group Manager at the UK Regulatory Agency with direct management responsibility for 3 therapy areas (Cardiovascular-Diabetes, Anti-infectives and Oncology) and an Honorary Cardiologist at St. Thomas' hospital, London. He has worked for MHRA, the UK regulatory agency since 2002 initially as reviewer progressing to lead the cardio-renal-diabetes areas and subsequently to the current post. His areas of special interest in cardiology include heart failure, CV risk factors, arrhythmias, cardiomyopathies and sudden death, and is a long-standing member of European Society of Cardiology. He has a keen interest in clinical trials, trial methodology and CV endpoints for CV and diabetes and renal trials as well as in biomarkers. His experience includes review of renal toxicity biomarkers, applications for renal diseases and CV outcomes in renal disease patients. Krishna is a regular participant in the regulatory roundtable dialogues with European Society of Cardiology and European Heart Failure association.
An active member of two different EMA/CHMP working groups- cardiovascular-Diabetes WP (2008) and the Pharmacogenomics WP (2005), he has coordinated several regulatory guidelines in these areas. He is an author and rapporteur for several EMA/CHMP guidelines in CV area including the heart failure guidelines, lipid lowering agents, and has lead the European efforts in harmonising the Ich E14 guideline including the Q and As.

Agata Ptaszynska (Bristol-Myers Squibb, USA)

Agata Ptaszynska currently works in the Clinical Lead Innovative Medicines in Princeton, NJ. Prior to this, she worked in the Diabetes Development Unit Lead (program included dapagliflozin, saxagliptin, metformin), Medical Lead for irbesartan (including development in hypertension and diabetic nephropathy), Medical Lead for dapagliflozin. She completed her Postgraduate training in internal medicine and cardiology at Medical Center in Warsaw, Poland and obtained her medical degree from the Medical University of Warsaw, Poland.

Brian Pullin (FDA, USA)

Brian Pullin, MS is the Assistant Director for the Vascular and Endovascular Devices Team (VEDT) in the Office of Cardiovascular Devices, Office of Product Evaluation and Quality in the Center for Devices and Radiological Health. Brian joined FDA in 2010 and worked as a premarket reviewer of surgical, rehabilitation and neurological devices. He has experience in all areas of premarket regulation and submissions, including Investigational Device Exemptions (IDEs) for clinical studies, Premarket Notifications (510(k)s) and Premarket Approvals (PMAs) for marketing, and work on the reclassification of several device types as both a reviewer and policy advisor. Serving as the head of VEDT since 2014, Brian oversees the review of vascular surgery devices such as endovascular and vascular grafts and hemodialysis access devices.

Brian earned his B.S.E. Degree from Duke University and his M.S. from Northwestern, both in Biomedical Engineering.

Susan Quella (Rochester, USA)

Susan Quella, RN, BSN, had a 37 year career at Mayo Clinic, first as a Physician Extender in Urology for 11 years, then as a clinical trial nursing chair for a 35 U.S. clinic Oncology research group (NCCTG, North Central Cancer Treatment Group), then became the Project Manager for international clinical trials, and finally Lead RN for Nicotine Research Clinical Trials.
Susan has been published in several U.S. medical journals and has received the Literary Award from the British Journal of Medicine. Susan had developed the Oncology Patient Advocate Committee for Mayo Clinic and since retirement has volunteered for research committees at Mayo as a patient advocate herself.

Natarajan Ranganathan (Kibow Biotech, USA)

Natarajan Ranganathan is the key founder and Managing Director (R&D) of Kibow Biotech located in Newtown Square, PA - USA. Kibow Biotech Inc. is a 21-year-old biotechnology company specializing in the clinical utility of probiotics/prebiotics towards Chronic Kidney Disease (CKD) and related applications. Dr. Ranganathan has significant professional expertise and knowledge related to the fields of Gut Microbiome, Dysbiosis, and its stabilization with Probiotics and Prebiotics. Under his scientific leadership, Kibow was awarded, two consecutive Small Business Innovation Research (SBIR) fast-track grants from the National Institute of Diabetes, Digestive and Kidney (NIDDK) Diseases - NIH and additional funding from the United States Agency for International Aid (USAID) totalling $3.0 million. Additionally the company received a grant of quarter million dollars under the US Government's Qualifying Therapeutic Discovery Project, or QTDP, program.
Dr. Rangan has been a medical researcher and entrepreneur for over thirty plus years. He earned two master's degrees (organic chemistry and biochemistry) from the University of Poona, India and obtained a Ph.D. in Bio organic chemistry from Temple University, Philadelphia. He received further academic training at the University of Pennsylvania, Hahnemann Medical College, Philadelphia, and Johns Hopkins Medical Institutions, Baltimore. His postdoctoral work and subsequent academic efforts were focused in the disciplines of reproductive, radiation and nuclear medicine. Dr. Rangan was a former member on the Board of Directors of the International Probiotics Association (IPA) and the Scientific Visitors Board of the School of Science and Technology at Temple University, Philadelphia

