3rd EDITION

KIDNEY DISEASE CLINICAL TRIALISTS

INI CRCT
CARDIOVASCULAR & RENAL CLINICAL TRIALISTS

FINAL PROGRAM

June 15 & 16, 2018

Washington, DC, USA

www.kdctmeeting.com

Summary

3rd EDITION
KIDNEY DISEASE CLINICAL TRIALISTS

www.kdctmeeting.com

Introduction

Dear faculty and industry members,

I am pleased to welcome you to the 3rd 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.

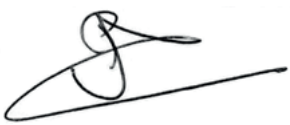
Our objectives are to produce relevant data from controlled kidney disease clinical trials that will contribute to better clinical care and to understand the problems associated with making decisions about what constitutes relevant information, how to improve kidney disease clinical trials, and, as is 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, USA and Australia as well as NIH, EMA and FDA representatives, patient 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

VENUE OF THE MEETING

Embassy of France
4101 Reservoir Rd NW
Washington, D.C. 20007
USA

ON-SITE CONTACTS

Patrick Wahby: +33 (0)6 21 02 74 02
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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 30 minutes before the session starts (or during the coffee breaks).

LOGISTICS AND TECHNICAL ORGANIZATION

Overcome
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SCIENTIFIC SECRETARIAT

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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: 33453AF
Travel Valid Period: 10/06/2018 to 21/06/2018
Event location: WASHINGTON

For further information, please visit our website.

3rd Kidney Disease Clinical Trialists (KDCT) Workshop
June 15-16, 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 (Tucson, USA); Luis Ruilope (Madrid, ESP)

More evidence-based data are eagerly warranted in order to improve chronic kidney disease patient outcomes. Large-size and well conducted randomized clinical trials are of paramount importance, as highlighted by recent initiatives (ASN Kidney Health Initiative, KDIGO Controversy conferences, ISN and CVCT/INI-CRCT workshops held in 2015 and 2016).

Cardiovascular Clinical Trialists (CVCT) Workshops (http://www.globalcvctworkshop.com/home) have become the authoritative meeting place for cardiovascular trial principal investigators, statisticians, Pharma R&D experts and regulators from the major international agencies. Brainstorming topics including CV drugs, device and biomarker development and trial design, conduct, ethics, interpretation, approvability and implementation. Following the template of the CVCT workshop, the Kidney Disease Clinical Trialists (KDCT) Workshop is a high-level think-tank, with an exceptional expert faculty. It involves a limited number of attendees (70) and includes distinguished nephrologists, clinical trialists, principal investigators and statisticians from academia, R&D pharma and devices, NIH, EMA and FDA.

The objectives are:

- To produce relevant data from controlled kidney disease clinical trials (beyond cardiovascular outcomes trials) that can be translated into successful product development and so will contribute to better patient centered clinical care.
- To understand the problems associated with making decisions about what constitutes relevant information, how to improve the awareness, design and infrastructure of kidney disease clinical trials, and, as is commonly the case, how to satisfy regulatory authorities and payers.

KDCT Workshops aim to foster an international exchange of ideas and perhaps innovative thought leadership (not the creation of guidelines or rule-making). During our time together we have the opportunity to brainstorm on trial design, conduct, ethics, interpretation, approvability and Implementation encompassing drugs, devices, biomarkers and therapeutic strategies for kidney diseases.

Retaining the long established CVCT ethos, the meeting should allow ample time for discussion and brainstorming. Speakers/discussants' presentations should mainly serve as prompts for lively panel discussion, aiming to move the lines and whenever possible, achieve breakthroughs. Emphasis is on interaction among highly knowledgeable experts with as little lecturing as possible. Importantly, presentation time should be restricted to 10 mins max for speakers and 5 mins max for each discussant. Moderators have the critical task to keep time and give each panelist a chance to be involved. In order to achieve an optimal think tank dynamic, attendance at the entirety of the Workshop is kindly requested from each member.

Scientific program

Friday, June 15, 2018

SESSION 1: KDCT in the eyes: key methodological and conduct insights from game changers and neutral trials

1:30 – 3:15PM

Moderator: Rajiv Agarwal (Indianapolis, USA)

Speaker: George Bakris (Chicago, USA)
Speaker: Faiez Zannad (Nancy, France)
Speaker: Paul Kimmel (NIH, USA)
Discussant: Luis Ruilope (Madrid, ESP)
Discussant: Meg Jardine (Sydney, AUS)
Discussant: Robert Star (NIH, USA)
Discussant: Yves Rosenberg (NHLBI)
Discussants: FDA, EMA
Panel discussion

3:15 – 3:45PM **Coffee Break**

SESSION 2: Trial design issues for acute kidney failure trials (including primary prevention for contrast-induced nephropathy)?

Considerations related to selection of patients for enrollment; endpoints for establishing clinical benefit; use of biomarkers of acute kidney injury- for patient selection and as response biomarkers; and evaluating safety. what endpoints might be suitable for phase 2 and what endpoints might be suitable for approval.

3:45 – 7:15 PM

Moderator: Patrick Rossignol (Nancy, FRA);
Martin Gallagher (Sydney, AUS)

Speaker: Ravindra L Mehta, (San Diego, USA)
Speaker: David Charytan (Boston, USA)
Speaker: Martin Gallagher (Sydney, AUS)
Discussant: Jay Koyner (Chicago, USA)
Discussant: Christopher Wilcox (Washington, USA)
Discussant: Alexandre Mebazaa (Paris, FRA)
Discussant: Matthieu Legrand (Paris, FRA)
Discussants: Andreas Bergmann and Joachim Struck (Sphingotec, GER)
Discussant: Ida Grundberg (Olink, USA)
Discussants: FDA, EMA
Panel discussion

SATURDAY, JUNE 16, 2018

SESSION 3: Specific trials designs in CKD on hemodialysis
Which level of evidence warranted for new dialysis techniques? For patient monitoring?

