CVCT WASHINGTON, DC US

Maison Française, French Embassy

20th Global Cardio Vascular Clinical Trialists Workshop

Course Directors:

Faiez ZANNAD, Nancy - FRA, Bertram PITT, Ann Arbor - USA

DECEMBER

2017 SUNDAY 3 - MONDAY 4

www.globalcvctforum.com

20th Global Cardio Vascular Clinical Trialists Workshop

Summary

CVCT WASHINGTON, DC US

20th CardioVascular Clinical Trialists Workshop

Introduction

3 December 2017
French Embassy, 4101 Reservoir Rd NW, Washington, DC

Dear all,

Welcome to the 20th Global CardioVascular Clinical Trialists Workshop, an intimate gathering of international experts at which we discuss crosscutting issues in trial design, implementation and interpretation.

We are delighted to welcome you to this two-day session, where we foster an international exchange of ideas following our three-day Forum sessions. The unique organization of the CVCT Workshop allows for a free and open exchange among cardiovascular trial principal investigators, statisticians, R&D experts and regulators from the major transatlantic agencies.

During our time together we have the opportunity to brainstorm on CV drugs, device and biomarker development and trial design, conduct, ethics, interpretation, approvability and implementation.

We aim to advance the science of controlled clinical trials that will contribute to better clinical care and understand the problems associated with making decisions about what constitutes relevant information, how to improve clinical trials and how to satisfy regulatory authorities and payers.

Moderators have accepted the critical task to keep time and give each participant a chance to be involved. To assist them, we kindly ask for yoru full engagement and attendance at the entirety of the two-day Workshop.

It is our pleasure to continue this work with each of you.

With our best regards,

Faiez Zannad

Bertram Pitt

General information

VENUE OF THE CONGRESS

Embassy of France

4101 Reservoir Rd NW
Washington D.C. 20007
USA

ON SITE CONTACTS

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

LOGISTIC AND TECHNICAL ORGANIZATION

OVERCOME

13 – 15 Rue des Sablons
75116 Paris Cedex, France
Tel: +33 (0)1 41 92 01 20
US Tel: +1 415 839 8874

SCIENTIFIC SECRETARIAT

FAIEZ ZANNAD

Personal Assistant: Stéphanie GROJEAN
EDDH - European Drug Development Hub, Fondation Force
2, Rue du Doyen Jacques Parisot BP7
54500 VANDOEUVRE LES NANCY

DINNER

Sunday, December 3, 2017

6:15 pm - we will leave directly from the embassy following the CVCT Workshop

Morton's Steakhouse Georgetown
3251 Prospect St NW, Washington, DC 20007

Scientific program

SUNDAY, DECEMBER 3, 2017

8.00 – 10.00 am ▸ **How to evaluate the net benefit of a drug or device? Net clinical benefit, balancing benefit vs. risk. Trade off between safety and efficacy.**

Moderator:
Faiez Zannad (Nancy, FRA)

Speaker:
Paul Armstrong (Edmonton, CAN)

Discussants:
Angeles Alonso Garcia (EMA, GBR)
Jeffrey Borer (New York,USA)
Robert Temple (FDA, USA)

10.00 – 10.30 am — **Coffee break**

10.30 – 12.30 pm ▸ **Data sharing: enhancing insight or creating chaos?**

Moderator:
Chris O'Connor (Washington, USA)

Speaker:
Michael Lauer (Bethesda, USA)

Discussants:
John Jarcho (NEJM, USA)
Alexandre Mebazaa (Paris, FRA)
Krishna Prasad (EMA, GBR)

12.30 pm – 1.30 pm — **Lunch break**

1.30 pm – 3.30 pm ▸ **How best could big data, meta-overview and artificial intelligence be used in clinical trials?**

Moderator:
Michael Lauer (Bethesda, USA)

Speaker: Michael Lauer (Bethesda, USA)

Discussants: Alan Fraser (Cardiff, GBR)
Yves Rosenberg (Bethesda, USA)

3.30 pm – 4.00 pm — **Coffee break**

4.00 pm – 6.00 pm ▸ **Patient advocacy, interaction with regulatory and inclusiveness in trials**

Moderator:
Roxana Mehran (New York, USA)

Speaker:
Prabir Roy-Chaudhury (Tucson, USA)

Discussants:
Marilyn Mann (Washington, USA)
Norman Stockbridge (FDA, USA)

MONDAY, DECEMBER 4, 2017

8.00 – 10.00 am ▸ **Pragmatic trials, large, simple and cheap RCT. The good the bad, the future**
Moderator:
Milton Packer (Dallas, USA)

Speaker: Nancy Geller (Bethesda, USA)

Discussant: Bertram Pitt (Ann Arbor, USA)

10.00 – 10.30 pm **Coffee break**

10.30 – 12.30 pm ▸ **Role of media in communicating clinical research results.**

Moderator:
Bertram Pitt (Ann Arbor, USA)

Speaker:
Larry Husten (CardioBrief, USA)

Discussants:
Ron Winslow (Freelance Writer, USA)

12.30 pm – 1.30 pm **Lunch break**

1.30 pm – 3.00 pm ▸ **Adaptive designs. Should all trials be adaptive? Bayesian methods**

Moderator:
Janet Wittes (Statistics collaborative, USA)

Speaker:
Stuart Pocock (London, GBR)

Discussants:
Nancy Geller (Bethesda, USA)
Cyrus Mehta (Boston, USA)
Sue Jane Wang (FDA, USA)

3.00 pm – 4.30 pm ▸ **Non-RCT evidence generation. Would improving post approval real world evidence generation fill the gap?**

Moderator:
Angeles Alonso (EMA, GBR)