Rohini Retarekar (FDA, USA)

Rohini Retarekar is a medical device reviewer at FDA. Dr. Retarekar received her PhD in Biomedical Engineering from the University of Iowa in 2012. The focus of her research was on evaluation of hemodynamics of unruptured brain aneurysms. After completing her education, Dr. Retarekar worked as a research and development engineer in the medical device industry for a few years. Dr. Retarekar joined FDA in 2015 and serves as a lead reviewer in the Vascular and Endovascular team within the office of cardiovascular devices. As a lead reviewer, she reviews a variety of medical devices including endovascular stent grafts, vascular grafts, and balloon catheters. Dr. Retarekar serves as a primary lead reviewer of medical devices pertaining to vascular access for hemodialysis.

Alain Romero (Relypsa, USA)

Alain Romero is the head of medical and scientific affairs at Relypsa, a Cifor Pharma

Group Company and graduated from the School of Medicine and Pharmacy at the University of Rennes and obtained a PhD in Biomedical and Pharmaceutical Sciences at the University of Rhode Island.

Prior to joining the industry, he practiced at the Rennes teaching hospital, was a Research Fellow at Ciba-Geigy and served on FDA mandated audits. He was an adjunct professor at the University of Rennes and the Miller Medical School in Miami. Alain joined Pfizer in New York where he spent 18 years working in early clinical research, translational medicine, late-stage clinical development and medical affairs domestically and internationally, filing then launching key medicines in various therapeutic areas.

Dr. Romero was vice president of Medical Affairs at Actelion US where he launched the first Endothelin Receptor Antagonist with Morbidity/Mortality RCT data in PAH. He joined Relypsa on August 2015 one year prior to its acquisition by Vifor Pharma.

Romero has led clinical programs across a wide-range of therapeutic areas, including drug delivery, anti-infective, neuroscience, cardiovascular and renal medicine, resulting in the successful filings, supplemental filings and launches of several pharmacological treatments. He has authored over 30 publications including use patents and currently participates in the KHI.

Yves Rosenberg (NIH, USA)

Yves Rosenberg is Chief of the Atherothrombosis and Coronary Artery Disease Branch at the National Heart, Lung, and Blood Institute, a part of the United States National Institutes of Health (Bethesda, Maryland). Dr. Rosenberg obtained his MD from the University of Lyon, France, and is Board certified in Preventive Medicine. He also has an MPH from the Johns Hopkins School of Hygiene & Public Health.

Dr. Rosenberg's main research interests are the design and conduct of large multicenter phase III clinical trials, especially trials of treatment strategies, comparative effectiveness and pragmatic trials.

As a Program Director at NHLBI for over 20 years he has led and participated in the development, conduct, analysis and reporting of more than a dozen major international clinical trials, the results of which have usually been incorporated in clinical guidelines and are influencing today's practice of cardiovascular medicine in the United States and all over the world.

Patrick Rossignol (Nancy, FRA)

Patrick Rossignol, MD, PhD, is professor of Therapeutics, Nephrologist and Vascular medicine specialist, head of Nancy Plurithematic Clinical Investigation center (CIC)-Inserm. He has participated/is participating in several EU FP6-7 programs (Ingenious Hypercare: Coord A; Zanchetti; MEDIA: Coord: W. Paulus; HOMAGE & FIBROTARGETS: Coord F. Zannad, Nancy CIC). He is coordinating a French network of excellence endorsed by F-CRIN (French Clinical research Infrastructure Network, the French affiliate of ECRIN/ERIC: Cardiovascular and Renal Clinical Trialists (INI-CRCT www.inicrct.org) since 2014.