The examples of online hemodiafiltration vs hemodialysis, frequent vs usual hemodialysis, usefulness of body composition monitor, sodium concentration in bath, volume and electrolyte regulation, 24/7 monitoring and telemedicine, vascular access monitoring, novel vascular access approaches, innovative RRT (portable, wearable, implantable devices)

8:00 – 10:00 AM **Moderator: Prabir Roy-Chaudhury (Tucson, USA)**

Speaker: John Daugirdas (Chicago, USA)
Discussant: Rajiv Agarwal (Indianapolis, USA)
Discussant: Jennifer Flythe (Boston, USA)
Discussant: Prabir Roy-Chaudhury (Tucson, USA)
Patient Discussant: Caroline Wilkie (Punta Gorda, USA)
Discussant: Brigitte Schiller (Satellite Healthcare, USA)
Discussant: Noah Bartsch (TVA Medical, USA)
Discussants: FDA, EMA
Panel discussion

10:00 – 10:30 AM **Coffee Break**

SESSION 3: Specific trials designs in CKD on hemodialysis
Which trials are warranted, using which designs/comparators for the management of anemia? Of potassium, phosphorus?

Considerations related to selection of patients for enrollment; endpoints for establishing clinical benefit; use of biomarkers of acute kidney injury- for patient selection and as response biomarkers; and evaluating safety. what endpoints might be suitable for phase 2 and what endpoints might be suitable for approval.

10:30 – 12:30 PM **Moderator: George Bakris (Chicago, USA)**

Speaker: Rajiv Agarwal (Indianapolis, USA)
Speaker: Thierry Schulmann (Vifor, SUI)
Discussant: Brigitte Schiller (Satellite Healthcare, USA)
Discussant: Patrick Rossignol (Nancy, FRA)
Discussant: Rahul Kakkar (Corvidia, USA)
Discussants: FDA, EMA
Panel discussion

12:30 – 1:30 PM **Lunch Break**

SESSION 4: Further empowering RCTs

Patient enrollment hurdles in CKD trials RCTs embedded in registries? Real world evidence generation? e-Health to enable RCTs? Cluster RCTs?

1:30 – 3:30 PM **Moderator: Luis Ruilope (Madrid, ESP)**

Speaker: John Daugirdas (Chicago, USA)
Speaker: Laura M Dember (Philadelphia, USA)
Speaker: Katherine Tuttle (Washington, USA)
Speaker: Deidra C Crews (Baltimore, USA)
Patient Discussant: Caroline Wilkie (Punta Gorda, USA)
Discussant: Alain Romero (Relypsa, USA)
Discussant: Barbara Gillespie (Covance, USA)
Discussant: Joseph Stauffer (Cara Therapeutics, USA)
Discussant: Abhinav Sharma (San Francisco, USA)
Discussants: FDA, EMA
Panel discussion

Faculty & Participants

ACADEMIA

Rajiv Agarwal (Indianapolis, USA)
George Bakris (Chicago, USA)
David Charytan (Boston, USA)
Deidra Crews (Laurel, USA)
John Daugirdas (Chicago, USA)
Laura Dember (Philadelphia, USA)
Jennifer Flythe (Chapel Hill, USA)
Martin Gallagher (Sydney, AUS)
Meg Jardine (Sydney, AUS)
Jay Koyner (Chicago, USA)
Matthieu Legrand (Paris, FRA)
Alexandre Mebazaa (Paris, FRA)
Ravindra Mehta (San Diego, USA)
Bertram Pitt (Ann Arbor, USA)
Patrick Rossignol (Nancy, FRA)
Prabir Roy-Chaudhury (Tucson, USA)
Luis Ruilope (Madrid, ESP)
Abhinav Sharma (San Francisco, USA)
Katherine Tuttle (Spokane, USA)
Melissa West (Washington, USA)
Chris Wilcox (Washington, USA)
Faiez Zannad (Nancy, FRA)

REGULATORY

Albert Deisseroth (FDA, USA)
Frank Holtkamp (EMA, NL)
Frank Hurst (FDA, USA)
Krishna Prasad (EMA, GBR)
Norman Stockbridge (FDA, USA)
Aliza Thompson (FDA, USA)

NIH

Nancy Geller (NIH, USA)
Paul Kimmel (NIH, USA)
Susan Mendley (NIH, USA)
Yves Rosenberg (NIH, USA)
Robert Star (NIH, USA)

MEDIA

Stuart Spencer (The Lancet, GBR)

INDUSTRY

Noah Bartsch (TVA Medical, USA)
Andreas Bergmann (SphingoTec, GER)
Maria Borentain (BMS, USA)
Kerry Cooper (Amgen, USA)
Michael Davidson (Corvidia Therapeutics, USA)
Nathalie Dervaux (Servier, FRA)
Bruno Flamion (Idorsia, SUI)
Jyothis George (Boehringer Ingelheim, GER)
Barbara Gillespie (Covance Inc, USA)
Scott Grant (Vascular Dynamics INC., USA)
Ida Grundberg (Olink, SWE)
Nicolas Guzman (AstraZeneca, USA)
Sibylle Hauske (Boehringer Ingelheim, GER)
Mark Houser (AstraZeneca, USA)
Robert Huizinga (Aurinia Pharma, CAN)
Rahul Kakkar (Corvidia Therapeutics, USA)
Douglas Kling (Corvidia Therapeutics, USA)
Jeffrey Lawson (Humacyte INC., USA)
Dustin Little (AstraZeneca, USA)
Robert Melder (Medtronic, USA)
Michaela Petrini (Boehringer Ingelheim, USA)
Alain Romero (Relypsa – Vifor, USA)
Brigitte Schiller (Satellite Health, USA)
Thierry Schulmann (Relypsa – Vifor, SUI)
Gigi Shafai (Akebia Therapeutics, USA)
Salim Shah (Sarfez, USA)
Amit Sharma (Akebia Therapeutics, USA)
Joseph William Stauffer (Cara Therapeutics, USA)
James Strickland (FAST BioMedical, USA)
Joachim Struck (SphingoTec, GER)
Dan Wilson (Relypsa – Vifor, USA)
Fred Yang (KBP Biosciences, USA)

PATIENT ADVOCACY

Caroline Wilkie (Punta Gorda, USA)

Rajiv Agarwal (Indianapolis, USA)

Rajiv Agarwal is a practicing nephrologist and a tenured Professor of Medicine at Indiana University School of Medicine. Dr. Agarwal earned his medical degree from the All India Institute of Medical Sciences in New Delhi after completing residency in Internal Medicine at the University of Texas. In July 1997, he joined Indiana University as Clinical Assistant Professor and within 10 years was promoted to the rank of full Professor. Dr. Agarwal has published over 250 original papers and reviews in Nephrology. He has received the Indiana University Trustee's teaching award, the young scholar award of the American Society of Hypertension, and the Clinical Excellence award from the American Nephrologists of Indian Origin (ANIO). He serves on the Editorial Board of several nephrology journals and as an Editor for Nephrology Dialysis Transplantation and the American Journal of Nephrology. He also served as an Associate Editor of NephSAP and the Journal of the American Society of Hypertension.