Speaker:
Yves Rosenberg (Bethesda, USA)

Discussants:
Janet Wittes (Statistics collaborative, USA)

Faculty

Kirkwood Adams (Chapel Hill, USA)

Kirkwood F. Adams Jr., M.D., is Associate Professor of Medicine and Radiology in the Division of Cardiology, University of North Carolina at Chapel Hill, where he founded and for many years directed the UNC Heart Failure Program and served as the first transplant cardiologist for two decades. Dr. Adams has been involved in more than 130 completed grant- and industry-funded research projects, and he is currently leading or participating in multiple drug development trials, several registry and database studies, and NIH/NHLBI-funded trials. Dr. Adams is the principal investigator for the national multicenter database group, UNITE-HF, which focuses on registries of patients with heart failure. In addition to drug development for acute and chronic heart failure, his current research interests are heavily focused on personalized medicine with ongoing projects related to novel biomarkers for heart failure, pharmacogenomics of heart failure therapeutics, and biomarker guided therapy for improving outcomes in CHF. He is very actively involved on the Executive Committee for the NHLBI sponsored trial of NT-proBNP guided therapy known as the GUIDE-IT Trial.

Angeles Alonso Garcia (EMA, GBR)

Angeles Alonso Garcia is a Senior Medical Assessor in the Medicines and Healthcare products Regulatory Agency (MHRA) Cardiology Member of the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) Active member of the Scientific Advice Working Party Honorary Consultant in Cardiology. Imperial College Healthcare. NHS. United Kingdom, since 2014.

Dr Alonso graduated from the School of Medicine at the Universidad Autónoma de Madrid (1979). PhD at the Medical School (1991).

Staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid), since 1987 until 2013 with several posititons: Head of the Coronary Care Unit (1987-2000). Senior Consultant as a Clinical Cardiologist (involved in clinical trials on Heart Failure, Ischaemic Heart Disease and Cardiovascular Prevention) 2000- 2013. Member of the Committee for Ethics and Clinical Investigation (2000-2009).

General Secretary of the Spanish Society of Cardiology: 2001-2003 and President of the International Relations Department of the Spanish Society of Cardiology and Member of the Editorial Committee of the Spanish Heart Journal. Fellow of the European Society of Cardiology since 2001. Nucleus member of Cardiovascular Pharmacology Working Group.

Paul Armstrong (Edmonton, CAN)

Paul Armstrong is a Distinguished University Professor at the University of Alberta. He serves in a broad range of consultative, editorial, and research leadership roles and is the recipient of numerous awards for scholarly and societal contributions. He publishes extensively, frequently lectures in national and international academic forums, and plays an active leadership role in the conduct of a number of ongoing cardiovascular clinical trials and data safety monitoring boards. He serves as an associate editor for the Journal of the American College of Cardiology and Circulation: Heart Failure, a guest editor for the American Heart Journal, Circulation and JACC Heart Failure, and is a member of several editorial boards including those of the American Heart Journal, the European Heart Journal, JAMA Cardiology and Circulation. Dr. Armstrong's commitment to the education, training, and mentoring of healthcare professionals, research trainees, and faculty spans over 40 years and is a key signature of his career. He is internationally recognized for his expertise in acute coronary disease and heart failure and has a particular interest in novel approaches to the design of clinical trials and their interpretation. Dr. Armstrong is the founding Director of the Canadian VIGOUR Centre (Virtual Coordinating Centre for Global Collaborative Cardiovascular Research), a University of Alberta Research Centre devoted to enhancing cardiovascular health for current and future generations through the conduct of innovative clinical investigations. He was the founding President of the Canadian Academy of Health Sciences (CAHS) and is a Fellow of the Royal Society of Canada.

Elisabeth Bjork (AstraZeneca, SWE)

Elisabeth Björk is Vice President and global head of late phase development for Cardiovascular,
Metabolic and Chronic Kidney Disease at AstraZeneca since 2012. Prior to this, Elisabeth led the development of Dapagliflozin (FORXIGA), a first-in-class diabetes drug and has also been involved in the development of several other key products/drugs.
In 2014, Elisabeth moved back to Sweden after spending seven years in the US at the
AstraZeneca US R&D site. She was then appointed scientific leader for the research site at Gothenburg. Elisabeth is an endocrinologist by training and an associate professor of medicine at Uppsala University, and was Head of the Diabetes and Endocrinology Unit at the University Hospital, Uppsala, before joining AstraZeneca in 2002.

Jeffrey S. Borer (New York, USA)

Jeffrey S. Borer, MD, is a Professor of Medicine, Cell Biology, Radiology and Surgery and Adjunct Professor of Public Health at the SUNY Downstate Medical Center, where for several years he was Chief, Division of Cardiology and Chairman, Department of Medicine. He now directs two research institutes. Dr. Borer's BA is from Harvard, MD from Cornell, and he trained at the Massachusetts General Hospital. He spent 7 years in the Cardiology Branch, NHLBI, and a year at Guy's Hospital(London) as Senior Fullbright Hays Scholar, completing the first clinical demonstration of nitroglycerin's utility in acute MI. Returning to the NIH, he developed stress radionuclide cineangiography, enabling the first non-invasive assessment of cardiac function with exercise. Dr Borer returned to Cornell for 30 years as Gladys and Roland Harriman Professor of Cardiovascular Medicine and Chief, Division of Cardiovascular Pathophysiology (and now is Adjunct Professor of Cardiovascular Medicine in Cardiothoracic Surgery). He performs clinical service, teaching and research, primarily development of prognosticators for regurgitant valve diseases, and assesses the effects of therapeutic heart rate modification. He has been Advisor to the USFDA for 38 years, chaired the CardioRenal Drugs Advisory Committee for three terms and the Circulatory Devices Advisory Panel for one term, was a life sciences Advisor to NASA for 24 years, has served as officer/board member of several national professional societies, has published almost 500 scientific papers and 8 books, is editor-in-chief of the journal, Cardiology, and has received several awards and other recognitions for his work.