He is coordinating the University Hospital "French Government Investment for the Future" Fighting Heart Failure program (2016-2020). He is the PI of the ongoing double blind (spironolactone vs. placebo) cardiovascular outcome randomized controlled trial in hemodialysis (ALCHEMIST: ClinicalTrials.gov Identifier: NCT01848639) and carotid barostimulation in resistant hypertension trial (ESTIM –rHTN NCT02364310), and steering committee member of several international randomized clinical trials.

He is serving in several DSMCs and event adjudication committees. He is a EURECA-m (cardiorenal working group of ERA-EDTA: The European Nephrology Dialysis Transplantation Association) member since its creation in 2009 and got elected as board member (2013-2016). Since 2016 is a Heart Failure Association of the European Society of Cardiology "Translational" and "Cardiorenal" board member. He currently participates in the KHI.

Professor Rossignol is the co-founder of CardioRenal and is the Director of the KDCT Workshop.

Courtney Rothwell (BD Peripheral Intervention, USA)

Courtney Rothwell is in project management at Becton Dickinson Peripheral Intervention in Tempe, AZ. Courtney has created, managed, and assisted with ESRD clinical trials at BD since 2016 working with a variety of technologies in the vascular portfolio. Prior to her time at BD, Courtney's background was in the facilitation of electrophysiology device trials. Courtney is originally from Arizona and has a Bachelor's of Science in Biological Sciences from Arizona State University.

Prabir Roy-Chaudhury (Chapel Hill, USA)

Prabir Roy-Chaudhury MD, PhD, FRCP (Edin) is a Professor of Medicine and Co-Director of the University of North Carolina (UNC) Kidney Center. After graduating from the Armed Forces Medical College, Pune, India, he trained in Internal Medicine and Nephrology at the University of Aberdeen, Scotland and at the Beth Israel Hospital, Harvard Medical School, Boston, USA. In addition to being an active transplant nephrologist, Dr. Roy-Chaudhury's main research interest is in uremic vascular biology (including both dialysis vascular access dysfunction and cardiovascular complications in kidney disease patients). He currently leads a translational research program in this area funded through the National Institutes of Health, the Veterans Administration research program, and through industry grants. Dr. Roy-Chaudhury has been the recipient of extensive NIH research grant funding, has received national and international awards, has published over 175 papers, and is a sought after invited speaker, both nationally and internationally.

Dr. Roy-Chaudhury was also the founding American Society of Nephrology co-chair of the Kidney Health Initiative, which is a public-private partnership between the ASN and the FDA, which aims to bring together nephrologists, industry partners, patient advocacy groups and regulatory agencies; in an attempt to facilitate the passage of drugs, devices and biologics into the kidney disease space. He is also a member of ASN Council which is the apex leadership body for the American Society of Nephrology. Dr. Roy-Chaudhury has been actively involved in the public policy and administrative aspects of dialysis vascular access care and hemodialysis as a previous or current board member/councilor/committee chair for the American Society of Diagnostic and Interventional Nephrology, the Renal Network, the Interventional Nephrology Advisory Group of the American Society of Nephrology (ASN), the ASN Board of Advisors and Capitol Hill advocacy team, the ASN Post Graduation Education Committee and the International Society of Nephrology-India and South Asia Committees, as well as being the previous President of the American Nephrologists of Indian Origin (ANIO).

Luis Ruilope (Madrid, ESP)

Luis Ruilope graduated as an MD at the University of Madrid and his residence and fellowship in Nephrology was at the Jimenez Diaz Foundation in Madrid. He is currently the Professor at the Public Health and Preventative Medicine department of the Autonomia University and Head of Cardiovascular and Renal Risk at the Insituto de Investigacion 12 de Octubre.

He is an international fellow of the Council for High Blood Pressure Research and of the Council of the Kidney in CV disease of the AHA. Pr. Ruilop is the President of the Spanish Hypertension Society and was an Officer at large for the Scientific Council of the European Society from 1993 – 1997. Currently he is also a member of the the Steering Committee for the following studies: HOT, INSIGHT, SCOPE, CONVINCE, ROADMAP, ASCEND and the European coordinator of the study IDNT.

A member of the editorial board of: Journal of Hypertension, Blood Pressure, Medicina Clinica, Hypertension, Journal of Human Hypertension, Journal American Society of Nephrology and Nephrology, Dialysis & Transplantation.

AnnaLotta Schiller (Olink, SWE)

AnnaLotta Schiller Vestergren works for the Swedish company Olink Proteomics as Regional manager for Northern Europe. AnnaLotta Schiller has a Ph.D. in molecular biology and nutrigenomics and more than 20 years' experience as a life science professional with previous roles in research & development, application support, marketing and product management. Dr. Schiller has a thorough understanding of science as well as marketing strategy and are now leading the Southern European team to ensure a successful introduction of the Olink protein biomarker panels.

