CVCT WASHINGTON, DC US

Maison Française, French Embassy

# 18th Global Cardio Vascular Clinical Trialists Workshop

**Course Directors:**

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

## DECEMBER 2015

## SUNDAY 6 & MONDAY 7

www.globalcvctworkshop.com



Instituts thématiques Inserm Institut national de la santé et de la recherche médicale

UNIVERSITÉ DE LORRAINE

NIH National Heart, Lung, and Blood Institute

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

FDA

# 18th Global Cardio Vascular Clinical Trialists Workshop

Summary



CVCT WASHINGTON, DC US

18th CardioVascular Clinical Trialists Workshop

# Introduction

**6 December 2015**
**French Embassy, 4101 Reservoir Rd NW, Washington, DC**

Welcome to the 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 our exceptional expert faculty and partners from Inserm, NHLBI, FDA and EMEA, who join other important stakeholders from academia, as well as the pharmaceutical and device industry.

Now in its 18th edition, the CVCT Workshop provides an opportunity for a free exchange among cardiovascular trial principal investigators, statisticians, pharma R&D experts and regulators from the major transatlantic agencies. Over two days, we brainstorm on CV drugs, device and biomarker development and trial design, conduct, ethics, interpretation, approvability and implementation.

Following the meeting, we aim to:

- produce relevant data from controlled clinical trials that will contribute to better clinical care
- understand the problems associated with making decisions about what constitutes relevant information, how to improve clinical trials and how to satisfy regulatory authorities

We welcome your voice at the table as we foster an international exchange of ideas – and perhaps innovative thought leadership.

I ask that moderators pay close attention to timekeeping in order to allow ample time for a robust discussion. Further, it is kindly requested that participants remain with us for the entirety of the Workshop, two full days on Sunday 6 and Monday 7 December.

With my best regards

**Faiez Zannad**

# General information

## VENUE OF THE CONGRESS

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

## ON SITE CONTACTS

Mary GILLIVER: +1 407 747 2247

Patrick WAHBY: +33 (0)6 21 02 74 02

## 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**
3-5, boulevard Paul-Emile Victor
92523 Neuilly-sur-Seine cedex, France
Tel: +33 (0)1 41 92 01 20
US Tel: +1 415 839 8874
Email: cvct@overcome.fr

## SCIENTIFIC SECRETARIAT

**FAIEZ ZANNAD**
Personal Assistant: Stéphanie GROJEAN
**EDDH - European Drug Development Hub, Fondation Transplantation**
2, Rue du Doyen Jacques Parisot BP7
54500 VANDOEUVRE LES NANCY
Tel: +33 (0)3 83 50 19 21
Email: cvct.zannad@chu-nancy.fr

## DINNER

**Sunday December 6th,2015**

**6.30 pm** - Meet in the Lobby of the Georgetown Inn at 7:15 for a transfer by coach to a cosy dinner with a French touch at Bistrot Lepic.

Patrick WAHBY: +33 (0)6 21 02 74 02

# Scientific program

## SUNDAY 6 DECEMBER 2015

**8.30 – 10.30 am**

1

**Meta-analyses: getting ever more complex, and still many are of poor quality. Can journals agree on a set of standards of publishable meta-analyses?**

**Chairperson: Faiez Zannad (Nancy, FRA)**

Speaker: David DeMets (Madison, USA)
Discussants: John Jarcho (Boston, USA); Hubert Pouleur (Pfizer, USA)

**10.30 – 11.00 am** — Coffee break

**11.00 – 1.00 pm**

2

**The primary endpoint is negative: what next?**

**Chairperson: Marc Pfeffer (Boston, USA)**

Speaker: Stuart Pocock (London, GBR)
Discussants: Yves Rosenberg (NHLBI, USA); Hans-Juergen Woerle (Boehringer Ingelheim, GER)

**1.00 pm – 2.00 pm** — Lunch break

**2.00 pm – 4.00 pm**

3

**The primary endpoint is positive: is that good enough?**

**Chairperson: Christopher O'Connor (Washington, DC, USA)**

Speaker: Jean-Claude Tardif (Montréal, CAN)
Discussants: Milton Packer (Dallas, USA); Stuart Pocock (London, GBR); Robert Temple (FDA, USA)

**4.00 pm – 4.30 pm** — Coffee break

**4.30 pm – 6.00 pm**

4

**Mode of data sharing within and among regulatory agencies, among DSMBs, among IRBs**

**Chairperson: Jeffrey Borer** (New York, USA)

Speaker: Bertram Pitt (Ann Arbor, USA)
Discussants: Pieter De Graeff (EMA, NED); Ellis Unger (FDA, USA); Janet Wittes (Washington, DC, USA);

## MONDAY 7 DECEMBER 2015

**8.30 – 10.30 am** ▸ 5

**New models of clinical trials leveraging electronic health records: opportunities and challenges**

**Chairperson: Yves Rosenberg (NHLBI, USA)**

Speaker: Christopher O'Connor (Washington, DC, USA)
Discussants: Hubert Pouleur (Pfizer, USA); Monica Shah (NHLBI, USA)

**10.30 – 11.00 am** — Coffee break

**11.00 – 1.00 pm** ▸ 6

**Global CV device trials, regional differences and impact on approvability**

**Chairperson: Roxana Mehran (New York, USA)**

Speaker: Bram Zuckerman (FDA, USA)
Discussants: Ileana Piña (New York, USA); Ken Stein (Boston Scientific, USA)

**1.00 pm – 2.00 pm** — Lunch break

**2.00 pm – 3.30 pm** ▸ 7

**Gender representation issues in trials. Why are females underrepresented in trials? Should we, and how to take action?**

**Chairperson: Angeles Alonso (EMA, GBR)**

Speaker: Roxana Mehran (New York, USA)
Discussants: Amany El-Gazayerly (EMA,NED); Karen Hicks (FDA, USA)

**3.30 pm – 4.00 pm** — Coffee break

**4.00 pm - 5.30 pm** ▸ 8

**Irreproducibility in clinical trials: causes, consequences and possible cures**

**Chairperson: Janet Wittes (Washington, DC, USA)**

Speaker: Milton Packer (Dallas, USA)
Discussant: Tomas Andersson (AstraZeneca, SWE); Nancy Geller (NHLBI, USA)

# Faculty

## **Angeles Alonso** (EMA, GBR)

Honorary Consultant in Cardiology. Imperial College Healthcare. NHS. United Kingdom

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 in the European Society of Cardiology. Active member in the Spanish Society of Cardiology.