Michael R. Bristow (Aurora, USA)

Michael R. Bristow, MD, PhD is Professor of Medicine (Cardiology) at the University of Colorado

Anschutz Medical Campus, and Director of the Section of Pharmacogenomics in the University of Colorado Cardiovascular Institute

Dr. Bristow has served as Chairman, National PI or on the Steering Committee of multiple heart failure multicenter clinical trials dating back to 1985, including MDC, BEST, U.S. Carvedilol, COMPANION and GENETIC-AF, and was the DSMB Chairman of TOPCAT. Dr. Bristow has authored more than 450 peer-reviewed papers and chapters on heart failure, cardiac transplantation, pharmacogenomics and other cardiovascular topics. He has received many academic and industry honors, including the Therapeutics Frontiers Award by the American college of Clinical Pharmacy (1993), the Pharmaceutical Research and Manufacturers of America Clinical Trial Exceptional Service Award (2008), the Lifetime Achievement Award by the Heart Failure Society of America (2008), Scientist of the Year by the ARCS Foundation (2008), University of Illinois Alumni Achievement Award, (2009) and the Distinguished Scientist Award (Translational Domain) by the American College of Cardiology (2014).

Javed Butler (New York, USA)

Javed Butler, MD, MPH, MBA, is Professor of Medicine, Professor of Physiology and Biophysics, Chief of Cardiology, and Co-Director of the Heart Institute, Stony Brook University, New York. Prior to

joining Stony Brook, he was Professor of Medicine at Emory University, Atlanta, Georgia, and prior to that, the Director of the Cardiac and Heart-Lung Transplant Programs at Vanderbilt University, Nashville, Tennessee.

He received his medical degree at Aga Khan University, Karachi, Pakistan. He completed a residency at Yale University, and then completed a cardiology fellowship and advanced heart failure and transplant fellowship at Vanderbilt University, and a cardiac imaging fellowship at Massachusetts General Hospital, Boston. He also received a Master of Public Health from Harvard University, Cambridge, Massachusetts, and a Master of Business Administration from Emory University.

Dr. Butler is board certified in cardiovascular medicine, as well as in advanced heart failure and transplant medicine. His research interests include the management and treatment of patients with heart failure. He serves on several American College of Cardiology/American Heart Association committees, on several National Institutes of Health study sections, and is a member of the Heart Failure Society of America Board of Directors. He is the recipient of the Simon Dack Award by the American College of Cardiology as well as the Time, Feeling, and Focus Award by the American Heart Association.

Dr. Butler has authored more than 440 peer-reviewed publications. He serves on the editorial board of several peer reviewed cardiovascular journals. He has been cited numerous times in America's Best Doctors list.

Lawrence Fine (NIH, USA)

Lawrence J. Fine, M.D., Dr. P.H. is the branch chief of the Clinical Applications and Prevention Branch in the Division of Cardiovascular Sciences at NHLBI. This branch administers approximately hundred active clinical trials. He was Project Officer of the SPRINT trial (https://www.sprinttrial.org/public/dspHome.cfm). He was appointed to be a member of the JNC 8. Current scholarly interests range from the prevention of coronary heart disease, efficacy studies treatment of hypertension and heart failure, better methods for patient reported outcomes and effectiveness studies of evidence based cardiovascular medicine. He is board certified in Internal Medicine.

Mona Fiuzat (Durham, USA)

Mona Fiuzat is an Associate Professor of Medicine at Duke University, Scientific Advisor at the FDA, and Executive Editor of JACC: Heart Failure, and Former Senior Scientific Advisor to the FDA Commissioner. She received her PharmD at Mercer University School of Pharmacy in Atlanta, Georgia, and has worked in clinical trials for 20 years. Dr. Fiuzat worked in the pharmaceutical industry for Solvay Pharmaceuticals and SmithKline Beecham Pharmaceuticals, and was Director of Clinical Development at ARCA biopharma, Inc. Her clinical research experience has been in cardiovascular trials with a focus on pharmacogenetics in heart failure, and she helped file an NDA for the first proposed pharmacogenetically targeted heart failure drug. She worked as a Clinical Pharmacist at the West Los Angeles and San Francisco Veterans Affairs Medical Center, and as an Adjunct Assistant Professor at the University of Southern California, University of California, San Francisco, University of Colorado, and University of North Carolina. She worked in the Heart Failure Research Program at Duke on a number of key clinical trials as an investigator and steering committee member, and has authored or co-authored over 100 papers in the field of heart failure. She holds national leadership roles with the American College of Cardiology, and as Program Co-Chair for the Heart Failure Society of America's (HFSA) Scientific Sessions, as well as Membership Co-Chair, and is now on the HFSA Board of Directors, HFSA Task Force for Research Networks and FDA liaison to the HFSA. Most recently, she developed and facilitated the "Heart Failure Collaboratory", a joint effort of government agencies, academicians, stakeholders, patients, societies and advocacy groups to impact heart failure research and therapeutic development.

Alan Fraser (Cardiff, GBR)

Alan Fraser is Consultant Cardiologist at the University Hospital of Wales, Cardiff, UK; Visiting Professor in Cardiovascular Imaging and Dynamics at the University of Leuven; and Emeritus Professor of Cardiology at the

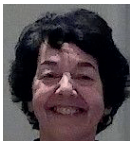
Wales Heart Research Institute, Cardiff University. He qualified in Edinburgh, undertook postgraduate training in Scotland and Wales, and was research fellow at the Thoraxcentre in Rotterdam. He is a Past-President of the European Association of Echocardiography, and he chairs the Committee on Regulatory Affairs of the European Society of Cardiology. His research interests include cardiac imaging, heart valve disease, heart muscle disease, and the pathophysiology and diagnosis of heart failure.