Olink Proteomics provides innovative solutions for targeted human protein biomarker discovery. Olink's protein panels can contribute to the identification of new biomarkers aiding the understanding of the pathomechanisms, diagnosis and/or treatment follow up of patients.

Friedrich Schulze (Boehringer Ingelheim, GER)

Friedrich Schulze is currently heading the medical CKD pipeline projects team at Boehringer Ingelheim were he oversees the clinical development of new compounds in the renal space.

Before joining Boehringer Ingelheim in 2013, he held different positions in the Renal Pharmaceuticals department at Fresenius Medical Care since 2008. Friedrich started his professional career in the Department of Clinical Pharmacology at the University Medical Center Hamburg-Eppendorf where he did 8 years of academic research on cardiovascular risk factors and biomarkers of endothelial function before joining pharmaceutical industry.

Deborah Schwartz (Kyowa Hakko Kirin, USA)

Deborah Schwartz has spent approximately 20 years in clinical and 20 years in regulatory affairs. Currently working at Kyowa Kirin, Deborah serves as a global regulatory lead on a number of development projects. An expert in GCPs, regulations and having a strong interest in current HA thinking and regulatory intelligence, Deborah provides advice to developing programs and teams.

Gigi Shafai (Akebia, USA)

Gigi Shafai is Director of Medical Affairs at Akebia Therapeutics and is currently responsible for medical affairs strategy, leading health economic research and publication efforts, and collaborations with clinical development team initiatives related to a drug currently in development for anemia in CKD. Gigi Shafai earned a Pharm.D. from Northeastern University in Boston and completed a fellowship in Clinical Study Management at Roche where she served on the study team during the design and initiation of anemia clinical trials. Gigi has over 12 years of clinical pharmacy and cross-functional industry experience in a variety of therapeutic areas, including nephrology (iron and ESA) and gastroenterology. Gigi has also worked at US NIH, Tufts NEMC dialysis clinic in Boston, and Global Pharmacovigilance efforts at Roche in Paris. Gigi has been serving as a volunteer at Boston's French Cultural Center and French-American Chamber of Commerce of New England for several years and is a core member of the French-American Biotech Springboard. She is passionately committed to bridging the gap between French and US healthcare initiatives and companies, with a goal of furthering science and innovation to support unmet medical needs in the best interest of patients.

Kimberly Smith (FDA, USA)

Kimberly Smith, MD, MS, is a nephrologist in the Division of Cardiovascular and Renal Products within the Office of New Drugs, Center for Drug Evaluation and Research (CDER), at the FDA. Prior to joining the FDA, she was with the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS). Dr. Smith is a graduate of the University of Michigan Medical School, and she completed her residency and chief residency in Internal Medicine and fellowship in Nephrology at Vanderbilt University Medical Center. She then returned to the University of Michigan as faculty and obtained a master's degree in Health and Healthcare Research through the Robert Wood Johnson Foundation Clinical Scholars Program.

Stuart Spencer (The Lancet, GBR)

Stuart joined The Lancet in 1999 and throughout his time there has led the Fast Track team that aims to select, review and publish prestigious manuscripts within four weeks of receipt. Although dealing with all areas of research, he deals with most of the cardiology submissions.
Stuart's background is in research which started at the Brompton Hospital, London, looking at spinal curvature in children before moving to the Veterinary School site at Bristol University. During this period he was invited to establish a research unit in The Netherlands. Later he set up a research team for a major pharmaceutical company in Switzerland for a year, and then spent 9 years as a senior researcher in New Zealand.

He has also had two senior research fellowships at Leuven University, Belgium, and visiting professorships at King's College, London and Hong Kong University, and an honorary doctorate of medicine from Umea University, Sweden. A broad biomedical research base in different settings (Universities, government and industry) in front-line research has given a clear understanding of principles in research and publications applicable across disciplines. Stuart is also a Trustee of the Scoliosis Association (UK), is on the British Scoliosis Research Fund grants committee and the steering Committee of the Swedish national GP Research School.

