CVCT WASHINGTON, DC US

Maison Française, French Embassy

19th Global Cardio Vascular Clinical Trialists Workshop

Course Directors:

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

DECEMBER 2016

SUNDAY 4 & MONDAY 5

www.globalcvctworkshop.com

Inserm · UNIVERSITÉ DE LORRAINE · NIH National Heart, Lung, and Blood Institute · EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH · FDA

19th Global Cardio Vascular Clinical Trialists Workshop

Summary

CVCT WASHINGTON, DC US

19th CardioVascular
Clinical Trialists Workshop

Introduction

4 December 2016
French Embassy, 4101 Reservoir Rd NW, Washington, DC

Dear all,

Welcome to the 19th 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. Our extraordinary faculty and partners from Inserm, NHLBI, FDA and EMA join other important stakeholders from academia, as well as the pharmaceutical and device industry. The unique organization of the CVCT Workshop allows for a free exchange among cardiovascular trial principal investigators, statisticians, pharma 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.

Following on from CVCT Workshop, 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 your 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

Dr Bertram Pitt

General information

VENUE OF THE CONGRESS

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

ON SITE CONTACTS

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TECHNICAL INFORMATION

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

LOGISTIC AND TECHNICAL ORGANIZATION

OVERCOME
3-5, boulevard Paul-Emile Victor
92523 Neuilly-sur-Seine cedex, France
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SCIENTIFIC SECRETARIAT

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EDDH - European Drug Development Hub, Fondation Transplantation
2, Rue du Doyen Jacques Parisot BP7
54500 VANDOEUVRE LES NANCY
Email: cvct.zannad@chu-nancy.fr

DINNER

Sunday, December 4, 2016

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

Dinner will be held in the Middleburg room at the 1789 Restaurant
(1226 36th Street Northwest, Washington, D.C. 20007).

Scientific program

SUNDAY 4 DECEMBER 2016

8:30 – 8:40 am ▸ **Welcome and introductory remarks**

Faiez Zannad

8:40 – 10:30am ▸ **Is there any place for non-randomized studies for evidence generation?**

1

Moderator: Faiez Zannad (Nancy, FRA)

Speaker: Michael Lauer (NHLBI, USA)
Discussant: Nancy Geller (NHLBI, USA)
Discussant: Amany El Gazayerly (EMA, NED)
Discussant: Ellis Unger (FDA, USA)

10:30 – 11:00am 🍽 **Coffee Break**

11:00am – 1:00pm ▸ **Open access and data sharing: the pros and cons**

2

Moderator: Joseph A. Hill (Dallas, USA)

Speaker: Frank Rockhold (Durham, USA)
Discussant: Marc Pfeffer (Boston, USA)
Discussant: : John Jarcho (Boston, USA)
Discussant: Stuart Spencer (London, GBR)

1:00 – 2:00pm 🍽 **Lunch Break**

2:00 – 4:00pm ▸ **How to tackle competing risk in recurrent event analysis: new methodologies**

3

Moderator: Janet Wittes (StatCollaborative, USA)

Speaker: Cyrus Mehta (Cytel, USA)
Discussant: Stuart Pocock (London, GBR)
Discussant: Scott Solomon (Boston, USA)

4:00 – 4:30pm 🍽 **Coffee Break**

4:30 – 6:00pm ▸ **Is big data a fix to limitation of observational research? Should we be interacting with Google: big data analytics and the methodology of observational big data**

4

Moderator: Roxana Mehran (New York, USA)

Speaker: Nihar Desai (New Haven, USA)
Discussant: Kenneth Stein (Boston Scientific, USA)

MONDAY 5 DECEMBER 2016

8:00 – 9:45am ▸ **Meta analysis: where do we stand? Pre-specified coordination among trialists for later meta-analyses on individual data**

1

Moderator: Jean-Claude Tardif (Montreal, CAN)

Speaker: Peter Jüni (Toronto, CAN)
Discussant: Roxana Mehran (New York, USA)
Discussant: Rick Turner (Quintiles, USA)
Discussant: Krishna Prasad (EMA, GBR)

9:45 – 10:15am 🍽 **Coffee Break**

10:15am – 12:00pm ▸ **Decision-making in the health industry: what determines how (or whether) a drug/ device is developed?**

2

Moderator: Jeffrey Borer (New York, USA)

Speaker: Kenneth Stein (Boston Scientific, USA)
Discussant: Hans-Juergen Woerle (Boehringer Ingelheim)
Discussant: : Xingli Wang (Novartis, CHE)