Wendy Gattis-Stough (Expert Medical Communication, USA)

Wendy Gattis Stough, PharmD, is Adjunct Professor of Clinical Research and Pharmacy Practice at Campbell University College of Pharmacy and Health Sciences and Owner of Expert Medical Communications and Consulting, LLC, in Cary, North Carolina.

Dr. Stough received her doctor of pharmacy degree magna cum laude from Campbell University School of Pharmacy and completed residency and fellowship training at Duke University Medical Center. She spent 10 years in full-time academics at Duke University Medical Center, where she conducted research establishing the role of the pharmacist as a valued member of the heart failure management team and maintained a clinical role on the heart failure service. She also served as a principal investigator, co-principal investigator, and project leader for numerous multicenter Phase II-IV clinical trials at the Duke Clinical Research Institute. In 2005, Dr. Stough established Expert Medical Communications and Consulting, LLC.

Dr. Stough has worked with leading professional cardiology organizations including Cardiovascular Clinical Trialists (CVCT), Investigation Network Initiative-Cardiovascular and Renal Clinical Trialists (INI-CRCT), European Society of Cardiology (ESC), Heart Failure Association (HFA) of the ESC, Heart Failure Society of America (HFSA), and the American College of Cardiology (ACC). Dr. Stough has authored or co-authored over 140 papers in peer reviewed medical journals including JAMA, European Heart Journal, Journal of the American College of Cardiology, Circulation, European Journal of Heart Failure, Archives of Internal Medicine, American Journal of Cardiology, among others.



Nancy Geller (NHLBI, 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 a number of 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 MD PhD is Global Head of Diabetes Clinical Development, Boehringer Ingelheim and Associate Clinical Professor at the University of Warwick, UK.

Leadership roles in CV Outcome Trials include: EMPA-REG-OUTCOME trial (leading to first CV indication for a glucose-lowering drug), CAROLINA (Lina vs. active-comparator), CARMELINA (in a renally enriched type 2 diabetes population) and EMPEROR-Reduced, EMPEROR-Preserved (Empagliflozin trials in heart failure with reduced and preserved ejection fractions, respectively) and the Empagliflozin outcome trial in CKD.

Fully accredited in Internal medicine with fellowships from the Royal College of Physicians and the American

College of Endocrinology, Jyothis served previously as Chief Investigator and member of OCDEM management board at the University of Oxford - an unparalleled opportunity to learn from legendary outcome triallists in diabetes (Holman, Oxford) and cardiovascular disease (Califf, Duke).

Robert Golub (JAMA Cardiology, USA)

Robert M. Golub, MD, is Deputy Editor, JAMA. His roles include oversight of the JAMA scientific content and managing the peer review process; he is also responsible for directing JAMA educational activities. He is Associate Professor of Medicine at the Feinberg School of Medicine at Northwestern University, with academic appointments in the Division of General Internal Medicine and the Department of Preventive Medicine. He served as chair of the Northwestern University Medical School Curriculum Committee. Areas of research are in medical decision making (decision analysis, cost-effectiveness analysis, psychology of decision making, and assessing patient preferences). He has served on the Board of Trustees for the Society for Medical Decision Making and as visiting faculty for the Stanford University Faculty Development Program and the University of Buenos Aires Program in Clinical Effectiveness. Dr. Golub received his undergraduate degree from Princeton University, and his MD from Columbia University College of Physicians and Surgeons. He completed his internship and residency at Northwestern University School of Medicine/Northwestern Memorial Hospital, where he also served as chief resident. He is board certified in internal medicine.

Larry Husten (CardioBrief, USA)

Larry Husten is a veteran medical journalist who writes the CardioBrief blog, which appears on CardioBrief.Org and MedPage Today. Prior to starting CardioBrief early in 2009 he was the editor of TheHeart.Org, from its inception in 1999 until December 2008. Following the purchase of TheHeart.Org by WebMD in 2005 he also served as the editorial director of WebMD professional news, encompassing TheHeart.Org and Medscape Medical News. From January 2010 until June 2015 he was a consulting editor and news director at CardioExchange, an online cardiology community published by the New England Journal of Medicine.

Before helping to start TheHeart.Org he was a freelance medical journalist who wrote for the Lancet, the New York Times, Discover, and many other medical and computer publications. In 1994-1995 he was a Knight Science Journalism Fellow at MIT. He has a PHD in English from the State University of New York at Buffalo and drove a taxicab in New York City before falling into a career in medical journalism.

Helina Kassahun (Amgen, USA)

Helina Kassahun is a Clinical Research Medical Director within the Cardiovascular and Metabolic Therapeutic Area at Amgen. She joined the team in 2014 as a Senior Medical Scientist on the Repatha program, supporting the GLAGOV (Global Assessment of Plaque Regression with PCSK9 Antibody as measured by Intravascular Ultrasound) study and leading other clinical trials. Currently, she is the clinical development lead for a new molecule in the early phase of development.

Helina earned her medical degree from Harvard Medical School and completed her internal medicine internship and residency at Johns Hopkins. She completed a fellowship in cardiovascular medicine at Weil Medical College, New York Presbyterian Hospital in New York City. Prior to joining Amgen, Helina was Assistant Professor of Medicine at the University of Minnesota and developed its PET imaging program in addition to her contribution of launching a cardiovascular CT program.