Joseph Stavas (Twin City Bio, USA)

Joseph Stavas is a Consultant for Twin City Bio, LLC for medical and regulatory interactions regarding safety and efficacy; medical trial design, professional training programs including percutaneous device delivery systems, protocol development and interventional radiology education for Clinical sites; IRB, and FDA. Identifies strategic opportunities and emerging medical and health care practices that impact management of CKD and use of cell-based product, NKA/REACT. Facilitates and/or delivers scientific/medical research findings of NKA/REACT through symposia, lectures and publications.

Dr. Stavas has 30 years of community hospital and academic medical center experience in the practice and training of minimally invasive interventional radiology in adult and pediatric populations, including over 200 publications, scientific presentations and invited lectures.

Norman Stockbridge (FDA, USA)

Norman Stockbridge has been a medical officer in the FDA/CDER Division of Cardiovascular and Renal Products since 1991 and has served as the Division Director since 2004.

Joachim Struck (Sphingotec, GER)

Joachim Struck has been Head of Research & Development at Sphingotec GmbH since 2013 (for Clinical Research and Scientific Affairs of innovative Biomarkers for Acute Care and Preventive Medicine and Prototype Assay Development) and Head of Research & Development at Adrenomed AG for Pre-clinical Development of a drug candidate anti-Adrenomedullin antibody.

He is Co-author of over 150 peer-reviewed scientific publications and co-inventor of over 50 patent families.

Anna Sundgren (AstraZeneca, USA)

Anna Sundgren completed her studies in molecular biology at Stockholm University, then obtained a PhD with a focus on neuroimmunomodulation & ion channel pharmacology, then a post doc at Northwestern University, Chicago, with a focus on G protein signaling. Moving back to Sweden, she began industry research at AstraZeneca in Sodertalje. She has led multiple cross functional global teams and as worked in the drug development value chain from the very early target validation phase, through all phases, up to and including generic products. She also worked in global medical affairs in London; in this role she engaged with multiple licensing opportunities and launch preparations.

She acquired an MBA in 2017, in Gothenburg with a focus on Asia. She currently works in cardiovascular renal and metabolic late stage development based in Gaithersburg driving the development for AZ's first brand to launch in renal globally. Sundgren has been very active in the renal disease area and has led the renal strategic work for 5 years within AZ.

Aliza Thompson (FDA, USA)

Aliza Thompson is a Clinical Team Leader in the Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research (CDER), at the U.S. Food and Drug Administration (FDA).

Dr. Thompson joined the FDA in 2007; her team focuses on products being developed to treat renal-related indications. She received her medical degree from Johns Hopkins Medical School and completed her Internal Medicine and Nephrology training at Columbia University/New York-Presbyterian Hospital.

She holds a Master of Science in Biostatistics/ Patient Oriented Research Track from the Columbia University Mailman School of Public Health.

Ron Wald (Toronto, CAN)

Ron Wald is a nephrologist at St. Michael's Hospital in Toronto, Canada, and serves as Medical Director of the hospital's hemodialysis program.

He is also an Associate Professor of Medicine and Health, Policy Management and Evaluation at the University of Toronto. His research interests are in critical care nephrology and hemodialysis and he has been involved in several clinical trials in these areas.

He is currently co-leading a multinational randomized controlled trial on the timing of renal replacement therapy in acute kidney injury as well as a trial- which will commence in the coming months- comparing intensive vs liberalized phosphate control in patients with end-stage kidney disease receiving dialysis.

Christoph Wanner (Würzburg, GER)

Christoph Wanner is Professor of Medicine and head of the Division of Nephrology at the University Hospital of Würzburg, Germany. He has published more than 690 scientific papers and articles on diabetic kidney disease (HF 75), lipid disorders, statin treatment and rare kidney diseases. He is steering committee member of the EMPA-REG Outcome, the EMPEROR and the EMPA-KIDNEY trials, aiming in slowing the progression of kidney disease and improving cardiovascular outcomes.
He is an Associate Editor of the Clinical Journal of the America Society of Nephrology and until this year was the Editor-in-Chief of the Journal of Renal Nutrition. He has received the 2016 Award from the ERA-EDTA for Outstanding Clinical Contributions to Nephrology and in 2018 from the DGfN the Franz Volhard medaille, the highest awards from the German & European Societies of Nephrology.