Dr. Agarwal is an internationally recognized leader in the area of clinical and translational research in nephrology. He has recently uncovered through a randomized clinical trial the ill effects of parenteral iron in CKD. His foremost contribution has been in the area of hypertension in hemodialysis patients. He has refined the techniques to diagnose and treat hypertension in this complex group of patients and performed important randomized trials in this difficult group of patients.

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.

Noah Bartsch (TVA Medical, USA)

Noah Bartsch, Vice President of Clinical and Regulatory Affairs at TVA Medical, Inc. Extensive experience leading the growth and advancement of novel medical device technologies through clinical study, regulatory approval, and quality compliance on a global scale. Transforming Vascular Access at TVA Medical by leading global clinical research initiatives and regulatory submission strategies in the USA and international markets.

Andreas Bergmann (Sphingotec, GER)

Andreas Bergmann got his PhD in Biochemistry in 1988. He is President at Sphingotec Therapeutics GmbH and is also CEO of "Waltraut Bergmann Foundation to Support Cancer Research" since 2010.

Maria Borentain (BMS, USA)

Maria Borentain is a graduate from the University of Paris Medical School. She was trained in Cardiology with subsequent sub-specialization in Echocardiography and Sports Medicine, and holds a Master's in Cardiovascular Pharmacology and Biostatistics. She is currently a Medical Director in Global Development Cardiovascular at Bristol-Myers Squibb. After several years in clinical practice, she joined Bristol-Myers Squibb 13 years ago and held various positions in Medical Affairs, Field Medical Management and Global Clinical Development. She is involved in early and clinical development of several assets in Heart Failure. Her interests also include Innovative Clinical Trial Designs and Patient Engagement.

David Charytan (Boston, USA)

David Charytan is Associate Professor of Medicine at Brigham & Women's Hospital and Harvard Medical School.

He is a board-certified nephrologist and serves as the director of the ICU nephrology at the Brigham & Women's Hospital and the Director of Renal Research at the Baim Institute.

Dr. Charytan's research focuses on cardiovascular disease in the setting chronic kidney disease and clinical trials in the areas of chronic kidney disease, and acute kidney injury.

Dr. Charytan is the principal investigator on multiple NIH grants and is one of the Principal Investigators of the Hemodialysis Novel Therapy Network.

Kerry Cooper (Amgen, USA)

Kerry Cooper is a nephrologist with over 30 years of clinical experience with expertise in the field of bone and mineral disorders. He was previously an Associate Professor of Medicine at Yale University.

He joined Amgen in 2010 and has held positions of increasing responsibility in both clinical development and medical affairs. He is currently an Executive Medical Director at Amgen and is the Global Medical Affairs Leader for Nephrology.

Particular areas of interest include the role of calcimimetics in the management of patients with Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) and the role of fibroblast growth factor (FGF-23) as a mediator of adverse outcomes in CKD.

Deidra C Crews (Baltimore, USA)

Deidra Crews is a nephrologist and epidemiologist. She is an Associate Professor of Medicine in the Division of Nephrology at the Johns Hopkins University School of Medicine and is Associate Vice Chair for Diversity and Inclusion in the Department of Medicine. Her core area of research addresses disparities in the care and outcomes of chronic kidney disease. She has examined the contribution of social determinants of health, including poverty and access to healthful foods, to disparities in kidney disease. Her work in end-stage renal disease includes studies of the optimal timing and setting of dialysis initiation among vulnerable groups, and patient preparation for the start of renal replacement therapy.

Dr. Crews was the inaugural Gilbert S.

Omenn Anniversary Fellow of the Institute of Medicine (2013-2015). She is the former Chair of the American Society of Nephrology Chronic Kidney Disease Advisory Group, and is currently a member of the Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance Team, the ASN Diversity and Inclusion Committee, the Board of Directors of the National Kidney Foundation of Maryland and the Addressing Disparities Advisory Panel of the Patient Centered Outcomes Research Institute.

Dr. Crews is founding director of the Doctoral Diversity Program, which is a research-intensive post-baccalaureate program of the Johns Hopkins Initiative for Careers in Science and Medicine.

John Daugirdas (Chicago, USA)

John Daugirdas is Clinical Professor of Medicine at the University of Illinois at Chicago. His main research interests have focused on hypotension during dialysis and hemodialysis adequacy.

He was Co-Chair of the KDOQI Hemodialysis Adequacy work groups that reported in 2006 and in 2015.

He was a Co-Investigator or Consultant in many NIH-funded trials of CKD or hemodialysis, including the HEMO Study, the Frequent Hemodialysis Network Trials, and the cluster randomized TiMe trial, and he participated as Co-Principal Investigator in the design phase of the CRIC (Chronic Renal Insufficiency Consortium). His current interests also include the effect of dialysis on residual kidney function, quantification of incremental hemodialysis, and mineral balance, especially as it pertains to phosphorus.

Michael Davidson (Corvidia Therapeutics, USA)

Michael H. Davidson is Professor of Medicine and Director of Preventive Cardiology at the University of Chicago.

Dr. Davidson earned his medical degree from The Ohio State University College of Medicine in Columbus. He then completed his residency and fellowship in cardiology at Rush University Medical Center in Chicago.

An active researcher, Dr. Davidson's clinical research background encompasses both pharmaceutical and nutritional clinical trials. His extensive research on statins, novel lipid-lowering drugs, and nonpharmacologic risk factor reduction has established him as a key opinion leader in this area. A prolific author and lecturer on lipid disorders, nutrition, and atherosclerosis, Professor Davidson has coordinated more than 1,000 clinical trials in areas of preventive cardiology and published more than 250 articles for leading medical journals and has written 3 books on Lipidology.

Dr. Davidson is board-certified in internal medicine, cardiology, and clinical lipidology. He is a Fellow of the American College of Cardiology and the American College of Chest Physicians. In addition, he was President (2010-2011) of the National Lipid Association. Expertscape ranks Professor Davidson one of the top five lipid experts in the world; he has been named one of the The Best Doctors in America for the past 12 years and was named Father of the Year by the American Diabetes Association in 2010.