12:00 – 1:00pm 🍽 **Lunch Break**

1:00 – 2:15pm ▸ **The role of payers in clinical trials: how to overcome the misalignment between approval and reimbursement?**

3

Moderator: Yves Rosenberg (NHLBI, USA)

Speaker: Angeles Alonso (EMA, GBR)
Discussant: Jeff Borer (New York, USA)
Discussant: Thomas Clutton-Brock (NICE, GBR)
Discussant: Robert Temple (FDA, USA)

2:15 – 2:45pm 🍽 **Coffee Break**

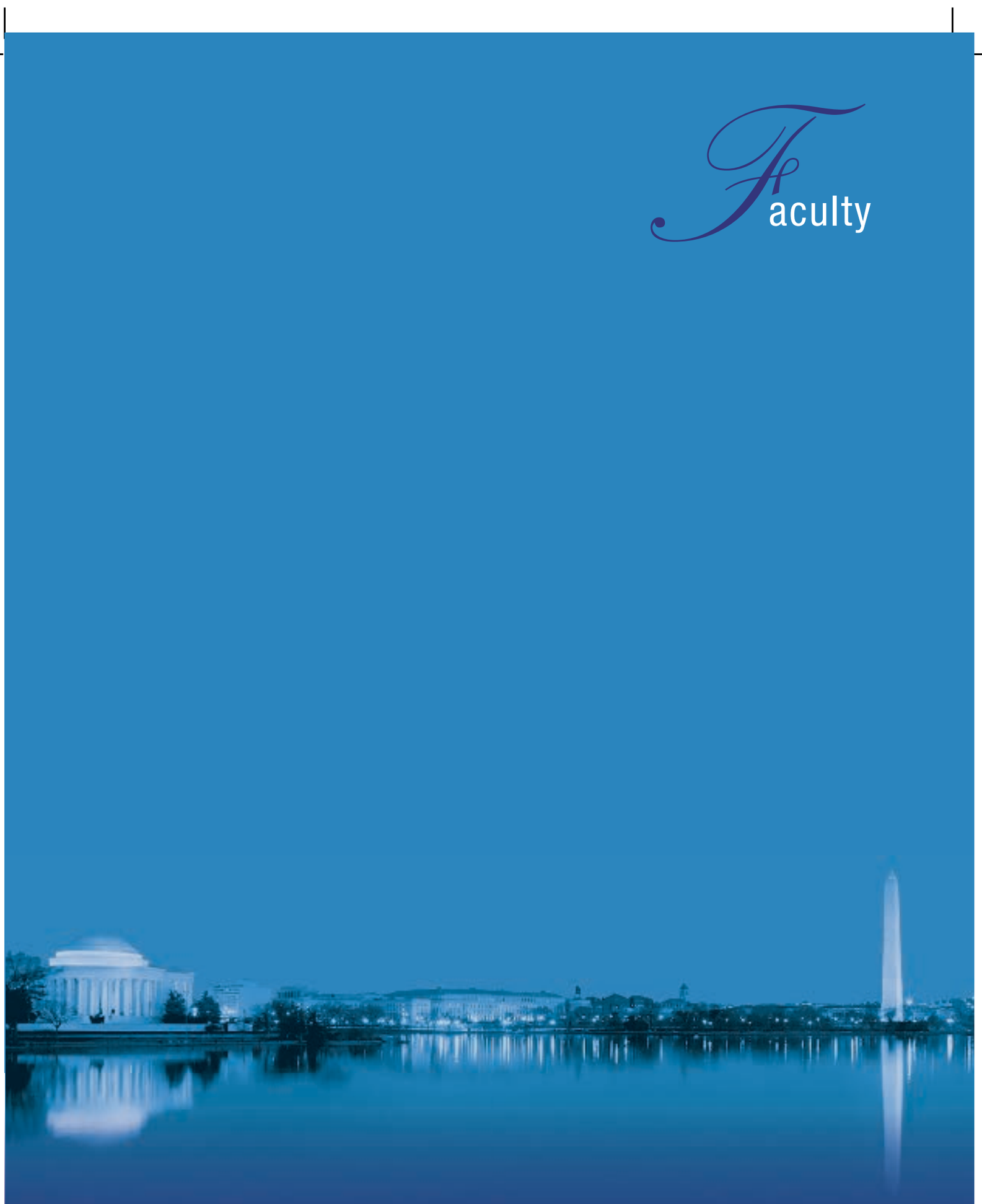
2:45 – 4:00pm ▸ **Should p value be banned from future trials?**