Dr. Alonso graduated from the School of Medicine at the Universidad Autónoma de Madrid (1979). Ph.D at the Medical School (1991). Staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid), since 1987. 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- 2012. Member of the Committee for Ethics and Clinical Investigation (2000-2009). Coordinator, Chairperson and speaker of several post-degree Ph D Courses at the Academic Hospital Puerta de Hierro de Madrid since 1986.

Member of the Heart Failure, Ischemic Diseases, Women and CV Disease, Pharmacology Working Groups of the Spanish Society of Cardiology, General Vice-Secretary elect of the Spanish Society of Cardiology: 1999-2001, 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, currently involved in several proyects with the European Society of Cardiology (Clinical Guidelines, Cardiovascular Round Table, Congress Program Committee, Registries and Pharma Working Group).

## **Tomas Andersson** (AstraZeneca, SWE)

Tomas Andersson, MD, PhD, is Vice President, Clinical Cardiovascular and Chronic Kidney Disease, AstraZeneca, heading up the medical teams for late phase clinical development in these areas.

Dr Andersson obtained his MD degree at Lund University, Sweden in 1991, and his PhD in 1990. He was post-doctoral research fellow at The William Harvey Research Institute in London (GBR), 1992-1994, and subsequently became Board Certified as specialist in Clinical Pharmacology at the University Hospital, Lund, Sweden. Dr Andersson has a long standing interest in cardiovascular pharmacology and late phase drug development, having worked in senior positions in both Cardiovascular/CKD and Respiratory with Brilinta and Symbicort. Recently he was medically responsible for the readout, interpretation and regulatory submission of the Pegasus study, investigating the effects of Brilinta in patients with a history of myocardial infarction.

## **Corine Bernaud** (AstraZeneca, GBR)

Corine Bernaud is currently Global Medical Affairs VP Cardiovascular based in Cambridge, UK. Corine joined AstraZeneca in 2006 in France initially as Medical Director CV, Metabolism and Thrombosis before being promoted as Medical Affairs Director Cardiology Europe in 2007, then Medical Director Europe in 2011, before moving back to France as Medical Director in 2012. In these roles she delivered innovative life cycle clinical programmes and established important scientific partnerships. Corine Bernaud is a physician certified in Sports Biology & Medicine with a master's degree in Medical Science & Biology from Besançon University, France and a degree in Statistics, Clinical Research & Epidemiology from Paris VI University, France. She started her career as a General Practitioner before joining the pharmaceutical industry with Pfizer where she worked 14 years, first as a Medical Scientific Liaison, then Clinical Research Physician and finally as a Medical Manager responsible for Cardiovascular portfolio. In 2004 she moved to Sankyo France to set up and lead the Medical Department. She has contributed to the design, monitoring and steering of several clinical trials and registries in cardiology and a number of publications in peer reviewed journals.

## **Jeffrey Borer** (New-York, USA)

Jeffrey S. Borer, MD, is Professor of Medicine, Cell Biology, Radiology and Surgery at the SUNY Downstate Medical Center where for several years was Chief, Division of Cardiology and Chairman, Department of Medicine, administrative positions he recently relinquished to direct two research institutes and to establish a clinical trials unit at Downstate.

Dr Borer's BA is from Harvard, MD from Cornell, and training 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. He returned to Cornell for 30 years as Gladys and Roland Harriman Professor of Cardiovascular Medicine and Chief, Division of Cardiovascular Pathophysiology. He performs clinical service, teaching and research, primarily developing prognosticators for regurgitant valve diseases, and assessing the effects of therapeutic heart rate modification. He has been Advisor to the USFDA for 38 years, chaired the CardioRenal Drugs Advisory Committee for 3 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 6 books, is editor-in-chief of the journal, Cardiology, and has received several awards and other recognitions.

## **Karsten Bruins Slot** (EMA, NOR)

Dr Bruins Slot received his MD degree in 2002 (University of Groningen, The Netherlands) and a PhD in cerebrovascular medicine in 2009 (University of Oslo, Norway). Prior to joining the Norwegian Medicines Agency (NoMA), he worked as a physician and research fellow at the Oslo University Hospital and Western General Hospital (University of Edinburgh, GBR).

Dr Bruins Slot has been a member of EMA's Committee for Medicinal Products for Human Use (CHMP) and Cardiovascular Working Party since 2010. He still holds a post-doctoral research position in cerebrovascular medicine at the Oslo University Hospital and has recently published on thrombolytic stroke treatment and the use of factor Xa inhibitors for prevention of stroke in patients with atrial fibrillation.

## **Pieter de Graeff** (EMA, NED)

JPieter de Graeff, PhD, MD, was born in 1950. Following medical training at the University of Groningen, he graduated in 1975. Following his military service, he fulfilled a yearlong internship in internal medicine in the US in Youngstown, Ohio. In October 1977 he started his training as an intern at the department of Internal Medicine, University Hospital, Groningen.

In January 1983 he was registered as an internist, practicing up to 2015. Subsequently, he became a clinical advisor for the Dutch Medicines Evaluation Board, keeping a position as associate professor at the depts of Internal Medicine and Pharmacology/Clinical Pharmacology.

In 1989 he finished his thesis, titled "Effects of captopril on the heart. Mechanisms and Therapeutic Potentials." In 1994 he was co-registered as a clinical pharmacologist. In 1996 he became professor in pharmacotherapeutics. In 2003 he was elected as "teacher of the year".

He maintained a part-time position as senior clinical adviser of the MEB and as head of the cardiovascular subdivision until 2007.

In 2007 he became an alternate member of the CHMP and in 2013 a full member. He has fulfilled a number of positions at various organisations, among which the cardiovascular subgroup WP of the EMA (since 1999), which he is currently chairing.

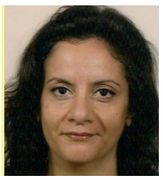
He (co-) authored more than 120 publications in peer-reviewed journals with a focus on cardiovascular pharmacology and regulatory science. He has been involved in writing a number of regulatory cardiovascular guidelines, including those on antihypertensive, lipid-lowering, heart failure and anti-arrhythmic agents.

## **David DeMets** (Madison, USA)

David L. DeMets, PhD is currently the Max Halperin Professor of Biostatistics and former Chair of the Department of Biostatistics and Medical Informatics at the University of Wisconsin – Madison. He has co-authored numerous papers on statistical methods, collaborative research and four texts on clinical trials, two specifically on data monitoring.