Michael Lauer (NIH, USA)

Michael Lauer, M.D., is the Deputy Director for Extramural Research at the National Institutes of Health (NIH), where he serves as the principal

scientific leader and advisor to the Director of the NIH on all matters relating to the substance, quality, and effectiveness of the NIH extramural research program and administration.

He received education and training at Rensselaer Polytechnic Institute, Albany Medical College, Harvard Medical School, Harvard School of Public Health, and the NHLBI's Framingham Heart Study. He spent 14 years at Cleveland Clinic as Professor of Medicine, Epidemiology, and Biostatistics.

During his tenure at the Clinic, he led a federally funded internationally renowned clinical epidemiology program that applied big data from large-scale electronic health platforms to questions regarding the diagnosis and management of cardiovascular disease.

From 2007 to 2015 he served as a Division Director at the National Heart, Lung, and Blood Institute (NHLBI), where promoted efforts to leverage big data infrastructure to enable high-efficiency population and clinical research and efforts to adopt a research funding culture that reflected data-driven policy.

He has received numerous awards including the NIH Equal Employment Opportunity Award of the Year and the Arthur S. Flemming Award for Exceptional Federal Service in recognition of his efforts to grow a culture of learning and accountability.

Martin Lefkowitz (Novartis, USA)

Martin Lefkowitz, MD, is Cardiovascular Therapeutic Area Head at Novartis Pharmaceuticals Corporation. Over his 20-year career, Dr. Lefkowitz has been involved in the clinical development of compounds primarily in cardiovascular medicine, including the design and execution of several major outcome trials. He has largely worked in cardiovascular medicine with a focus on heart failure, hypertension, thrombosis and coronary artery disease.

He 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. Dr. Lefkowitz was in the clinical practice of nephrology prior to joining the pharmaceutical industry.

Marilyn Mann (Patient Advocate, USA)

Marilyn Mann has family members with familial hypercholesterolemia, including her daughter who was diagnosed in 2001 at age eight. There is a family history of early heart attacks in her husband's family. She moderates an online community of FH patients and their family members, responding to questions and providing information. She is patient advisor for Circulation: Cardiovascular Quality and Outcomes, and edits a series of articles written by patients with cardiovascular disease or their family members. She was an attorney at the U.S. Securities and Exchange Commission for 23 years, until her retirement in 2014.

Alexandre Mebazaa (Paris, FRA)

Alexandre Mebazaa, MD, PhD, FESC, 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. Dr Mebazaa also serves as the Chair of Department of Anesthesiology and Critical Care in Paris.

Roxana Mehran (New York, USA)

Roxana Mehran is Professor of Medicine, Cardiology and Professor of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai is internationally renowned in the field of interventional

cardiovascular disease. As Director of Interventional Cardiovascular Research and Clinical Trials at Mount Sinai, she has developed a globally-respected data and clinical coordination center. A prolific researcher and author, she has served as principal investigator for numerous large global studies, developed risk scores for bleeding and acute kidney injury, and authored >800 peer-reviewed articles. Dr. Mehran has received numerous prestigious awards, most recently the 2017 Bernadine Healy Leadership in Women's CV Disease Award. She is co-founder of the Academic Research Consortium (ARC) and Women in Innovation (WIN), and a founding physician of the Cardiovascular Research Foundation, where she is currently Chief Scientific Officer. Prior to her position at Mount Sinai, Dr. Mehran held appointments at Columbia University Medical Center and Washington Hospital Center. She completed internal medicine training at University of Connecticut and fellowships in cardiovascular disease and interventional cardiology at Mount Sinai Medical Center.

Cyrus Mehta (Boston, USA)

Cyrus Mehta is President and co-founder of Cytel Corporation and Adjunct Professor of Biostatistics, Harvard University. Cytel (www.cytel.com) is a leading provider of software, clinical services and strategic consulting on the design, interim monitoring and implementation of adaptive clinical trials, with offices in the United States, Europe and India. Dr. Mehta consults extensively with the biopharmaceutical industry on group sequential and adaptive design, offers workshops on these topics, and serves on data monitoring and steering committees for trials in many therapeutic areas. He has over 110 publications in leading statistics and medical journals. He is a past co-winner of the George W. Snedecor Award from the American Statistical Association, is a Fellow of the American Statistical Association, and an elected member of the International Statistical Institute. He was named Mosteller Statistician of the Year by the Massachusetts Chapter of the American Statistical Association in 2000, and Outstanding Zoroastrian Entrepreneur by the World Zoroastrian Chamber of Commerce in 2002. He has received the Lifetime Achievement Award from the International Indian Statistical Association (2015) and the Distinguished Alumi Award from the Indian Institute of Technology, Bombay (2016).

Chistopher O'Connor (Washington, USA)

Christopher O'Connor is the Executive Director and CEO of the Inova Fairfax Heart and Vascular Institute, a 5-hospital center in the Northern Virginia / Washington, DC area. He is a Professor of Medicine in Cardiology at Duke University, and was previously the chief of the Division of Cardiology and director of the Duke Heart Center. Under his leadership, Duke Heart Center was ranked the #4 Heart Center in the country by U.S. News and World Report. Dr. O'Connor, who first joined the Duke faculty in 1989, is an internationally recognized cardiologist and authority on heart failure. His clinical investigations have dramatically expanded the understanding of numerous aspects of cardiac function and dysfunction, including the influence of depression and stress on heart failure patients. His research has led to profound insights into both pharmacologic and non-pharmacologic therapies to treat heart failure and has had a direct impact on the lives of thousands of patients.