Albert Deisseroth (FDA, USA)

Albert Deisseroth joined the US FDA in 2009, prior to this he worked on the development of new directions in the treatment of leukemias and solid tumors through the use of molecular targeting and genetic therapy. Following several years of training at the University of Rochester, Harvard University, the NIH and the Dana Farber Cancer Center, Dr. Deisseroth held several academic positions at the NCI as Head of the Experiment Hematology Section, Ensign Professor of Medicine and Chief of Medical Oncology at Yale University School of Medicine, the Anderson Professor of Cancer Treatment and Research and Chairman of the Department of Hematology at the UT MD Anderson Cancer Center, and Professor of Medicine at UCSF and Chief of the Medical Oncology/Hematology Division at the San Francisco VAMC. He now works at the US

FDA as the Supervisory Associate Division Director in the Division of Hematology Products of the Office of Hematology and Oncology Drug Products.

Laura M Dember (Philadelphia, USA)

Laura M. 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.

Nathalie Dervaux (Servier, FRA)

Nathalie Dervaux is a Cardiologist, e-health Project Director at WeHealth by Servier and has worked at Servier since 2010. She was a medical student at Université Paris Descartes from 1995 to 2001 and then continued her education at the Université de Rouen from 2001 to 2006. During her time at the Université of Rouen, Dr Dervaux was a research fellow at the National Institute of Health in Baltimore, USA in 2004. From 2006 to 2009 she worked at the Hopital Européen George Pompidou as an Assistant Professor of Medicine for Cardiovascular prevention and medicine.

Bruno Flamion (Idorsia, SUI)

Bruno Flamion is VP, Head of Strategic Development at Idorsia Pharmaceuticals in Allschwil, Switzerland (since June 2017). He previously held the same position at Actelion Pharmaceuticals, also in Allschwil.

Dr. Flamion is a Belgian national, MD with clinical expertise in internal medicine and nephrology (1983-1996), and PhD in renal physiology from the University of Brussels, Belgium. He was Research Associate at the NIH, Bethesda, MD, USA (1988-1992), and at the Belgian National Fund for Scientific Research (1992-1996). He headed the Laboratory of Physiology and Pharmacology, and was Professor of Physiology and Pharmacology, at the University of Namur, Belgium, for twenty years (1996-2016). He is still Professor of Clinical Pharmacology at that university. Bruno also worked at the European Medicines Agency, London, UK, for 12 years (2000-2012), as a member of CHMP and CAT, chair of the Pharmacokinetics Group, and, most importantly, chair of the Scientific Advice Working Party (2005-2010). In Belgium, he chaired the Committee for Reimbursement of Medicines for 3 years (2010-2012).

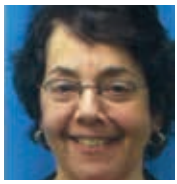
Jennifer Flythe (Boston, USA)

Jennifer Flythe is a nephrologist and clinical investigator at the University of North Carolina (UNC) Kidney Center and Director of Dialysis Services at UNC Hospitals in Chapel Hill, NC. She completed medical school at the UNC School of Medicine and Nephrology fellowship training at the Brigham and Women's Hospital-Massachusetts General Hospital

Combined Program. She earned her Master's in Public Health from the Harvard School of Public Health. Dr. Flythe's research interests include identifying modifiable morbidity and mortality determinants among maintenance dialysis patients and developing innovative treatment strategies to reduce these risks. The majority of her work focuses on dialysis hemodynamics, fluid management, and blood pressure patterns among maintenance hemodialysis patients. She also incorporates patient-centered outcomes and patient preferences into her work to ensure that patient-stated priorities drive outcomes research.

Martin Gallagher (Sydney, AUS)

Martin Gallagher received his primary degree from the University of Adelaide and has additional qualifications of an MPH (Hons) and a PhD from the University of Sydney. He completed a Harkness Fellowship at Yale University in 2009-2010. He currently works as a Clinical Academic in the Concord Clinical School at the University of Sydney. His research interests encompass acute kidney injury, clinical trials and renal epidemiology, and he works as part of a team of clinical renal researchers at the Renal Division of the George Institute for Global Health, along with international collaborators.



Nancy Geller (NIH, USA)

Nancy L. Geller has been the Director of the Office of Biostatistics Research at the National Heart, Lung and Blood Institute of the National Institutes of Health since 1990. She directs a group of 11 statisticians who collaborate in the design, implementation, monitoring and analysis of multicenter clinical trials in heart, lung and blood diseases and sleep disorders and administers all statistical activities of the National Heart, Lung and Blood Institute. She has been or is involved in the design and analysis of many cardiovascular trials, including PEACE, AFFIRM, WHI (Women's Health Initiative), FREEDOM, ACCORD, COAG, the ongoing Tailored Antiplatelet Initiation to Lessen Outcomes Due to Decreased Clopidogrel Response after PCI (TAILOR-PCI) and trials of the Cardiovascular Surgery Network. She has published over 200 papers in the statistical and medical literature. She is an Associate Editor of Biometrics and a Fellow of the International Statistics Institute, the American Statistical Association and the Society for Clinical Trials. She was the winner of the 2009 Janet L. Norwood Award for outstanding achievement by a woman in the statistical sciences and was 2011 President of the American Statistical Association.

Jyothis George (Boehringer Ingelheim, GER)

Jyothis George is an entrepreneurial physician-scientist with a track-record in global leadership. Leading clinical development of BI's cardio-metabolic portfolio (which includes two blockbusters – Empagliflozin and Linagliptin).

His career aim is to maximize value at every step of medical innovation- from proof of concept to product access for population health.

His experience includes, early development (MRC, Edinburgh), using novel neuropeptides and rare-disease genotypes led to first-in-class candidates, including the AZ spin-off MLE4901. And Phase 3 experience include Type 1 Diabetes (EASE), and the innovative multi-drug pediatric program (DINAMO).

The Global outcome-trial leadership include the pragmatic trial EXSCEL, the active-comparator trial CAROLINA, the CARMELINA trial with a renal-enriched population and the EMPEROR Heart Failure Program.

This decade-long experience in clinical development (>40,000 patients from >40 countries), helped design a lean global registration programme in CKD, with world-leading university partners (EMPA-KIDNEY).

Pr George has been published in dozens of of prestigious journals and multiple award-winning presentations complement of over 15 years of clinical practice -including senior roles in world-renowned tertiary hospitals.

His multiple roles at the University of Oxford (e.g OCDEM board) was a unique opportunity

to advance methodological skills. Leading purpose-driven peers (e.g YDEF) yielded leadership skills to harness intrinsic motivation. Now deepening strategic skills with structured (e.g Duke CE) and work-based learning (e.g Agile) to drive medical innovation, to add value, to address unmet need.