Melissa West (Washington D.C., USA)

Melissa West is the Project Director for the Kidney Health Initiative (KHI), a public-private partnership between the American Society of Nephrology, U.S. Food and Drug Administration and over 75 member companies and organization focused on fostering innovation and enhancing patient safety in kidney disease. Prior to joining KHI in 2012, Ms. West served as a consultant for the pharmaceutical industry coordinating their activities at scientific conferences. She was employed with Abbott Laboratories during their launch of Zemplar Capsules in 2004-2006. Her career started in the not-for-profit industry with Smith, Bucklin and Associates, including management positions with the American Society of Psychiatric Nurses, International Society of Clinical Densitometry and ending with the American Society of Nephrology. She joined the American Society of Nephrology as a full time employee in 2000 as Director of Programs with Kidney Week and assisting with corporate development. With her 16 year career in nephrology, Ms. West is please to lead the Kidney Health Initiative and ideally help facilitate the passage of drugs, device and biologics for kidney disease patients.

David White (Hillcrest Heights, USA)

David M. (Dave) White is a healthcare consultant with subject matter expertise in person-centered care, patient engagement, and living with a serious illness. His mission is to promote population health through advocacy and engagement. White, a very grateful kidney transplant recipient, serves on the boards of directors of the American Association of Kidney Patients, the Kidney Health Initiative, Quality Insights Renal Network 5, and the Veterans Transplantation Association. Dave also chairs the Kidney Health Initiative Patient and Family Partnership Council and the Patient-Centered Outcomes Research Institute's Advisory Panel on Patient Engagement, and he is also a member of the National Kidney Foundation Kidney Advocacy Committee. White enjoys public speaking, writing, and exercise, and has made regional and national television appearances.

Daniel Wilson (KBP Biosciences, USA)

Daniel Wilson joined KBP in December 2018 at as Senior Vice President of Clinicial Development. Prior to that he was at Relypsa and Pfizer. Dr. Wilson received his Doctor of Medicine at Rush Medical University, and completed postgraduate training in Internal Medicine, Hypertension and Nephrology, at the Cleveland Clinic Foundation. He has held academic and clinical appointments at the Cleveland Clinic Foundation, Bowman Gray School of Medicine - Wake Forest University, and at the Mayo Clinic - Mayo Medical School.

Janet Wittes (Statistics Collaborative, USA)

Janet Wittes, PhD is President of Statistics Collaborative, Inc. which she founded in 1990. Previously, she was Chief, Biostatistics Research Branch, National Heart, Lung, & Blood Institute (1983–89). The 2006 monograph, "Statistical Monitoring of Clinical Trials – A Unified Approach" by Proschan, Lan, and Wittes, deals with sequential trials. Her research has focused on design of randomized clinical trials, capture recapture methods in epidemiology, and sample size recalculation. She has served on a variety of advisory committees and data monitoring committees for government (NHLBI, the VA, NEI, and NCI) and industry. For the FDA, she has in the past been a member of the Circulatory Devices Advisory Panel and of the Cell and Gene Therapy Advisory Committee. She was formerly Editor in Chief of Controlled Clinical Trials (1994-98).

Melanie Wright (Novartis, SUI)

Melanie Wright is currently working as the lead statistician supporting renal indications at Novartis Pharma AG and has been working as a statistician in the pharmaceutical industry since 1996. During her career she has worked on a range of projects at all stages in development (phase I through to lifecycle management). She obtained an MSc in Biometry from the University of Reading.

Shen Xiao (FDA, USA)

Shen Xiao is a senior medical officer in the Division of Cardiovascular and Renal Products, Office of New Drug, Center for Drug Evaluation and Research, US Food and Drug Administration (FDA). He has been working in FDA since 2002. Prior to joining the FDA, he had research fellowship positions in the Division of Nephrology, Johns Hopkins University Hospital, and Division of Cardiology, University of North Carolina at Chapel Hill. He holds a Ph.D. degree in Renal Physiology and Cell Biology in West Virginia University. Dr. Xiao received his medical training in internal medicine and nephrology in China. Dr. Xiao's current work focuses on the review of cardiovascular and renal drug and biological products.

Fred Yang (KBP Biosciences, USA)

Fred Yang's expertise in drug development is focusing on end to end development planning/ execution and clinical trial design (Phase I –Phase IV) with solid clinical operation knowledge in both in house and outsourcing model. With a rich regulatory experience (multiple NDA/BLA/MAA/JNDA/Adcom) / medical affair experience (KOL/publication/ etc.) and sound therapeutic area knowledge on Cardiorenal, infectious disease, oncology, metabolic to neonatal care.