Dr. O'Connor was one of the first investigators to lead initiatives to study therapies in acute decompensated heart failure, which has led to a number of novel therapeutic interventions. He was the Principal Investigator of the landmark HF-ACTION clinical trial, which studied exercise training in more than 2,000 heart failure patients, and eventually led to a change in the international guidelines, change in the national reimbursement of cardiac rehabilitation for heart failure patients by CMS, and validation of two novel biomarkers that were later approved by the FDA. Dr. O'Connor was an editor of the textbook, Managing Acute Decompensated Heart Failure, the first one published on the topic. He is currently the editor-in-chief of the Journal of the American College of Cardiology: Heart Failure, and serves on the editorial boards for several journals, including the New England Journal of Medicine, Journal of the American Medical Association, and Journal of the American College of Cardiology. Dr. O'Connor is a Fellow of the American College of Cardiology (ACC), the European Society of Cardiology (ESC), and the Heart Failure Society of America (HFSA). He has served on over 90 CEC and DSMC committees in 25 years and served as Chair or Co-Chair on more than 15 of these committees. He has an extensive record of successful mentorship of trainees and has published over 500 manuscripts. He currently serves as Editor-in-Chief of JACC: Heart Failure and is President of the HFSA.

Milton Packer (Dallas, USA)

Milton Packer is the Distinguished Scholar in Cardiovascular Science at the Baylor University Medical Center in Dallas. He has been the principal investigator of 20 multicenter trials that have evaluated novel interventions for the treatment of acute and chronic heart failure. He has served frequently as a member of government advisory committees, study sections, task forces or Data and Safety Monitoring Boards for the NIH. He served as a member of the Cardiac and Renal Drugs Advisory Committee to the US Food and Drug Administration from 1986-1992 and then as its Chair from 1997-2001, and he continues to serve on various FDA advisory committees. Dr. Packer was President of the Heart Failure Society of America from 2000-2002 and has served on numerous guidelines and standards committees for the American Heart Association and American College of Cardiology. He has received many teaching awards and has mentored dozens of young clinical investigators, many of whom have become leaders in basic and clinical research

Ileana Pina (New York, USA)

Ieana L. Piña, MD, MPH is a Professor of Medicine, Epidemiology & Population Health at the Albert Einstein College of Medicine in the Bronx, NY. Dr. Piña also serves as advisor/consultant to the Food and Drug Administrations' (FDA) Center for Devices and Radiological Health and their section of Epidemiology. Dr. Piña earned her undergraduate degree in Chemistry from the University of Miami in Florida. She completed her medical degree and cardiology fellowship at the University of Miami School of Medicine, an internal medicine residency at the University of South Florida Tampa, where she was Chief Resident, and fulfilled a surgery internship at the University of Miami Hospitals and Clinics. She earned a master's degree in public health from Case Western Reserve University School of Medicine in Cleveland, OH. Dr. Piña's research interests include transition of care in heart failure patients, and the role of natriuretic peptide-guided management for patients hospitalized for heart failure, biomarkers of myocardial stress and fibrosis in chronic heart failure, and the clinical implications of chronic heart failure phenotypes. She is the author/co-author of more than 100 publications.

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.

Stuart Pocock (London, GBR)

Stuart has been professor of medical statistics at the London School of Hygiene and Tropical Medicine since 1989. His main research interests concern randomised clinical trials, both in statistical methods for their design, monitoring, analysis and reporting, and also in collaborations on specific major trials especially in cardiovascular disease. He directs an experienced group of academic medical statisticians, who collaborate widely on clinical trials research, from planning to publication.

A particular expertise is in data monitoring and as an independent statistical center for industry-sponsored trials. Stuart and his group also research on epidemiology, especially pharmaco-epidemiology, meta-analyses, and journal reporting guidelines. Stuart's international collaborations are diverse, and include particular long-standing relationships with research institutes in Madrid and New York. He is a frequent lecturer/teacher at international conferences, workshops and short courses.

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, since 2002 initially as reviewer, progressing to the current post. His is a long-standing member of European Society of Cardiology with special interest in heart failure, CV risk factors, arrhythmias, cardiomyopathies and sudden death. Dr Prasad is a regular participant in the regulatory roundtable dialogues with European Society of Cardiology and European Heart Failure association. An active member of two EMA/CHMP working groups- cardiovascular-Diabetes WP (2008) and the Pharmacogenomics WP (2005), he has coordinated several regulatory guidelines in these areas. He is closely involved in the International Committee of harmonisation expert groups for E-14 and E-18 guidelines as Regulatory chair/ Rapporteur.

Yves Rosenberg (NHLBI, 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 was born 1969, married, 3 children, Patrick Rossignol, MD, PhD, is professor of Therapeutics, Nephrologist and Vascular medicine specialist, Deputy Director 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 largest double blind (spironolactone vs. placebo) academic cardiovascular outcome randomized controlled trial in hemodialysis (ALCHEMIST: ClinicalTrials.gov Identifier: NCT01848639) and steering committee member of several international randomized clinical trials. 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) and he is now serving as scientific advisor. Since 2016 is a Heart Failure Association of the European Society of Cardiology "Translational" and "Cardiorenal" board member. He is CardioRenal cofounder.

Prabir Roy-Chaudhury (Tucson, USA)

Prabir Roy-Chaudhury MD, PhD, FRCP (Edin) is a Professor of Medicine at the University of Arizona Health Sciences. He is also the Director of the Division

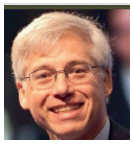
of Nephrology and the Director of the Arizona Kidney and Vascular Center. After graduating from the Armed Forces Medical College, Pune, India, he trained in Internal Medicine and Nephrology at the University of Aberdeen, Scotland and at the Beth Israel Hospital, Harvard Medical School, Boston, USA. In 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) and he currently directs the Arizona Kidney and Vascular Center. This translational research program is funded through the National Institutes of Health, the Veterans Administration research program and through industry grants. Dr. Roy-Chaudhury has also been actively involved in the public policy and administrative aspects of dialysis vascular access care and kidney disease as 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). He is 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). Dr. Roy-Chaudhury is also the American Society of Nephrology co-chair of the Kidney Health Initiative which is a public-private partnership between the ASN and the FDA.