He has served on many NIH and industry-sponsored data monitoring committees for clinical trials in diverse disciplines. He served on the Board of Directors of the American Statistical Association, as well as having been President of the Society for Clinical Trials and President of the Eastern North American Region (ENAR) of the Biometric Society.

In addition he was Elected Fellow of the International Statistics Institute, the American Statistical Association, the Association for the Advancement of Science, the Society for Clinical Trials and the American Medical Informatics Association. In 2013, he was elected as a member of the Institute of Medicine.



## **Amany El-Gazayerly** (EMA, NED)

Amany El-Gazayerly is a senior clinical assessor in the Dutch Medicines Evaluation Board, the Netherlands. She obtained her Bachelor in Medicine and Surgery degree from Cairo University, Egypt. She worked as a researcher in the research institute of Ophthalmology in Cairo. Then she obtained a Master and PhD degrees in Pharmacology from Cairo University. She then followed an academic career and worked as a lecturer and assistant professor in pharmacology in Cairo University. Since 2005 she pursued a career in the regulatory field, working as a cardiovascular assessor in the Dutch agency. She is also a member of the Scientific advice group of the European Medicines Agency EMA, and a member of the Cardiovascular working group in EMA. This is the group responsible for drafting and updating EU regulatory guidelines. Her main fields of interests are pulmonary arterial hypertension, anticoagulants, and antiarrhythmics.

## **Wendy Gattis Stough** (Cary, USA)

Wendy Gattis Stough, PharmD, is Owner of Expert Medical Communications and Consulting, LLC, in Cary, North Carolina. She also maintains an active faculty appointment as an Adjunct Professor of Clinical Research and Pharmacy Practice at Campbell University College of Pharmacy and Health Sciences in 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 established a clinical practice in the management of patients with heart failure as a member of the multidisciplinary heart failure team. 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 been an active contributor to many (>20) publications from CVCT meetings. Dr. Stough has worked with other leading professional cardiology organizations including European Society of Cardiology (ESC), Heart Failure Society of America (HFSA), Heart Failure Association (HFA) of the ESC, and the American College of Cardiology (ACC). Dr. Stough has authored or co-authored over 100 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 12 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 (Clarification of Optimal Anticoagulation through Genetics), the ongoing Ranolazine ICD trial (RAID), and a recently published trial of surgical ablation of atrial fibrillation (versus no ablation) during mitral valve surgery.

She has published over 200 papers in the statistical and medical literature. She is an Associate Editor of Biometrics and a Fellow of both the International Statistics Institute and the American Statistical Association.

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.

## **Antonio Gómez-Outes** (EMA, ESP)

Antonio Gómez-Outes is medical assessor for cardiovascular and respiratory drugs at the Spanish Medicines Agency (AEMPS) and member of the Cardiovascular Working Party (CVSWP) of the European Medicines Agency (EMA).

He is specialist in Clinical Pharmacology at the Spanish Ministry of Health, Doctor of Philosophy in Medicine at the Complutense University of Madrid and Master in Pharmacoeconomics and Market Access at the Carlos III University of Madrid. Dr Gómez-Outes has

participated as clinical assessor of in a number of relevant centralised registration procedures within the European Union in the cardiovascular field, including the market authorisation application for new antiplatelet drugs, new anticoagulants, lipid-modifying agents and new drugs for pulmonary hypertension. As member of the CVSWP, he has been involved in writing/revising a number of regulatory cardiovascular guidelines, including those for prevention and treatment of thrombotic diseases.

## **David Gordon** (NHLBI, USA)

Dr Gordon, MD, PhD, MPH, is a cardiovascular clinical trialist and epidemiologist, who has served since 2013 as Associate Director of the NHLBI's Division of Cardiovascular Sciences (DCVS) and Director of the Prevention and Population Sciences Program (PPSP). He is a graduate of the University of Chicago undergraduate (1967) and MD/PhD (1973) programs and also received an MPH in epidemiology from the University of North Carolina in 1981. He first joined NHLBI as a post-doc in Ed Korn's Laboratory of Cell Biology in 1974, where he developed a procedure to isolate and purify actin from non-muscle cells.

In 1977, he moved to the NHLBI extramural Lipid Metabolism Branch as a medical officer for the Lipid Research Clinics (LRC) program. He has worked with numerous NHLBI clinical trials since then, including WAVE, ALLHAT, BARI 2D, CIRT, and the Cardiovascular Cell Therapy Network, and has published papers on the epidemiology of HDL, meta-analysis of cholesterol trials, seasonal variation of cholesterol, the correlates and predictive value of exercise testing, on data and safety monitoring in clinical trials, and on the factors influencing the impact and timeliness of publication of clinical trials.

He has also participated in all four National Cholesterol Education Program Adult Cholesterol Treatment panels.

Dr Gordon will step down from his current position on December 31, 2015 and will assume the role of senior advisor to the Director, DCVS.

## **Jean-Marc Guettier** (FDA, USA)

Jean-Marc Guettier, MD, is Director of the Division of Metabolism and Endocrinology Products at the Food and Drug Administration.

The Division of Metabolism and Endocrinology Products provides regulatory oversight for investigational studies involving new drugs for endocrine and metabolic conditions including new therapies for patients with type-2 diabetes mellitus.

In addition, the Division reviews applications for new drugs and biologicals for endocrine and metabolic conditions and makes decisions on the marketing approval of these products.

Finally, the Division monitors the safety of products already marketed for endocrine and metabolic conditions. Dr Guettier received his medical degree from McGill University, completed his internal medicine residency at the University of Minnesota and trained in endocrinology and metabolism at the National Institutes of Health.

Dr Guettier joined FDA and the Division of Metabolism and Endocrinology Products in January 2009 as a Medical Officer in the Diabetes Team, was team leader of the Diabetes Team from in 2011 to 2013, and has been Division Director since 2013.

## **Andrew Hamer** (FDA, USA)

Dr. Hamer is a Medical Director Global Development, at Amgen Inc. Prior to that he was VP of Medical Affairs at Capricor Therapeutics, a small biotech company, from Nov 2013 to Aug 2015.

He had a twenty year career as a cardiologist and clinical researcher. In his clinical practice, he combined all aspects of inpatient and outpatient cardiac care along with hospitalist responsibilities, in an underserved part of New Zealand. These activities led to his stewardship in numerous national healthcare quality improvement efforts in New Zealand and Australia.