Junichi Yasutake (Kyowa Hakko Kirin, JAP)

Junichi Yasutake is the Manager of the Nephrology R&D Management, in the Office in the Nephrology R&D Unit, R&D Division in Kyowa Hakko Kirin Co, where he has been since 2004.
He completed his studies in the School of Bioscience and Biotechnology of the Tokyo Institute of Technology in Japan and then in Juntendo University, followed by the school of Innovation Management in the Tokyo Institute of Technology.

KIDNEY DISEASE CLINICAL TRIALISTS

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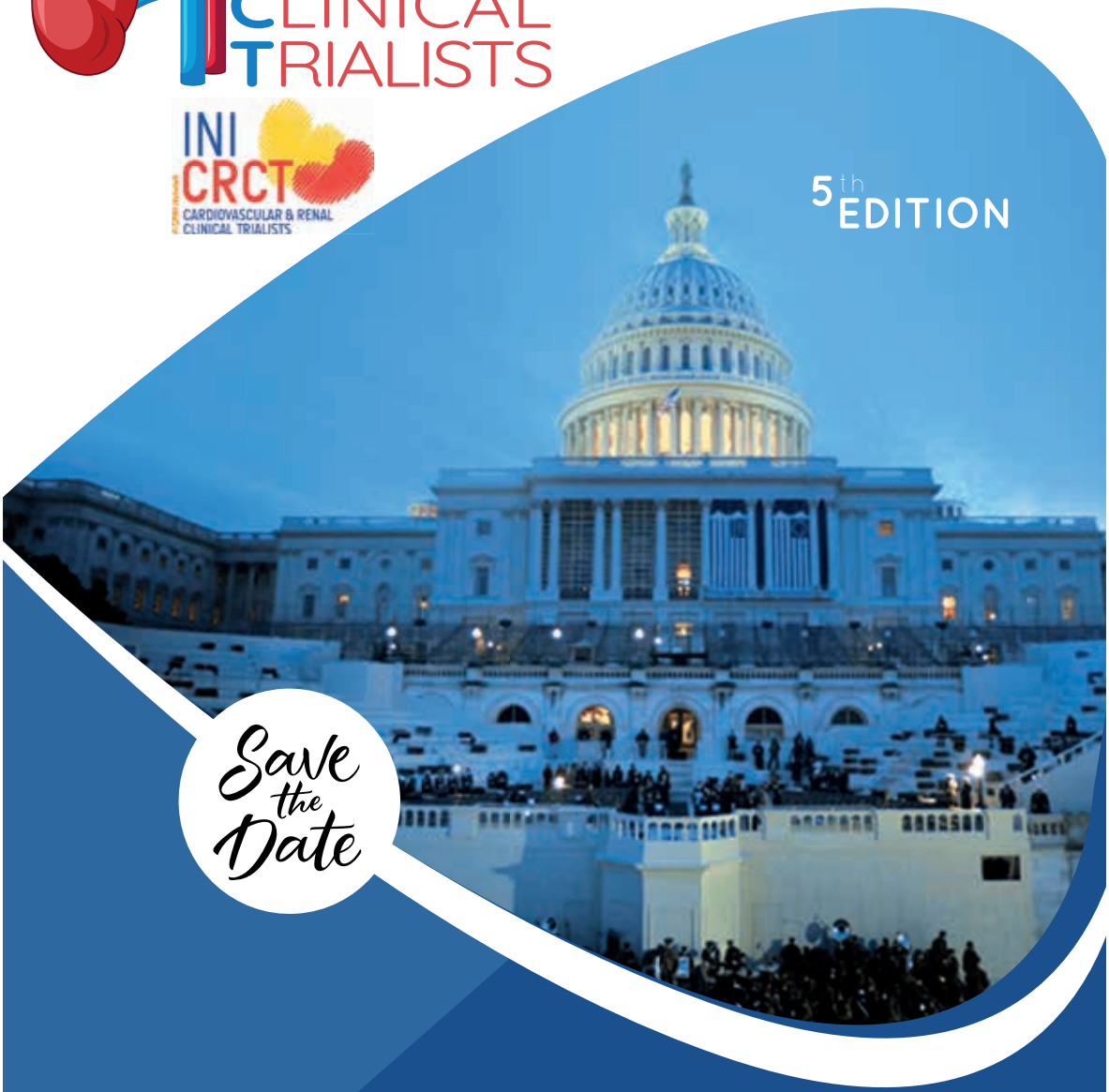

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May 15 & 16, 2020

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