Dan Schaber (Medtronic, USA)

Dan Schaber PharmD is Vice-President Heart Failure Clinical Research, Medtronic Inc. Dan has more than 30 years of experience in the pharmaceutical and medical device industry and is responsible for providing overall leadership and direction on a worldwide basis for new product approval, new indication approval and post market approval clinical research in heart failure. Dan joined Medtronic in 1987 from the University of Minnesota and Minneapolis Children's Medical Center where he taught respiratory and cardiovascular clinical pharmacology. He has held management positions in the clinical research, product development, regulatory and marketing organizations of Cardiac Rhythm Management in the US and in Europe. Dan is a Bakken Fellow the highest scientific and technical honor bestowed by Medtronic. He has a Doctor of Pharmacy degree from the University of Minnesota and was Pediatric Clinical Pharmacy Fellow at Minneapolis Children's Medical Center.

Stuart Spencer (The Lancet, London, 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 4 weeks of receipt. Although dealing with all areas of research, he deals with most of the cardiology submissions.After graduating Stuart moved into research which started at the Brompton Hospital, London, looking at scoliosis 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 a doctorate of medicine from Umea University, Sweden. Stuart's research expertise includes such diverse topics as, growth, neuroendocrinology, immunology and fetal development. He also had a Senior Fellowship in bioethics for 5 years. This broad research base 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



Kenneth Stein (Boston Scientific, USA)

Kenneth Stein, MD, FACC, FHRS, is Senior Vice President and Chief Medical Officer for Rhythm Management and Global Health Policy at Boston Scientific. Dr Stein is a Phi Beta Kappa graduate of Harvard College (in Economics), and earned his MD from New York University School of Medicine. He completed his medical internship and residency at The New York-Presbyterian Hospital/Weill Cornell Medical

Center, where he also completed his cardiology and cardiac electrophysiology training.
In 2009 Dr Stein held the position of Associate Director of Clinical Cardiac Electrophysiology at Weill Cornell Medical Center and Associate Professor of Medicine at Cornell University where he was widely published, authoring over 125 peer-reviewed scientific publications in the areas of cardiac electrophysiology with special interest in cardiac resynchronization therapy and risk stratification for sudden cardiac arrest. Dr Stein oversees the clinical trials, medical safety, and medical education and clinical communications for Boston Scientific's Cardiac Rhythm Management, Electrophysiology and Watchman Left Atrial Appendage Closure businesses as well as leading the corporate Global Health Policy team tasked with shaping the company's policies with respect to global health care delivery and reimbursement.
Dr Stein serves on the board of the Boston Scientific Political Action Committee and on the Scientific Advisory Board of Optum Labs. Since 2013, he has served on the board of Childrens HeartLink, a registered 501c(3) nonprofit organization that trains and mentors medical teams in underserved parts of the world to diagnose and treat children with heart disease.

Norman Stockbridge (FDA, USA)

Norman Stockbridge received his MD and PhD (Physiology) from Duke University. He did basic science research prior to joining FDA in 1991. Dr Stockbridge has been Director of the Division of Cardiovascular and Renal Products since 2004.

Jean-Claude Tardif (Montreal, Canada)

Jean-Claude Tardif is the Director of the Research Centre at the Montreal Heart Institute and Professor of Medicine at the University of Montreal. Dr Tardif graduated from the University of Montreal with his medical degree in 1987 and completed his training in cardiology and research in Montreal and Boston in 1994. Dr Tardif holds the Canada Research Chair (tier 1) in translational and personalized medicine and the University of Montreal endowed research chair in atherosclerosis. He founded the Montreal Health Innovations Coordinating Centre (MHICC) and is the Chairman of the steering committees of the CIHR funded Canadian Atherosclerosis Imaging Network (CAIN) and Medical Imaging Trials NEtwork of Canada (MITNEC).Dr Tardif and his team have created the Beaulieu-Saucier Pharmacogenomics Center at the Montreal Heart Institute and he has created the Center of Excellence in Personalized Medicine (CEPMed), the latter funded by the Network of Centers of Excellence (NCE) of Canada and which is also supported by multiple pharmaceutical and biotechnological companies. Dr Tardif has won multiple awards during his career, including the Research Achievement Award of the Canadian Cardiovascular Society, the Distinguished Lecturer Award of the Canadian Institutes for Health Research, the Genesis Award of Bio-Québec (for his outstanding contributions to life sciences) and the Armand-Frappier Award of the Government of Quebec, the highest scientific award in Quebec. He was also named scientific personality of the year by La Presse newspaper. Because of his accomplishments, In 2014, he was inducted into the Order of Canada, the highest distinction in the country.

Robert Temple (FDA, USA)

Robert Temple has been Deputy Center Director for Clinical Science at FDA's Center for Drug Evaluation and Research since 2009, participating in the direction of the Center's operations. He is also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr Temple served as Director, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of promotion through the Office of Prescription Drug Products (formerly, Division of Drug Marketing, Advertising, and Communication) and for assessing quality of clinical trials. Dr Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using "enrichment" designs.