Dr. Hamer is an experienced clinical researcher having been the principal investigator in over 35 global multicenter clinical trials in acute coronary syndrome, heart failure, hypertension, cholesterol disorders, atrial fibrillation, and diabetes. Dr Hamer received his undergraduate education at Christ's College, Christchurch, and his MBChB from the University of Otago Medical School, Dunedin, New Zealand.

He served as a house office at Wellington Hospital, New Zealand, a senior house office at University College Hospital, Middlesex Hospital, London, UK, and, an internal medicine and cardiology registrar at Canterbury Area Health Board, Christchurch, New Zealand. After which Andrew had the privilege of working as Professor Harvey White's clinical research fellow at Green Lane Hospital, Auckland.

## **Karen Hicks** (FDA, USA)

Karen A. Hicks, MD, is a senior medical officer in the Division of Cardiovascular and Renal Products at the Food and Drug Administration (Center for Drug Evaluation and Research).

Dr Hicks received her undergraduate degree from Duke University and MD degree from the Georgetown School of Medicine. She completed her internship and residency in Internal Medicine and fellowship in Cardiovascular Disease at Walter Reed Army Medical Center. She completed her Interventional Cardiology training at The Johns Hopkins Hospital and subsequently was Director of the Cardiac Catheterization Laboratory at Madigan Army Medical Center. After completing her military commitment, she was in private practice in the Washington, DC area and joined the FDA in December 2003.

She remains clinically active at Walter Reed National Military Medical Center. She leads two large multi-stakeholder Initiatives to Standardize Data Collection for Cardiovascular Trials.

In addition to chairing the Writing Committee for the 2014 American College of Cardiology (ACC)/ American Heart Association (AHA) Key Data Elements and Definitions for Cardiovascular Endpoint Events in Clinical Trials, Dr Hicks has participated in other ACC/AHA writing committees. Her interests include interventional cardiology, definition and harmonization of cardiovascular endpoints, clinical trial design, cardiovascular outcome trials, and cardiovascular risk factor modification.

## **Joseph Hill** (Dallas, USA)

Dr Hill, MD, PhD is a cardiologist-scientist whose research focuses on molecular mechanisms of remodeling in the stressed myocardium. He graduated with an MD, PhD from Duke University. Next, he pursued postdoctoral scientific training at the Institut Pasteur in Paris, followed by clinical training in Internal Medicine and Cardiology at the Brigham and Women's Hospital, Harvard Medical School. Dr Hill served on the faculty of the University of Iowa for 5 years before moving in 2002 to the University of Texas Southwestern Medical Center to assume the role of Chief of Cardiology and Director of the Harry S. Moss Heart Center.

Dr Hill's research group strives to decipher mechanisms of structural, functional, and electrical remodeling in heart disease with an eye toward therapeutic intervention. Dr Hill serves on numerous committees, boards, and study sections, and he lectures widely. In addition, he serves on several editorial boards, including Circulation, Circulation Research, Journal of Biological Chemistry, and American Journal of Cardiology. He serves as editor-in-chief of a recently published textbook entitled Muscle: Fundamental Biology and Mechanisms of Disease. He has received numerous recognitions and awards, including election to the Association of American Professors; he recently served as President of the Association of University Cardiologists and chair of the Academic Council of the American College of Cardiology. He was recently named the next Editor-in-Chief of Circulation. Dr Hill maintains an active clinical practice focusing on general cardiology, hypertension, and heart failure.

## **John Jarcho** (Boston, USA)

John Jarcho, MD, is a deputy editor at the New England Journal of Medicine, assistant professor of medicine at Harvard Medical School, and a member of the cardiovascular division at Brigham and Women's Hospital in Boston, Massachusetts.

Dr Jarcho received his MD degree from the University of Utah School of Medicine in Salt Lake City, Utah. He completed a residency in internal medicine and a fellowship in cardiovascular disease, both at Brigham and Women's Hospital in Boston. He joined the faculty of Brigham and Women's Hospital in 1989. Dr Jarcho's professional career initially focused on basic research and led to the first identification of a genetic locus for hypertrophic cardiomyopathy. He then shifted his focus to clinical medicine, becoming a member of the Brigham Cardiac Transplant Service and ultimately medical co-director of that service. In 2002 his professional focus shifted again; he became cardiology deputy editor at the online medical reference UpToDate.

Finally, in 2005, he joined the editorial staff of the New England Journal of Medicine, where he has served for the past 10 years as the principal editor responsible for the review, revision and editing of manuscripts in the field of cardiovascular disease.

He has led efforts by the Journal to establish a capacity for expedited review and rapid online publication of practice-changing clinical trials. He maintains a clinical role with the Brigham Advanced Heart Disease Service.

## **Michael Lauer** (NHLBI, USA)

Michael Lauer, MD, 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.

## **Roxana Mehran** (New York, USA)

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI is Professor of Medicine (cardiology) and Health Evidence and Policy and Director of Interventional Cardiovascular Research and Clinical Trials at The Zena and Michael A. Weiner Cardiovascular Institute at The Icahn School of Medicine at Mount Sinai in NYC. She is also Chief Scientific Officer of the Cardiovascular Research Foundation (CRF). Dr Mehran is internationally recognized for her work in multicenter, multinational clinical trials specializing in complex data analyses and outcomes research. Her research interests include mechanisms of restenosis, treatment and prevention of acute kidney injury (AKI) in cardiac patients, gender differences in cardiovascular disease (CVD), and pharmacologic and interventional treatments for acute coronary syndromes and acute myocardial infarction. Dr Mehran possesses almost 20 years of experience working with regulatory agencies to design and conduct clinical trials and help shape health policy. She currently serves on the board of trustees of the Society for Cardiovascular Angiography and Interventions (SCAI) and is a member of the Program Committee for the American Heart Association Scientific Sessions. As an interventionalist, Dr Mehran is a highly-skilled clinician devoted to improving patient outcomes and also enjoys teaching and mentoring fellows in the hospital's cardiology program.