4

Moderator: Nancy Geller (NHLBI, USA)

Speaker: Janet Wittes (StatCollaborative, USA)
Discussant: Stuart Pocock (London, GBR)
Discussant: John Jarcho (Boston, USA)
Discussant: Joseph A. Hill (Dallas, USA)

Faculty



Kirkwood Adams (Chapel Hill, USA)

Kirkwood F. Adams Jr., MD, 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, helping to establish this treatment at UNC. Dr Adams has been involved in more than 130 completed grant and industry funded research projects, and he is currently leading or participating in five drug development trials, several registry and database studies, and continues to be involved in

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.

Dr Adams has published more than 175 manuscripts in refereed journals, a number of book chapters and monographs, and more than 150 abstracts. Dr Adams served as chair of the Guidelines/Clinical Positions Committee of the Heart Failure Society of America from 1996 to 2006 and is a past member of the Executive Council of this society. 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 NTproBNP guided therapy known as the GUIDE-IT Trial.

Angeles Alonso (EMA, GBR)

Angeles Alsonso is the 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) and Active member of the Scientific Advice Working Party Honorary Consultant in Cardiology at Imperial College Healthcare, NHS in the United Kingdom since 2014.

Dr Alonso graduated from the School of Medicine at the Universidad Autónoma de Madrid (1979) with a PhD at the Medical School (1991). She was Staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid) from 1987 to 2013 with several posititons during this time. These positions include: 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) and member of the Committee for Ethics and Clinical Investigation (2000-2009).

Dr Alonso was General Secretary of the Spanish Society of Cardiology from 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.

Since 2001 she has been a fellow of the European Society of Cardiology and Nucleus member of the Cardiovascular Pharmacology Working Group.

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.

Thomas Clutton-Brock (NICE, GBR)

Dr Tom Clutton-Brock qualified in medicine from Bristol University (UK) in 1980. He went on to gain an FRCP, FRCA and FFICM. Tom has been a Senior Lecturer and then Reader in Anaesthesia and Intensive Care Medicine at the University of Birmingham (UK) since 1990. He has maintained a career long research interest in medical technology with particular interests in patient monitoring systems and point-of-care testing. Tom was a part-time Senior Medical Officer (Devices Clinical) at the Medicines and Healthcare products Regulatory Agency (MHRA) for many years. As well as having a clinical commitment at University Hospitals Birmingham, Tom is Associate Medical Director at UHB, Chair of NICE Interventional Procedures Advisory Committee and a past member of Council at the Royal College of Anaesthetists where he chaired the Safe Anaesthesia Liaison Group. Since 2013 Tom has been the Clinical Director of the NIHR Trauma Management Health Technology Cooperative and from October 2014 the Interim and then Deputy Director of the Institute of Translational Medicine in Birmingham.

Nihar Desai (New Haven, USA)

Nihar R. Desai, MD, MPH is an Assistant Professor of Medicine in the Section of Cardiovascular Medicine at Yale University School of Medicine and an Investigator at the Center for Outcomes Research and Evaluation. His interests focus on cardiovascular health services and comparative effectiveness research, examining patterns of care, identifying opportunities to improve clinical outcomes, and evaluating the impact of novel care delivery systems on cost and quality. In addition, he serves as a clinical consultant on the CMS acute myocardial infarction, heart failure, and coronary artery bypass graft surgery readmission and mortality measures. He graduated with highest honors from Lehigh University before completing an internship in the Clinton White House. He then attended the University of Connecticut School of Medicine where he received his Doctorate in Medicine and the Harvard School of Public Health where he received his Master's in Public Health. Dr Desai completed his residency training in Internal Medicine as well as his clinical fellowship in Cardiovascular Medicine at Brigham and Women's Hospital and Harvard Medical School. He completed a research fellowship at the TIMI Study Group with Dr Eugene Braunwald. His scholarly work has been published in New England Journal of Medicine, Journal of the American Medical Association, Circulation, and the Journal of the American College of Cardiology. He has served in leadership roles in the American Medical Association, the American College of Cardiology, and the American Heart Association and is deeply committing to advocating for our patients and our profession.

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 degree and PhD in Pharmacology from Cairo University. She followed an academic career and worked as a lecturer and assistant professor in pharmacology in Cairo University.