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. Dr. Thompson has served on several CDER biomarker qualification review teams and has been involved in larger efforts to define an evidentiary framework for CDER biomarker qualification. 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

Benoît Tyl (Servier, FRA)

Director of Cardiovascular Translational Research at Servier. He is a cardiologist with 13+ years of experience in pharmaceutical industry R&D as well as in clinic. Within SERVIER, he worked recently on several projects related to ischemic cardiomyopathies. He serves now as director of translational cardiovascular R&D within the company.

Bernard Vasseur (FDA, USA)

Bernard Vasseur MD has been a cardiothoracic surgeon for 20 years. Early on in his education at the Broussais hospital, he developed an interest in the study of mechanical heart devices. He completed his general surgery residency at the Yale University School of Medicine and his cardiothoracic surgery fellowship at The Cleveland Clinic Foundation. Dr Vasseur began a clinical practice, first at the University of Medicine and Dentistry of New Jersey and then in private practice in Pennsylvania. He then spent one year in France working as both a senior cardiac surgeon and a percutaneous valve fellow in the department of cardiology at the European Hospital and has witnessed the closing gap between the surgical and medical specialties. This has complemented his lifelong interest in the understanding of cardiac valves. He joined the Office of Device Evaluation at the FDA in 2015

Sue-Jane Wang (FDA, USA)

Dr. Sue-Jane Wang is Associate Director in Office of Biostatistics (OB), OTS/CDER/FDA. She is also the Biostatistics Liaison to Office of New Drugs (OND) for the FDA/CDER Biomarker Qualification Program. Dr. Wang has served Office Associate Director for Adaptive Design from 2005-2015. During her tenure on the adaptive design topic, Dr. Wang, representing OB under Office Director's leadership in coordination with OND, had provided CDER educational case sharing on regulatory review experiences using several real case submissions to CDER scientists from 2006-2011. She has also received a FDA/CDER group award for creating and publishing comprehensive draft guidance on adaptive designed clinical trials for implantation by the Agency in 2011. She has performed an internal survey on adaptive design proposals/implementations before and after the release of adaptive design draft guidance in 2013. Currently, she is helping the Biometrics Division that is responsible for cardio-renal, neurology, and psychiatry products, and medical imaging.

Ron Winslow (Freelance Journalist, USA)

Ron Winslow is a freelance journalist who recently retired from The Wall Street Journal where he was a reporter and editor for nearly 34 years. During his WSJ career, he covered the development of statins, stents and other technologies that have transformed treatment of heart disease over the past 25 years. He

is a winner of the Victor Cohn Prize for Excellence in Medical Science Reporting. His work has also been recognized by the Association of Health Care Journalists (AHCJ), the New York Press Club, the American Heart Association and other groups. He was co-chair of the 10th World Conference of Science Journalists, held in San Francisco in October 2017. He is a past president of the National Association of Science Writers and a founding board member of the AHCJ. Most recently his work has appeared in STAT, the online medicine and health publication owned by the Boston Globe

Janet Wittes (Washington, 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). Her 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 been a regular member of the Circulatory Devices Advisory Panel and has served as an ad hoc member of several other panels. Currently, she is a regular member of the Gene Therapy Advisory Committee. She was formerly Editor in Chief of Controlled Clinical Trials (1994-98). She received her Ph.D. in Statistics from Harvard University.

Faiez Zannad (Nancy, FRA)

Faiez Zannad is Professor of Therapeutics at the University of Lorraine, 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", Nancy, France. He is a cardiologist and heart failure (HF) specialist with a PhD in clinical pharmacology (Oxford, UK).Professor Zannad leads two EU FP7 granted programs: HOMAGE (omics biomarkers for mechanistic phenotyping and prediction of drug response [www.homage-hf.eu]) and FIBROTARGETS (fibrosis as a biotarget [www.fibrotargets.eu]). As the primary investigator, or member, of oversight committees of major clinical trials, he pioneered and/or made significant contributions to evidence-based therapy for HF (mainly mineralocorticoid receptor antagonists [RALES, EPHESUS, EMPHASIS-HF] and beta-blockers [CIBIS]) as well as for major comorbid diseases in HF (such as sleep disordered breathing [SERVE-HF], autonomic nervous dysfunction [NECTAR-HF, BEAT-HF], diabetes [EXAMINE, EMPEROR], hyperkalemia [PEARL-HF], chronic kidney disease [FOSIDIAL, AURORA, ALCHEMIST], and thrombosis [COMMANDER-HF]).He served as Chairman of the French Society of Hypertension, Chairman of the European Society of Cardiology (ESC) Working Group on pharmacology and drug therapy, and board member of the Heart Failure Association (HFA) of the ESC. He is the founder of, and is currently organizing, the Global CardioVascular Clinical Trialists (CVCT) Forum and Workshop; an annual international think tank gathering, dedicated to the science of clinical trials, with meetings in Paris and Washington DC, and in the Middle East and Asia. Professor Zannad has published more than 600 peer-reviewed papers, and several books and book chapters. He was awarded the 2014 European Society of Hypertension Paul Milliez Award and the 2017 Lifetime Achievement Award from the HFA of the ESC.

Bram Zuckerman (FDA, USA)

Bram Zuckerman is a graduate of the Boston University Medical School. He completed postgraduate training in internal medicine at Baltimore City Hospital and cardiology at the John's Hopkins program. Prior to joining the FDA in 1992, he was involved in basic research in emodynamics at the University of Colorado Medical School and practiced noninvasive and invasive cardiology in Denver, Colorado and Northern Virginia. He joined the FDA Division of Cardiovascular Devices (DCD) as a Medical Officer in 1992 and has been actively involved in development and review of clinical trials for many new cardiovascular devices. In May 2001 he was appointed a Deputy Director in DCD. Then in September 2002 he was appointed to his current position as Director of the FDA Division of Cardiovascular Devices.