Barbara Gillespie (Covance, USA)

Barbara S. Gillespie is a board-certified nephrologist who is currently a Vice President at Covance Global CRO where she is the Therapeutic Head of Nephrology and supports sponsors on renal drug & device development. She is also an Adjunct Professor at the University of North Carolina, Division of Nephrology and Hypertension; and on the Board of Directors at the Kidney Health Initiative, a public-private partnership between the FDA and American Society of Nephrology. Dr. Gillespie completed her residency in internal medicine at the University of North Carolina and her nephrology fellowship at Duke University Medical Center.

Dr. Gillespie worked at Quintiles for 11 years and as a Global Nephrology Lead she led CKD & ESRD trials from protocol development to trial execution, serving as a consultant to sponsors for Clinical Development Plans, Due Diligence, Regulatory submissions, Commercialization Plans, Health Economics Outcomes Research and Patient Reported Outcomes.

Dr. Gillespie serves on a few Workgroups at the KHI: Barriers to CKD patient participation in CV Trials Surrogate, Endpoints for IgA Nephropathy, and Endpoints for FSGS. She participates in several Advisory Boards and/or Stakeholder Panels including the NKF/FDA/EMA Workshop on Renal Endpoints (Stakeholder Committee and invited participant for March 2018), NKF CKD Registry (Scientific Advisory Board), UNC's PCORI grant on Building Research Capacity in the Dialysis Community (Stakeholder Advisory Panel), and the global Standardized Outcomes for Nephrology (SONG) Initiative.

Scott Grant (Vascular Dynamics INC., USA)

Scott Grant is a proven global market development and commercial operations executive with more than 30 years of experience in the medical device industry. His management and advisory work has encompassed both large and emerging technology companies in the areas of sales, market development, product development, clinical research and training. His corporate experience has included serving in Vice President positions at Nuvaira, Broncus Technologies, Inc., and Emphasys (acquired by Pulmonx) where he oversaw clinical trials, product launches, reimbursement strategy and global sales distribution.

Earlier in his career, Mr. Grant worked with medical device companies, Perclose (acquired by Abbott Vascular) and ACS (acquired by Guidant), throughout the world gaining invaluable clinical, sales and market development experience in the US, Europe, and Asia. Mr. Grant holds a Bachelor of Science degree in Health Management Services from Indiana University School of Medicine.

Ida Grundberg (Olink, USA)

Ida Grundberg received her PhD at Uppsala University from the prestigious research group which developed Olink's key technology and founded Olink. She continued as senior scientist at Olink for commercialization of the patented technology developed during her PhD. Following the market release of Olink´s multiplex product, Dr. Grundberg joined the commercial side and in 2015 she transferred to head the U.S. market entry for her scientific understanding of Olink's products, coupled with commercial experience.

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)

She is a Global Medical Director and Clinical Program Lead Diabetes & Nephrology at Boehringer Ingelheim.

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.

Mark Houser (AstraZeneca, USA)

Mark Houser is a former Academic Nephrologist with 20 years' experience in the Pharmaceutical Industry. He worked in multiple positions at Ortho Biotech in the Procrit Franchise, was CMO of a startup focusing on Catheter-related Blood Stream Infections and CKD Progression, Led Renal Development at Abbott/AbbVie including projects in Acute Kidney Injury and the Atrasentan Program culminating in the initiation of the pivotal SONAR study. Mark is currently Global Clinical Lead for the Roxadustat program at AstraZeneca.

Robert Huizinga (Aurinia Pharma, 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.
Rob 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).

Frank Hurst (FDA, USA)

Frank Hurst is currently a medical officer in the Renal Devices Branch at the Center for Devices and Radiological Health, the group responsible for the regulation of hemodialysis devices as well as other extracorporeal technologies at FDA. He is a Commander in the US Public Health Service, a part-time staff nephrologist at the Walter Reed National Military Medical Center, and an Adjunct Associate Professor in the Department of Medicine at the Uniformed Services University of the Health Sciences in Bethesda, MD. He completed his internship and residency in Internal Medicine at Tripler Army Medical Center in Honolulu, HI and his nephrology fellowship at the Walter Reed Army Medical Center in Washington, DC. He served as a staff nephrologist at the Walter Reed Army Medical Center prior to transitioning to FDA.

Meg Jardine (Sydney, AUS)

Meg Jardine is an A/Professor and 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 practicing nephrologist.
She 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 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.
A/Prof 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 focused on investigating the progression and complications of kidney disease and diabetes through epidemiological analyses of large scale datasets and the development and implementation of randomized clinical trials.

Rahul Kakkar (Corvidia, USA)

Rahul Kakkar is a founder and leads the clinical and strategic development activities at Corvidia Therapeutics. Rahul was Director for Emerging Innovations at AstraZeneca, responsible for preclinical through Phase 2 clinical studies both for compounds within the AstraZeneca pipeline and compounds to support out-licensing efforts enabling the raise of over $85M in venture-backed capital. He is a founder of multiple biotechnology and digital medicine startup companies. Rahul dual-trained via the American Board of Internal Medicine Fast Track program in molecular biology and clinical cardiology. His research at the Brigham and Women's and Massachusetts General Hospitals as well as TIMI Group in Boston focused on immune signaling and novel biomarkers in progressive heart failure. Rahul was a junior inductee of the Alpha Omega Alpha honor society and continues to practice critical-care medicine in Boston. Rahul received his BA/MD from Tufts University.

Paul Kimmel (NIH, USA)

Paul Kimmel directs three programs under the Division of Kidney, Urologic, and Hematologic Diseases. As director of the Acute Kidney Injury program, his 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 Therapeutics, USA)

Douglas Kling is a clinical development executive with over 20-years of experience. Doug 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.

Jay Koyner (Chicago, USA)

Jay Koyner is an Associate Professor of Medicine in the Section of Nephrology at the University of Chicago. He completed his Internal Medicine and Nephrology training at the University of Chicago Medical Center where he currently serves as the medical director of the Inpatient Dialysis Unit and Director of ICU Nephrology. His critical care nephrology research interests have focused on the utilization of plasma and urine biomarkers to improve patient risk stratification and outcomes in the setting of AKI. In addition to biomarkers, other research interests include predictive analytics, AKI following cardiac surgery, CRRT and AKI therapeutics. He has published over 80 peer-reviewed articles and book chapters on AKI and the care of patients in with kidney injury in the ICU.