Since 2005 she has 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.

Jean-Yves Fagon (Paris, FRA)

Jean-Yves Fagon's medical studies began in Paris, France where he proceeded to specialize in pulmonary disease and critical care medicine before undertaking a PhD (1991).

He was a Professor of Medicine for the Descartes Medical School in Paris and since 2002 has been the head of the medical intensive care unit at the Hospital

Georges Pompidou in Paris.

In 1999 he was appointed as Chairman of the board of medical directors for the HEGP and occupied the position until 2007 when he became the director of medical affairs and strategy for the AP HP (Public Care Parisien hospitals).

In 2010 he became Vice-Chairman of the Comité Economique des Produits de Santé responsible for drugs, CEPS (Healthcare products pricing committee). Following his term as Vice-President, Jean Yves became the delegate for Health innovation for the Ministry of Health in January 2016.

Wendy Gattis Stough
(Expert medical communication, USA)

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

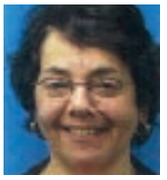
Dr Stough received her doctor of pharmacy degree magna cum laude from Campbell University School of Pharmacy and completed residency and fellowship training at Duke University Medical Center.

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 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 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 L. 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 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.

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 a 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.

Joseph A. Hill (Dallas, USA)

Dr Hill is a cardiologist-scientist whose research focuses on molecular mechanisms of remodeling in the stressed oral 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 five 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. Presently, he serves as Editor-in-Chief of Circulation. Dr Hill maintains an active clinical practice focusing on general cardiology, hypertension, and heart failure.

John Jarcho (Boston, USA)

A native of Salt Lake City, Utah, in the United States, John Jarcho attended Harvard College and the University of Utah School of Medicine. He completed house staff training in internal medicine and a fellowship in cardiology, both at Brigham and Women's Hospital in Boston, where he subsequently joined the medical staff. In the late 1980's, Dr Jarcho participated in research studies in molecular genetics leading to the first identification of a gene mutation causing hypertrophic cardiomyopathy. Subsequently he became a member of the advanced heart disease service at the Brigham, managing patients with heart failure as well as heart transplant recipients and those supported with ventricular assist devices. He was appointed medical co-director of the cardiac transplant service in 1995. In 2005 Dr Jarcho became a deputy editor at the New England Journal of Medicine, which now accounts for the majority of his professional time. He is also assistant professor of medicine at Harvard Medical School and an associate physician in the cardiovascular division at Brigham and Women's Hospital.

Peter Jüni (Toronto, CAN)

Dr Jüni is the Director of the Applied Health Research Centre (AHRC) at the Li Ka Shing Knowledge Institute of St. Michael's Hospital and a Professor at the Department of Medicine of the University of Toronto. He graduated from the Faculty of Medicine at the University of Bern, Switzerland, completed his training in Internal Medicine at various hospitals in Switzerland, was a Research Fellow at the Department of Social Medicine at the University of Bristol, UK, and held previous appointments as Director of the Institute of Social and Preventive Medicine and Founding Director of CTU Bern, the University of Bern's clinical trials unit. Dr Jüni is internationally known for his methodological work and for clinical trials and meta-analyses on the management of cardiovascular and musculoskeletal disorders. He served as editor of two Cochrane Review Groups and contributed to the Cochrane Risk of Bias tools for randomized trials and for non-randomised studies. A Fellow of the European Society of Cardiology, he has had leading roles in several major cardiovascular trials, including SIRTAX, LEADERS, FAME 2 and MATRIX. He served as a member of several task forces of the European Society of Cardiology and co-authored the European guidelines on myocardial revascularization and on the management of acute myocardial infarction. Dr Jüni has published over 300 papers and is listed as a Highly Cited Researcher by Thomson Reuters.

Carolyn Lam (Singapore, SGP)

Dr Carolyn Lam is a Senior Consultant of the National Heart Centre, Singapore, Professor of Duke-NUS Cardiovascular Academic Clinical Program, and

Chairperson of the Asia Pacific Association of Women's Cardiovascular Disease. She graduated from the Faculty of Medicine, National University of Singapore, completed advanced specialty training in Cardiology in Singapore, and pursued her Research Fellowship at the Cardiorenal Laboratory, Heart Failure Fellowship at the Division of Cardiovascular Diseases, and Advanced Cardiology and Master of Biomedical Sciences at Mayo Clinic, Rochester, MN. She further obtained training in clinical and genetic epidemiology at the Framingham Heart Study in Boston, MA before returning to Singapore in 2010 on the National Medical Research Council's Clinician Scientist Award.