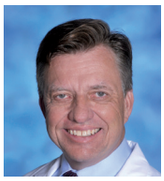
## **Michele Mercuri** (Daiichi Sankyo, USA)

Michele Mercuri, MD, PhD, FAHA, is a Sr. VP, Head of Clinical Development for the Americas, and Chief Medical Advisor at Daiichi Sankyo in Edison, NJ. A graduate from the University of Perugia (Italy) received additional training in Internal and Geriatric Medicine at the Universities of Parma, and Modena. Following Fellowships in Cerebrovascular Disease (J. Toole), and Vascular Ultrasound (G. Bond) at the Bowman Gray School of Medicine of Wake Forest University in Winston-Salem, NC, Michele served in the Faculty and as the co-Director of the Division of Vascular Ultrasound. Michele joined Merck in Rahway, NJ, in 1996 and worked in cardiometabolic drug development (J. Tobert and E. Stoner). In 2003, Michele joined Novartis in East Hanover, NJ, to lead Cardiometabolic Disease and Atherosclerosis drug development (JJ Garaud) and then the Global Protocol Review Committee (G. Della Cioppa). Michele moved to Daiichi Sankyo in 2008 to design, execute and file the edoxaban Phase 3 program, a factor Xa inhibitor which subsequently filed and approved in the major regions of the world as LIXIANA® and SAVAYSA®. Currently Michele looks after late stage development programs in the area of cardiovascular, metabolics, oncology and pain management.

## **Peter Mol** (EMA, NED)

Peter Mol is a principal assessor with a focus on cardiometabolic diseases at the Dutch Medicines Evaluation Board. He is a long-standing member

of EMA's Scientific Advice Working Party and has coordinated over 100 European advices. He is also an assistant Professor at the University Medical Center Groningen at the Department of Clinical Pharmacy and Pharmacology. His research interest is in regulatory decision-making and knowledge transfer with a specific interest in risk communication and medication safety.



## **Christopher O'Connor** (Washington, DC, USA)

Dr O'Connor is the CEO and Executive Director of the Inova Heart & Vascular Institute in Fairfax, VA. He previously served as director of the Duke Heart Center and chief of the Divisions of Cardiology and Clinical Pharmacology at Duke University Medical Center. A Fellow of the American College of Cardiology (ACC), the American Heart Association, and the European Society of Cardiology, 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 has served as principal investigator (PI) or co-PI for over 20 national and international clinical trials with an extensive record of NIH/NHLBI and industry grants, including the NIH Heart Failure Network Core Skills Development Training Grant, focused on the training of future cardiovascular (CV) investigators. He was PI of the ASCEND-HF Trial, the largest acute heart failure trial ever conducted.

He has served as PI for a number of other CV trials, including the NHLBI sponsored HF-ACTION Trial, the largest prospective randomized trial examining the effects of lifestyle intervention on outcomes in heart failure patients.

Dr O'Connor was also the lead investigator in the WIZARD Trial, a trial of antibiotic therapy in stable ischemic heart disease; SADHART, a randomized trial of antidepressant therapy in depressed post myocardial infarction patients; the ACTIV Trial, a randomized trial of vasopressin antagonists in moderate congestive heart failure; and RITZ 4, a trial of IV endothelin antagonists in acute heart failure. He is currently PI of the CAT-HF Trial, the largest trial in the US examining the treatment of sleep apnea in heart failure patients.

Dr O'Connor's research interests include: acute heart failure, co-morbidities in heart failure, clinical trials, biomarkers, and novel pharmacological and non-pharmacological approaches for the treatment of heart failure.

Dr O'Connor completed his undergraduate and medical school training at the University of Maryland. He completed his Internal Medicine residency and Cardiology Fellowships at Duke University Medical Center. He is a professor of medicine and associate professor in psychiatry and behavior sciences.

## **John Paolini** (Pfizer, USA)

John F. Paolini, MD, PhD, FACC is currently Vice President, Clinical Research Head of the Cardiovascular and Metabolic Diseases Research Unit at Pfizer, Inc. Dr. Paolini obtained an M.D., Ph.D. (Immunology) from Duke in 1995.

He subsequently completed a residency in Internal Medicine and a fellowship in Cardiovascular Medicine at the Brigham and Women's Hospital, including a postdoctoral fellowship at MIT. He joined the clinical faculty at the University of Pennsylvania as a Clinical Associate and served as an attending physician, precepting cardiology fellows in the HUP outpatient cardiology clinic until 2011.

He spent 8 years at Merck & Co., Inc., in Cardiovascular Clinical Research and Clinical Pharmacology, leading projects in thrombosis and dyslipidemia that spanned the early and late stage portfolio, including Zocor, Vytorin, Zetia, Tredaptive, and Aggrastat, as well as in-licensing activities. In 2008, Dr. Paolini joined Bayer HealthCare Pharma as Global Clinical Leader, where he was responsible for the Xarelto Atrial Fibrillation Phase III program and the NDA filing through launch.

In 2011, Dr. Paolini joined Cerenis Therapeutics in France as Chief Medical Officer, where he was responsible for portfolio clinical trials and regulatory strategy, leading up to two orphan designations in HDL deficiency in 2014 and an IPO on the Euronext in 2015. Dr. Paolini joined Pfizer in August 2015.

## **Marc Pfeffer** (Boston, USA)

Dr Marc Pfeffer, MD, PhD is the Dzau Professor of Medicine at Harvard Medical School, and Senior Physician in the Cardiovascular Division at the Brigham

and Women's Hospital in Boston. A noted researcher, Dr Pfeffer, along with his late wife, Dr Janice Pfeffer, and Eugene Braunwald MD, is credited with introducing the concept that angiotensin-converting enzyme inhibitors (ACEIs) could attenuate adverse ventricular remodelling following myocardial infarction and that this use would result in a prolongation of survival and other clinical benefits.

Since this initial discovery, he has had a principal role in several practice-changing clinical trials such as SAVE, CARE, HEART, VALIANT, CHARM, PEACE, ARISE, TREAT, ALTITUDE, TOPCAT and ELIXA.

Dr Pfeffer is considered as a team builder and takes pride in academic advancement of trainees and junior faculty collaborating on the trials. He is known for his fairness in data sharing and assisting others in developing meaningful scholarly works from study databases.

He sets high standards for relationships with the sponsors whether industry or NHLBI.

Dr Pfeffer is Senior Associate Editor of Circulation and is a member of the Editorial Board of several other prominent journals. He serves on the Data Safety Monitoring Boards of major international trials. An internationally recognized expert in the field of cardiology, he was recognized by Science Watch as having the most 'Hot Papers' (highly cited) in all of clinical medicine. Dr Pfeffer was listed as one of the highly influential biomedical researchers of 1996-2011 in the European Journal of Clinical Investigation.