Jeffrey Lawson (Humacyte, USA)

Jeffrey Lawson is a physician-scientist, practicing vascular surgery and pursuing basic, translational and clinical research. He is an innovator and leader in the fields of tissue engineering, surgical bleeding, and vascular surgery. Dr. Lawson serves as Professor of Surgery and Pathology at Duke and Chief Medical Officer at Humacyte Incorporated.

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.

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.

Alexandre Mebazaa (Paris, FRA)

Alexandre Mebazaa is Professor of Anaesthesiology and Critical Care Medicine at the Hôpital Lariboisière, University Paris 7, France.
His research interests include mechanisms of contractile impairment during acute heart failure and global studies on biomarkers in acute heart failure. He acted as member or Chair of several Steering Committees including SURVIVE, COMPOSE, TRUE-HF. He is also involved in several European and global registries on circulatory failure. He has authored or co-authored more than 200 papers and is Lead-Editor of the Acute Heart Failure textbook. Pr. Mebazaa also serves as the Chair of Department of Anesthesiology and Critical Care in Paris.

Ravindra L Mehta (San Diego, USA)

Ravindra Mehta is a Professor Emeritus of Medicine in the Division of Nephrology in the Department of Medicine at University of California San Diego where he directs the UCSD Masters in Clinical Research Program. He is an internationally recognized expert in the field of acute kidney injury (AKI). He chairs the annual International CRRT Conference that is in its 23rd year in 2018.

He is a founding member of the Acute Dialysis Quality Initiative (ADQI) and the Acute Kidney Injury network (AKIN). His research has informed the development of the RIFLE and AKIN diagnostic and staging criteria for AKI and development of KDIGO guidelines for AKI. He has spearheaded several innovative multicenter studies including the CRRT vs IHD study, PICARD network studies on AKI and several international projects supported through the NIH funded UAB/UCSD O'Brien Center for AKI research that have provided new knowledge in the field.

Robert Melder (Medtronic, USA)

Robert Melder is a Senior R&D Director and Bakken Fellow in the Coronary and Structural Heart business of Medtronic, supporting product development activities across the Cardiac and Vascular Group (CVG) and other businesses at Medtronic

A technical leader with a broad background in engineering and medicine, previously from the Harvard Medical School/MGH and the biopharmaceutical industry, providing leadership for scientific efforts across Coronary, Renal Denervation, Endovascular and Peripheral vascular areas. He frequently lectures and publishes on device performance as well as providing regulatory support for global product approvals and commercialization.

He leads a scientific service group within a major R&D division, providing multiphasic product development support from concept to post-market studies, including GLP, GMP and basic research support. He engages multiple touch points in a highly matrixed environment, providing support to Regulatory, Quality Assurance, Clinical, Marketing, Business Development, Legal departments as well as business leadership across CVG.

Susan Mendley (NIH, USA)

Susan Mendley oversees research studies related to acute and chronic kidney diseases that affect children, including congenital and acquired renal disorders.

In addition to progressive loss of renal function, these diseases impact growth, development, and lifelong potential for full rehabilitation.

Michaela Petrini (Boehringer Ingelheim, USA)

Michaela Petrini is an experienced Senior Associate Director in Clinical Development and Medical Affairs at Boehringer Ingelheim with a current focus on anticoagulation, stroke prevention and CKD.

13+ years of multifaceted pharmaceutical experience spanning clinical trials supply, clinical operations, global trial management, and medical writing.

Strong research professional skilled in all phases of clinical research across a variety of therapeutic areas including diabetes, cardiovascular disease, oncology, and pain management.

Strong project manager with experience managing complex, cross-functional research projects and a "go to" for organizational improvement initiatives. Valued as a strategic thinker and collaborator, passionate about mentorship, leadership and identifying opportunities for personal and professional growth.

A graduate of Quinnipiac University as a certified, licensed Physician Assistant with several years of hands-on Internal Medicine Experience.

Bertram Pitt (Ann Arbor, USA)

Bertram Pitt is a professor of medicine emeritus at the University of Michigan, School of Medicine. Dr. Pitt obtained his MD degree from the University of Basel in Switzerland in 1959. He completed a fellowship in cardiology at the Johns Hopkins University School of Medicine and remained on the faculty until 1977, when he left to direct the division of cardiology at the University of Michigan.

He has been chairman or co-chairman of a number of clinical trials in cardiology including:

SOLVD; ELITE I and II; Prevent; Rales and Ephesus. He is currently chairman of the steering committee of the NHLBI TOPCAT trial examining the effect of spironolactone in patients with HF and preserved LV systolic function; co-chairman of the Emphasis-HF trial examining the role of eplerenone in patients with NYHA Class II HF, chairman of Break- DHF, co-chairman of STOP-CKD, co-chairman of Exceed, co-chairman of Escape-SHF and Escape-DH F, chairman of a study evaluating the role of an aldostereone synthase inhibitor in patients with HF and is a member of the executive committee of the Accomplish trial. In addition, he serves as the chairman of the DSMB for the NHLBI HF-Action trial and has over 500 articles in peer reviewed journals.

Dr. Pitt has been a member of a number of medical organizations and has served as an advisor to the clinical trials branch of the NHLBI and a member of the FDA cardio-renal advisory board.

He has been awarded the James B. Herrick Award by the Council of Clinical Cardiology of the American Heart Association and has been elected to the Society of Scholars of the Johns Hopkins University.

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.

Alain Romero (Relypsa, USA)

Alain Romero is the head of medical and scientific affairs at Relypsa, a Vifor 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. Dr. Romero 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.

Dr. 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 twwute, 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. He is the co-founder of CardioRenal.

Prabir Roy-Chaudhury (Tucson, USA)

Prabir Roy-Chaudhury is a Professor of Medicine at the University of Arizona Health Sciences. He is also the Director of the Division of Nephrology and the Director of the Arizona Kidney and Vascular 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 disease in kidney disease patients).

Dr. Roy-Chaudhury is a 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 Cardio-Renal Society of America, the Cincinnati chapter of the National Kidney Foundation and the Medical Advisory Board of the Life Center (Ohio). A member of 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 President of the American Nephrologists of Indian Origin (ANIO).

He is the 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.

Luis Ruilope (Madrid, ESP)

Luis M. 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.