Dr Lam started the first Heart Failure with Preserved Ejection Fraction Programme and Women's Heart Health Clinic in Singapore, was awarded the L'Oreal Women In Science Award (2012) for her work in women's cardiovascular disease. She won the award for the JCI Ten Outstanding Young Persons of the World for 2014. She is the Programme Lead of the Asian network for Translational Research and Cardiovascular Trials and principal investigator of an ongoing nation-wide heart failure study in Singapore (SHOP study), a multinational Asian study of heart failure across 11 Asian countries (ASIAN-HF study), as well as a multinational Asian registry of diabetes in collaboration with the American College of Cardiology's Diabetes Collaborative Registry.

She serves as a consultant on several global advisory boards for cardiovascular disease, member of the Executive Committees of global heart failure trials, and Associate Editor for Circulation and European Journal of Heart Failure.

Michael Lauer (NHLBI, USA)

Michael Lauer, MD, is the Deputy Director for Extramural Research at the National Institutes of Health (NIH). He received education at Rensselaer Polytechnic Institute, Albany Medical College, Harvard Medical School, Harvard School of Public Health, and the NHLBI's Framingham Heart Study.

A board-certified cardiologist, he spent 14 years at Cleveland Clinic as Professor of Medicine, Epidemiology, and Biostatistics. From 2007 to 2015 he served as a Division Director at the National Heart, Lung, and Blood Institute (NHLBI). 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.

Roxana Mehran (New York, USA)

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI is a 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.

Cyrus Mehta (Cytel, USA)

Cyrus Mehta is President and co-founder of Cytel Corporation and Adjunct Professor of Biostatistics, Harvard University. Cytel is a leading provider of software and services for the design, interim monitoring and implementation of adaptive clinical trials. 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 including oncology, cardiology, neurology and metabolic disease. He has led the development of

the StatXact, LogXact and East software packages that are widely used by the biopharmaceutical industry, academic research centers and regulatory agencies. He publishes his methodological research in leading statistics journals and is a past co-winner of the George W. Snedecor Award from the American Statistical Association. He 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).

Christopher O'Connor (Washington, USA)

Christopher O'Connor, the Executive Director and CEO of the Inova Fairfax Heart and Vascular Institute and adjunct professor of medicine in cardiology at Duke University. He was the chief of the Division of Cardiology and director of the Duke Heart Center.

Dr O'Connor 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. He is the editor-in-chief of the Journal of the American College of Cardiology: Heart Failure, and serves on the editorial boards for several journals.

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 published over 500 manuscripts. He serves in leadership roles in the HFSA and ACC, and is currently President-Elect of the HFSA. His commitment to mentoring students, residents, and fellows at Duke has been recognized with the Joseph C. Greenfield Research Mentoring Award in 2006 and the 2013 Research Mentoring Award for clinical science research by the Schools of Medicine and Nursing. Dr O'Connor earned an undergraduate degree from the University of Maryland, College Park, and an MD from the University of Maryland, Baltimore. He went on to Duke to complete an internship, residency, chief residency, and cardiology fellowship.

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 colla-

borations 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 management responsibility for Cardiovascular-diabetes, anti-infective agents, oncology and musckuloskeletal therapy areas for the last 18 months. Dr Prasad's additional roles include Cardiology consultancy at St. Thomas' hospital, London. He has worked for MHRA, the UK regulatory agency since 2002 initially as reviewer progressing to lead the cardiology-diabetes areas and subsequently to the current post. Dr Prasad's areas of special interest in cardiology include heart failure, sudden death, cardiomyopathies and arrhythmias.

He is a member of the Cardiovascular working party since 2008, assuming responsibility for coordinating European guidances on heart failure, lipid modifying agents as well as paediatric guidances in these areas. He is participated in many regulatory-scientific dialogues and has a keen interest in harmonisation of global approaches to both clinical trials and regulatory guidance development.

Dr Prasad has authored reflection papers on pharmacogenomics and biomarkers. He has served as the Chair of the Pharmacogenomic working party of CHMP since 2013 and is currently serving the second term in that capacity. During this period he has been instrumental in raising the profile of the WP in Europe and in generating several guidances. He is closely involved in the International Committee of harmonisation expert groups for E-14 and E-18 guidelines as Regulatory Chair/ Rapporteur. As one of the proposers for the E-18 guideline on Genomic sample collection and storage he serves as the Regulatory Chair of the E-18 Expert group.