He is the recipient of the William Harvey Award of the American Society of Hypertension, the Okamoto Award from Japan's Vascular Disease Research Foundation, the Clinical Research Prize, the James B. Herrick Award as well as the Distinguished Scientist Award from the American Heart Association.

Dr Pfeffer is an Honorary Fellow of the Royal College of Physicians and Surgeons of Glasgow and is the recipient of an Honorary Doctoral Degree from Sahlgrenska Academy, University of Gothenburg, Sweden.

## **Ileana Piña** (New York, USA)

Ileana L. Piña, MD, MPH, received her Doctor of Medicine from University of Miami in 1976, followed by an internal medicine residency (University of South Florida) and cardiology fellowship (University of Miami). Between 1982 and 2006, Dr Piña served as a director at several institutions, in which she initiated cardiopulmonary testing of heart failure patients and established a cardiac rehabilitation program.

From 2006 to 2009 she completed a Quality Fellowship at the Cleveland VA and in 2010, obtained a Masters in Public Health.

Dr Piña served as principal investigator in multiple heart failure trials, including PRECISE, ELITE and ATLAS, co-investigator for VEST and Val-HeFT, and served on the DSMB of WARCEF.

She is a former member of the Heart Failure Society of America Executive Council and former Chair of NHLBI, via the HF-ACTION study and Clinical Trials Committee. A recent recipient of the prestigious AHA Chairman's Award (November 2013), Dr Piña continues in her efforts to further AHA's strategic goals.

She is currently on the Get With the Guidelines and Target HF committees and the Go Red for Women committee (AHA).

In July 2011, Dr Piña joined Albert Einstein College of Medicine and Montefiore Medical Center as Professor of Medicine and Epidemiology & Population Health, and Vice Chief for Academic Affairs, respectively. Her primary role is to reduce re-admission rates for heart failure patients, as she continues to co-direct the National Heart Failure Training program, a CME activity. To date, Dr Piña continues her involvement with the FDA as a consultant for devices.

## **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 subsequently did a fellowship in cardiology at the Johns Hopkins University School of Medicine and remained on the faculty there until 1977 when he left to direct the division of cardiology at the University of Michigan School of Medicine. 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; cochairman of Escape-SHF and Escape-DH F; chairman of a study evaluating the role of an aldosterone 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 numerous medical journal editorial boards. He has also 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 centre 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.

## **Hubert Pouleur** (Pfizer, USA)

Hubert Pouleur, M.D., Ph.D., is Vice President in the department of MDG, GIPB. His responsibilities include working closely with commercial colleagues to determine the CV/Metabolic strategy for the Primary Care Business Unit.

Dr. Pouleur received his M.D. degree from the University of Louvain, Belgium, in 1973 and joined a Fellowship Program in Internal Medicine and Cardiology. From 1977 to 1978, he was a NIH Fogarty International Fellow at the University of California at San Diego. He became specialist in Internal Medicine and in Cardiology in 1978 and obtained a PhD in Cardiovascular Physiology from the University of Louvain in 1980. From 1979 to 1993, Dr. Pouleur was a faculty member of the University of Louvain Medical School, becoming Associate Professor in 1983 and Professor in 1991. In 1993, Dr. Pouleur joined Pfizer Central Research in Groton and moved to the NY Headquarters in 2001.

Dr. Pouleur is a Fellow of the American College of Cardiology, a Fellow of the American Heart Association, a Fellow of the Council of Basic Sciences of the AHA and a Fellow of the European Society of Cardiology. He is author or co-author of more than 180 articles published in peer reviewed journals.

## **Lothar Roessig** (Bayer, GER)

Lothar Roessig received his MD form the Hannover Medical School, Germany. He is board certified in Cardiology and in Internal Medicine, and Lecturer in Medicine at the Goethe University of Frankfurt, Germany. As senior cardiologist and member of the faculty at the University Hospital Frankfurt he participated as clinical investigator in numerous cardiovascular trials until 2007 when he moved into clinical research industry. Since October 2009 he is appointed at Bayer HealthCare as Global Clinical Leader in heart failure development. He leads at Bayer the soluble guanylate cyclase stimulator in heart failure studies (SOCRATES). Lothar Roessig authored more than 40 international scientific publications, peer reviewed for various cardiovascular journals, and was finalist of the American Heart Association Samuel A. Levine Young Clinical Investigator Awards.

## **Yves Rosenberg** (NHLBI, USA)

Dr Rosenberg, MD, MPH is Chief of the Atherothrombosis and Coronary Artery Disease Branch, Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute, National Institutes of Health, in 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, and a MS in Clinical Pharmacology. Dr Rosenberg's main research interests are the design and conduct of large multicenter phase III clinical trials; the methodology of trials of treatment strategies and comparative effectiveness trials.

As a Program Director at NHLBI for the last 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.
Dr Rosenberg is currently the lead NHLBI Project scientist for CABANA (Catheter Ablation versus Antiarrhythmic Drug Therapy for Atrial Fibrillation), an international multicenter (125 sites, 2,200 participants) trial, and for ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) an 8,000 participants, 300 sites international trial. Dr Rosenberg served as a member of the Society for Clinical Trials Board of Directors.

## **Patrick Rossignol** (Nancy, FRA)

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 for 6 years in 2013.

## **Sebastien Roux** (Actelion, CHE)

Sébastien Roux, MD, studied cardiology both in France (Paris) and in Canada (Montreal Heart Institute).

He did his MSc in cell biology in the French research institute INSERM. He started his career in the pharmaceutical industry at F. Hoffmann La Roche (Switzerland) where he was leading drug discovery laboratories focused on antithrombotic research, vascular tone, atherosclerosis and angiogenesis. He moved to Actelion Pharmaceuticals Ltd in 2000 to lead the bosentan program which eventually allowed the worldwide registration of the first orally active endothelin receptor antagonist for the treatment of pulmonary arterial hypertension. He also was leading the endothelin program which encompassed various therapeutic areas such as scleroderma (digital ulcers), pulmonary fibrosis and subarachnoid hemorrhage. He is currently Head of Clinical Science Early Clinical Projects with a special mission to develop interface between Clinical Development and Drug Discovery groups at Actelion. He also has a special interest in the methodology of clinical trials and their adaptation to the specific situation of rare diseases. Actelion Pharmaceuticals Ltd is the top biopharmaceutical company in the field of pulmonary arterial hypertension.