Brigitte Schiller (Satellite Healthcare, USA)

Brigitte Schiller leads Satellite's Quality and Medical Policy Strategy and oversees the clinical strategy and development of the organization to improve patient outcomes. She directs the organization's applied research efforts and serves as chief of staff for Medical Directors and referring physicians.
Brigitte is recognized among the United States' most respected experts and researchers in the area of ESRD. Even with her well-earned accolades and industry awards, she retains a compassionate,

individualized approach to patient care she developed during her training in Europe and the US as well as a private practice nephrologist and primary care physician. Dr. Schiller also serves as a Consulting Clinical Associate Professor in the Division of Nephrology at Stanford University and is frequently invited to present at national and international meetings.

Brigitte graduated summa cum laude from the Albert Ludwig University of Freiburg, Germany and completed residency and research fellowships at Rush-Presbyterian-St. Luke's Medical Center, Northwestern University and the University of Chicago in Chicago, Illinois.

Thierry Schulmann (Vifor, SUI)

Thierry Schulmann, is a "Passionate Scientific Business Manager" thanks to twenty years of marketing and business acumen, product development and medical practice.

He possess strong leadership, change management experience, communication skills as well as analytical and strategic thinking skills: Key player in building organizations and Franchises from scratch both at European and affiliate levels (Pfizer Europe and Canada, Nycomed France, Takeda Europe and Canada). Similarly developed new Business Franchises in full accountability (Respiratory at Pfizer, Pain and OTC at Nycomed, Surgical Pain at Pharmacia.)

He has demonstrated track record of successful launches in various therapeutic and competitive areas such as Arthritis, Respiratory and Cardiovascular, including several business models (Hospital, retail and OTC markets) and co-promotion partnering.

Gigi Shafai (Akebia Therapeutics, 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.

Salim Shah (Sarfez, USA)

Salim Shah is the founder and president of Sarfez Pharmaceuticals Inc, a specialty pharmaceutical company based in Virginia. He is also the Chief Scientist and a faculty member at the Georgetown University Medical Center. As faculty member, he has published numerous article on small-chemical induced allosteric changes to disrupt protein-protein interactions. Previously, Salim was the managing director of APJ laboratories (India), a generic pharmaceutical company with multiple products including injectable and anti-invectives. Salim has received his PhD in physical biochemistry and molecular biology from the Jawaharlal Nehru University, Delhi, and JD from George Mason University, Virginia. He has done an externship with Judge Daniel Davidson at the FDA and Judge Pauline Newman, the Court of Appeals for the Federal Circuit, Washington DC. He is an inventor for several patents.

Abhinav Sharma (San Francisco, USA)

Abhinav Sharma has finished his medical school and internal medicine training at McMaster University. He completed his cardiology fellowship at the University of Alberta and he is currently completing his PhD in Medicine with Dr. Justin Ezekowitz at the University of Alberta. His research focuses on the intersection of heart failure and diabetes, evaluating optimal management strategies, risk prediction, and biomarker expression. Furthermore, he is interested in the use of mobile device to accelerate clinical care and clinical trial conduct. He has completed a cardiovascular research fellowship at Duke University under Dr. Michael Felker. He is currently undergoing a clinical advanced heart failure and transplantation fellowship at Stanford University which is expected to finish in July 2018.

Amit Sharma (Akebia Therapeutics, USA)

Amit Sharma serves as a Vice President of Medical Affairs at Akebia Therapeutics, Cambridge, MA. He has held senior positions at Reata, Keryx, and Relypsa / Vifor. His previous academic positions include Assistant Clinical Professor of Medicine at the University of California, San Diego, and Assistant Professor of Medicine at the Uniformed Services University of Health Sciences in Bethesda, Maryland.

He has published in many respected peer reviewed journals and he is a well-known presenter for national and international meetings. Dr. Sharma received his medical degree from Louisiana State University Medical Center-New Orleans. He completed his residency in internal medicine from the Naval Medical Center, San Diego, California. He completed his fellowship in Nephrology and Hypertension from University of California in San Diego in 2001.

Stuart Spencer (The Lancet, GBR)

Stuart Spencer 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.

Robert Star (NIH, USA)

Robert Star is the director of the Division of Kidney, Urologic, and Hematologic Diseases, and responsible for managing a research portfolio on basic, translational, and clinical studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. The Division supports research on important health problems, including chronic

kidney disease, end-stage renal disease, diabetic nephropathy, acute kidney injury, urinary incontinence, urinary tract infections, urologic chronic pelvic pain syndromes, hematopoiesis, hemoglobin disorders, sickle cell disease, and iron deficiency. The Division provides researchers with resources that advance the study of the kidney, urinary tract, and blood– for example, databases, registries, repositories, and scientific tools. His responsibilities also include oversight of programs that support the training and career development of individuals committed to academic and clinical research in these areas.

As senior investigator and chief of the Renal Diagnostics and Therapeutics Unit, Dr. Star leads a team that studies sepsis and acute kidney injury (AKI)– both are associated with high rates of illness and death. The team focuses on identifying markers to detect and therapies to treat or prevent sepsis and AKI. Their recent research findings include: models of sepsis and sepsis-AKI that better mimic human disease; how chronic kidney disease amplifies sepsis mortality and changes the mechanisms of sepsis; demonstrations of individual and combination agents that show promise for inhibiting sepsis and renal injury; and development of several imaging methods that could serve as noninvasive diagnostic tools to detect renal dysfunction.

Joseph William Stauffer (Cara Therapeutics, USA)

Joseph Stauffer is the Chief Medical Officer at Cara Therapeutics. He joined the industry in 2002 and has served as CMO in both public and private biopharma companies.

Dr. Stauffer began his pharma career as Global Medical Director at Abbott Laboratories. Prior to Abbott he worked at FDA as a Medical Review Officer in the Anti-Inflammatory & Analgesic Division of the CDER. He has served as an expert clinical research reviewer for the European Commission and has spoken internationally on topics ranging from clinical development, medical affairs, investor relations and the FDA regulatory process.

Dr. Stauffer has over 20 years of medical practice and clinical research experience. He practiced clinically for eight years, first as a Navy general medicine physician and then as an Anesthesiologist. He completed residency training in Anesthesiology & Critical Care Medicine at the Johns Hopkins University Hospital and maintained an appointment as part-time Assistant Professor in the Department of Anesthesiology and Critical Care Medicine at the Johns Hopkins University School of Medicine until 2016. He received his MBA from a joint program (TRIUM) between New York University, Stern School of Business, London School of Economics (LSE) and HEC (Hautes Etudes Commerciales) School of Management in Paris.

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.

James Strickland (FAST BioMedical, USA)

James Strickland is the President and Co-Founder of FAST BioMedical. Based in Indianapolis, Indiana, FAST BioMedical is a clinical-stage company with a novel technology for measuring GFR and plasma volume. Mr. Strickland has extensive experience developing new medical technologies, including designing and conducting clinical studies in the renal, cardiovascular, and orthopedic fields.

Joachim Struck (Sphingotec, GER)

Since 2013, Dr. Struck is Head of Research & Development at Sphingotec GmbH (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 >150 peer-reviewed scientific publications and co-inventor of >50 patent families.

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 John 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.

Katherine Tuttle (Washington, USA)

Katherine R. Tuttle is the Executive Director for Research at Providence Health Care and the regional Principal Investigator for the Institute of Translational Health Sciences, established Investigator at the Kidney Research Institute, and clinical Professor of Medicine in the Nephrology Division at the University Of Washington.

Dr. Tuttle has been a Chair for numerous major initiatives and programs, including: Institutional Review Board - Spokane (1999-2012), National Kidney Foundation - Kidney Disease Outcomes Quality Initiative for Diabetes and Chronic Kidney Disease (2004-2012), National Diabetes Education Program (2006-2011), Diabetes and Chronic Kidney Disease Consensus Conference of the American Diabetes Association (2014), National Kidney Foundation Young Investigator Awards (2014), International Society of Nephrology - World Congress of Nephrology (2017), Kidney Health Initiative Stakeholders Annual meeting (2017-2018). She has received numerous honors and awards such as the Garabed Eknoyan Award from the National Kidney Foundation (2017), the YWCA Woman of Achievement Award in Science (2009), and two Outstanding Clinical Faculty Awards at the University of Washington (1992, 2012). Dr. Tuttle serves on the Board of Directors for the Kidney Health Initiative and was Associate Editor for the Clinical Journal of the American Society of Nephrology from 2011-2016.

Melissa West (KHI, 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.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.

Christopher Wilcox (Washington, USA)

Christopher Wilcox received his MD from Oxford University, PhD in renal physiology from London University and specialist training in medicine, neurology, nephrology and hypertension at St. Mary's Hospital, London, UK. He has held faculty appointments at London and Cambridge Universities in the UK, Yale, Harvard and Florida Universities in the USA.

For the last 23 years, he has been a Professor of Nephrology, Chief of the Division and Director of the Hypertension Center at Georgetown University, USA. He is a Fellow of the Royal College of Physicians (UK), a Fellow of the Royal Society of Medicine (UK) and a Master of the American College of Physicians. He has published two books (in their third and sixth editions) and 300 papers. His work is supported by four grants from the National Institutes of Health for $15,000,000.

He holds two patents for new drugs. He directs a clinical faculty of five physicians, a research faculty of eight scientists (six trained in China), and 10 post-doctoral scientists or clinical nephrology fellows. Dr Wilcox' research interests include developing new drugs for hypertension or edema and the renal mechanisms of hypertension. He directs a basic science laboratory and a clinical research program.

Caroline Wilkie (Punta Gorda, USA)

Caroline Wilkie is a nocturnal home hemodialysis patient of 8 years, who is heavily involved in volunteer work with the National Kidney Foundation, and Kidney Health Initiative. Caroline is a member of the National Kidney Foundation's (NKF) Kidney Advocacy Committee and the NKF PEERS program. She is a member of the Kidney Health Initiative's (KHI) Patient and Family Partnership Council. She served on a KHI steering committee workgroup project entitled: "Prioritizing Symptoms of ESRD Patients for Developing Therapeutic Interventions."

She worked on a PCORI Project as part of the investigative team entitled: "Building Research Capacity in the Dialysis Community at the Local Level." She is also one of the co-chairs on a new KHI project entitled: "Fostering Innovation in Fluid Management," which focuses on new strategies for management of hypervolemia. She and her husband, Jeff Kuhns, reside in Southwest Florida.

Dan Wilson (Relypsa – Vifor, USA)

Dan 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.

Following 25 years of academic and clinical practice, Dr. Wilson joined Pfizer Global Pharmaceuticals in 2001 as a member of the Cardiovascular -- Regional Medical Research Specialist (RMRS) team. As a field-based Medical Director he focused on developing, and implementing innovative medical strategies in support of cardio-renal therapeutics. Dan was promoted to Senior Medical Director at Pfizer in 2007. In 2012 Dan joined Pfizer Clinical Affairs, as The PRECISION Study team as a Study Clinician and Medical Lead. He provided medical oversight, safety monitoring and quality management for the 24,000 subject clinical trial. Dr. Wilson has authored or co-authored multiple scientific abstracts, posters, articles and book chapters in cardiovascular disease, hypertension and nephrology. He is board certified In Internal Medicine and Nephrology. He is currently a fellow in the American College of Physicians, and the American College of Chest Physicians.

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.

Faiez Zannad (Nancy, FRA)

Faiez Zannad is Professor of Therapeutics at the University of Lorraine in Nancy, France. He earned his MD degree and cardiology specialty at the University of Lorraine in 1979 and PhD degree in clinical pharmacology at the University of Lyon in Lyon, France, in 1984. Pr Zannad is currently Head of the Division of Heart Failure and Hypertension and Director of the Inserm Clinical Investigation Center at "Institut Lorrain du Coeur et des Vaisseaux" in the Centre Hospitalier et Universitaire of Nancy.

Pr Zannad coordinates two EU FP7 grants in heart failure: HOMAGE (omics biomarkers for mechanistic phenotyping and prediction of drug response [www.homage-hf.eu]) and FIBROTARGETS (fibrosis as a biotargets [www.fibrotargets.eu]). As the primary investigator or member of the oversight committees in major clinical trials, Pr Zannad has made significant contributions to evidence-based heart failure life-saving therapy, mainly with beta-blockers (CIBIS) and mineralocorticoid receptor antagonists (RALES, EPHESUS, EMPHASIS-HF). He pioneered cardiovascular outcome trials in chronic kidney disease (FOSIDIAL, AURORA, ALCHEMIST) and the one of the first cardiovascular safety trials on glucose-lowering drugs in diabetes (EXAMINE).

He was Founder and is currently Chairman of the Global CardioVascular Clinical Trialists (CVCT) Forum and Workshop, an annual international meeting dedicated to the science of clinical trials, and of the International Workshop on Biomarkers in heart failure. He has authored more than 550 scientific publications.

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