## **Monica Shah** (NHLBI, USA)

Dr. Shah, MD, MHS, MSJ, is the Deputy Chief of the Heart Failure and Arrhythmias Branch in the Division of Cardiovascular Sciences at NHLBI. She is also the NHLBI AIDS Coordinator and leads the NHLBI AIDS program team.
Dr. Shah is a board-certified heart failure and transplant cardiologist. She oversees a research portfolio that includes a number of large clinical trials and clinical trial networks, and has been extensively involved in all aspects of clinical research, with special focus on heart failure, mechanical circulatory support, cardiac transplantation, resuscitation, and HIV-related cardiovascular disease. Dr. Shah has a special interest in the science of operationalizing clinical trials, strategies to streamline studies, and approaches to optimize enrollment, teamwork, and collaboration in clinical studies. Dr. Shah is also clinically active and attends on the Advanced Heart Failure Service at the University of Maryland, where she is an Associate Clinical Professor of Medicine. Dr. Shah completed her undergraduate and medical education at Brown University. She then completed a residency in internal medicine at the Johns Hopkins Hospital, and a fellowship in cardiology at Duke University Medical Center, where she received specialized training in clinical research at the Duke Clinical Research Institute. Dr. Shah also completed a fellowship in Heart Failure and Transplantation at the Brigham and Women's Hospital. Prior to joining the NHLBI, Dr. Shah was an attending cardiologist and the Director of Heart Failure Research at the Washington Hospital Center. She was also an attending cardiologist at Columbia University Medical Center and Duke

University Medical Center. In addition to her medical training, Dr. Shah has a Masters in Health Sciences from Duke University and a Masters in Journalism from the Columbia School of Journalism.

## **Mitchell Shein** (FDA/CDRH, USA)

Mitchell Shein, MS, FHRS, joined FDA's Center for Devices and Radiological Health in August, 1986, as a reviewer in the Division of Cardiovascular Devices. He is currently serving as an acting Deputy Director in that division and is responsible for all cardiac electrophysiological devices and patient monitoring equipment. His permanent position is Branch Chief for DCD's Implantable Electrophysiological Devices Branch. In addition to his FDA responsibilities, Mr. Shein is active in the development of standards for cardiac pacemakers and defibrillators and chairs the ISO Joint Working Group for Active Implantable Devices – Cardiac Pacemakers and Defibrillators. His educational background includes a B.S. in Biomedical Engineering from Duke University and a M.S. in Physiology from Georgetown University.

## **Stuart Spencer** (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 (GBR), is on the British Scoliosis Research Fund grants committee and the steering Committee of the Swedish National GP Research School.

## **Ken Stein** (Boston Scientific, USA)

Ken Stein, MD, FACC, FHRS, is currently Senior Vice President and Chief Medical Officer for Boston Scientific's Rhythm Management Group.

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 prior to joining Boston Scientific in September of 2009.

Dr Stein currently oversees the development and execution of clinical strategy for the Company's Rhythm Management Group including the Cardiac Rhythm Management, Electrophysiology and Watchman Left Atrial Appendage Closure businesses.

Ken is a Phi Beta Kappa graduate of Harvard College (magna cum laude in Economics), and he 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 electrophysiology training.

He has published widely in the areas of cardiac electrophysiology with special interest in cardiac resynchronization therapy and risk stratification for sudden cardiac arrest.

## **Jean-Claude Tardif** (Montréal, CAN)

Dr; 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 4 weeks of receipt. Although dealing with all areas of research, he deals with most of the cardiology submissions.

Jean-Claude Tardif, CM, MD, FRCPC, FACC, FAHA, FCAHS, 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 has authored and co-authored more than 800 articles and abstracts in peer-reviewed publications including The New England Journal of Medicine, The Journal of the American Medical Association, The Lancet, Circulation, Circulation Cardiovascular Genetics, the Journal of the American College of Cardiology, the European Heart Journal, Nature Genetics, Genes and Development, the British Journal of Pharmacology, and Cardiovascular Research. In addition, he has written more than 30 book chapters and has edited several books. He has given 500 invited lectures around the world and trained 60 graduate students. His citation index (more than 12,450 citations) shows an h value of 52.

His research covers the molecular and genomic aspects of atherosclerosis and related diseases and also involves animal models, mechanistic and observational clinical studies as well as large international randomized clinical trials. Dr Tardif is or has been the international principal investigator or part of the study leadership of several large clinical trials in the field of atherosclerosis and other cardiovascular diseases.

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. He was also named scientific personality of the year by La Presse newspaper. Because of his accomplishments, Dr Tardif was named Fellow of the Canadian Academy of Health Sciences (FCAHS) and recently inducted into the Order of Canada, the country's highest honor.

## **Robert Temple** (FDA, USA)

Dr 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.

## **Ellis Unger** (FDA, USA)

Dr Ellis F. Unger, MD, is the Director, Office of Drug Evaluation-I, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), US FDA. His Office oversees the regulation of drugs for cardiovascular, renal, neurological, and psychiatric disorders. Dr Unger obtained his medical degree from the University of Cincinnati, and received post-doctoral training in internal medicine at the Medical College of Virginia. He completed a fellowship in Cardiovascular Diseases at The Johns Hopkins Hospital. Dr Unger was a Senior Investigator in the Cardiology Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, from 1983 to 1997 where he led efforts in translational science on experimental promotion of angiogenesis. From 1997 to 2003, Dr Unger served as a Medical Officer, Team Leader, and subsequently Branch Chief in the Center for Biologics Evaluation and Research, FDA. When regulatory authority for therapeutic biologics was transferred from CBER to CDER in 2003, Dr Unger joined the Division of Cardiovascular and Renal Products in CDER, and became Deputy Director of that Division. Dr Unger was promoted to Deputy Director, Office of Drug Evaluation-I, in July, 2009, and became its Director in July, 2012.

## **David Van Wagoner** (Cleveland, USA)

David R. Van Wagoner, PhD, FHRS, FAHA, is a staff member of the Departments of Molecular Cardiology and Cardiovascular Medicine at the Cleveland Clinic, and an Associate Professor in the Department of Molecular Medicine of Case Western Reserve University. In 1985, Dr Van Wagoner earned a PhD from the Department of Pharmacology of Thomas Jefferson University (Philadelphia, PA), and did postdoctoral studies at the University of Pennsylvania and Case Western Reserve University. From a background in cardiovascular pharmacology, he has focused his research at the Cleveland Clinic on the mechanisms, treatment and prevention of atrial fibrillation (AF). With a background in cellular cardiac electrophysiology, Using surgical tissue specimens and animal models, Dr Van Wagoner has characterized the electrophysiologic and structural remodeling that occurs in patients with paroxysmal, persistent and long-standing persistent AF. His studies have linked systemic inflammation and oxidative stress pathways to the etiology of AF.

His NIH funded research seeks to clarify the mechanisms linking genetic loci associated with risk of AF to their impact on atrial gene expression and on cellular pathophysiology. As chair of the Heart Rhythm Society Research Committee, Dr Van Wagoner has collaborated with other scientists, cardiologists and surgeons to identify clinical and translational research priorities that will help to advance our understanding of AF, facilitate efforts to improve its treatment and eventually lower its incidence. He is interested in the roles of genetics, diet, and lifestyle on risk of AF, and in studies that evaluate the impact of changes in diet and lifestyle of AF burden. He serves on the editorial board of 8 cardiovascular journals and is a frequent reviewer for NIH, the AHA and other funding organizations.

## **Gina Wei** (NIH, NHLBI, USA)

Gina Wei is Senior Scientific Advisor in the Prevention and Population Sciences Program (PPSP) of the Division of Cardiovascular Sciences (DCVS) at the National Heart, Lung, and Blood Institute (NHLBI). She is Board Certified in Internal Medicine and an Adjunct Associate Professor of Medicine at the Uniformed Services University of the Health Sciences (USUHS).

Dr. Wei received her MD and completed her internal medicine residency at the George Washington University School of Medicine. After serving as chief medical resident, she completed a fellowship in general internal medicine in a joint program with the Walter Reed Army Medical Center and the DC Veterans Affairs Medical Center.

While in fellowship, she obtained her MPH at USUHS and received training in and conducted various types of clinical research, including clinical epidemiology, treatment disparities, and meta-analysis of clinical trials. She worked at the US Food and Drug Administration as a Medical Officer prior to joining the NHLBI.

While at the NHLBI, She has served as the project officer of the multi-center CARDIA (Coronary Artery Risk Development in Young Adults) study, followed by the multi-generational Framingham Heart Study.

She is actively involved in several trans-NHLBI scientific activities, including its ongoing Strategic Visioning process to help guide the future research directions of the Institute over the next five to ten years. She is an Expert Panel member of the Chronic Renal Insufficiency Cohort (CRIC) Study. She is also an Executive Committee member of the trans-NIH Big Data to Knowledge (BD2K) initiative.

## **Janet Wittes** (Washington, DC, USA)

Janet Wittes, PhD, is President of Statistics Collaborative, Inc. which she founded in 1990. One of Statistics Collaborative's main functions is to serve as the statistical reporting group for data monitoring committees.

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.

She has served on a variety of advisory committees and data monitoring committees for government (NIH and the VA) 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). In 2015 she received the American Statistical Association's W. J. Dixon Award for Statistical Consulting. Her research has focused on design of randomized clinical trials, capture recapture methods in epidemiology, and sample size recalculation.

She received her PhD in Statistics from Harvard University.

## **Hans-Juergen Woerle** (Boehringer Ingelheim, GER)

Hans-Juergen Woerle, MD, Professor, Internal Medicine, is the Vice President and Head of Medicine, Therapeutic Area Metabolism at Boehringer Ingelheim, Ingelheim, Germany.

Dr. Woerle received his medical certification from the Technical University of Munich, Germany in 1999 and in 2007 he became board certified Endocrinologist with a brought training in internal medicine including endocrinology, gastroenterology and intensive care medicine.

Since 2010, Dr. Woerle is a professor and lecturer for internal medicine at the University of Ulm, Germany. He is an internationally highly recognized expert in the field of cardio-metabolic disease who has received numerous prestigious research grants and awards and is authoring ~150 publications in various high-ranked, peer reviewed journals as well as several reviews and book chapters.

In his current role at Boehringer Ingelheim he is holding global responsibility for all international clinical development and medical affairs activities in the metabolic area including the indications T2DM, T1DM, NASH, diabetic retinopathy, nephropathy and obesity. He is responsible for design and conduct of some of the largest and most comprehensive clinical development programs in the space of metabolic diseases, allowing BI´s successful entry in the Diabetes/Metabolic space. This led to successful submission, registration and launch of several major diabetes products (Trajenta®, Jentadueto®, Jardiance®, Glyxambi® and Synjardy®) in all major markets.

Dr. Woerle holds responsibility for design, conduct and interpretation of the first cardiovascular outcome trial to demonstrate cardiovascular risk reduction in type 2 diabetes when treated with Jardiance®.

## **Faiez Zannad** (Nancy, FRA)

Faiez Zannad, MD, PhD is Professor of Therapeutics at Université de Lorraine, Nancy, France. He obtained his MD and cardiology specialty in Université de Lorraine, France and his PhD in clinical pharmacology at Université de Lyon, France with fellowship at MRC unit, Oxford, UK. He 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.

He coordinates 2 EU FP7 grants: HOMAGE, on omics biomarkers for mechanistic phenotyping and prediction of drug response and FIBROTARGETS on fibrosis as a biotarget, both in heart failure.

As the primary investigator or member of oversight committees in major clinical trials, he made significant contributions to evidence based heart failure therapy, mainly with beta-blockers (CIBIS) and mineralocorticoid receptor antagonists (RALES, EPHESUS, EMPHASIS-HF).

He has served as chairman of the French Society of Hypertension, chairman of the ESC Working Group on pharmacology and drug therapy and board member of the ESC Heart Failure Association.

He is currently and since 2004, chairman and founder of the annual international meeting: Global CardioVascular Clinical Trialists (CVCT) Forum and Workshop, dedicated to the science of clinical trials, and of the International Workshop on Biomarkers in Heart Failure.

As of October 2015, he has authored more than 500 scientific publications, totalling 66715 citations.

## **Bram Zuckerman** (FDA, USA)

Dr Bram Zuckerman is a graduate of the Boston University Medical School. He completed post-graduate training in internal medicine at Baltimore City Hospital and cardiology at the Johns Hopkins program.

Prior to joining FDA in 1992, he was involved in basic research in hemodynamics 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.

He was appointed to his current position as Director of the FDA Division of Cardiovascular Devices in September 2002.

# 18th Global Cardio Vascular Clinical Trialists Workshop