Yves Rosenberg (NHLBI, USA)

Dr Rosenberg is Chief of the Atherothrombosis and Coronary Artery Disease Branch, Division of Cardiovascular Sciences 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 John's 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, currently focusing on the methodology of trials of treatment strategies, comparative effectiveness and pragmatic 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) a 5,000 participants, 300 sites international trial. Dr Rosenberg served as a member of the Society for Clinical Trials Board of Directors.

Patrick Rossignol (Nancy, FRA)

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 was elected as board member for 6 years in 2013. Since 2016, Pr Rossignol is a Heart Failure Association of the European Society of Cardiology "Translational" and "Cardiorenal" board member. He is CardioRenal cofounder.

Sébastien Roux (Actelion, CHE)

Sébastien Roux, MD, studied cardiology both in France (Paris) and in Canada (Montreal Heart Institute). He completed 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 clinical bosentan program which eventually allowed the worldwide registration of the first orally active endothelin receptor antagonist for the treatment of pulmonary arterial hypertension. He led the pulmonary arterial hypertension development program that resulted in successful worldwide registrations of other oral therapies for pulmonary arterial hypertension such as macitentan and selexipag.
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.

Tabassome Simon (Paris, FRA)

Tabassome Simon is Professor of Medicine and Clinical Pharmacology at AP-HP, Saint-Antoine Hospital, Pierre and Marie Curie University (UPMC-Paris 06) in Paris, France. Dr Simon is currently the Chair of the European Association for Clinical Pharmacology and Therapeutics (EACPT).

Dr Simon is the Director of the Clinical Research platform of the East of Paris, including the Clinical Research Unit (URC-EST: http://www.urcest.chusa.upmc.fr/), the clinical Research Center, and the BioBank Research Center, that coordinates several multicenter national and international studies throughout centers in France. In addition to teaching pharmacology for medical students, she coordinates the Master Diploma of Clinical Research for physicians, pharmacists, and scientists, the university diploma for pharmacogenetics and personalized medicine, and the university diploma for the education of research nurses in France. Dr Simon has received several awards from the French Society of Cardiology, the French Society of Pharmacology, the French Society of Angiology, and the EACPT. The editors of Circulation have chosen one of her publications as Groundbreaking Studies in the Practice of Cardiovascular Medicine in 2009. She has published more than 165 original articles in international peer-reviewed journals, i.e., The New England Journal of Medecine, The Lancet, JAMA, Nature Med, Circulation, JACC, European Heart Journal, Hypertension, Atherosclerosis, Arteriosclerosis Thrombosis and Vascular Biology, Clinical Pharmacology and Therapeutics and J Clin Endocrinol Metab.

Scott Solomon (Boston, USA)

Scott D. Solomon, MD, is The Edward D. Frohlich Distinguished Chair, Professor of Medicine at Harvard Medical School, Director of Noninvasive Cardiology and Senior Physician at Brigham and Women's Hospital. He directs the Cardiac Imaging Core Laboratory and the Clinical Trials Endpoints Center at Brigham and Women's Hospital. He received his AB from Williams College and his MD from Harvard Medical School.

Dr Solomon has pioneered the use of cardiac imaging in cardiovascular drug and device development and

use of imaging in clinical trials. He led the NIH sponsored Celecoxib Cross-trials Safety Study which directly informed regulatory agencies about the safety of widely used non-steroidal anti-inflammatory agents. He directs the Cardiac Imaging Center for the NHLBI Atherosclerosis Risk in Communities (ARIC) study and Hispanic Community Health Study – Study of Latinos (HCHS-SOL), the two largest NIH cohort studies. He served as member of the executive committee for the PARADIGM-HF trial, led the first successful Phase II trial in heart failure with preserved ejection fraction and is currently leading the ongoing PARAGON-HF outcomes trial in HFpEF.

Dr Solomon has directed the Harvard Medical School Cardiovascular Clerkship and the Echocardiography training program at Brigham and Women's Hospital. He has authored more than 350 peer-reviewed articles, reviews and editorials, two textbooks of cardiac imaging, and the Echocardiograph/Imaging sections for the 10th edition of Braunwald's Heart Disease and 19th edition Harrison's Principles of Internal Medicine. He is listed by Thomson-Reuters as one of the most highly cited scientists in the past 10 years. He is a Cardiology Section Editor at UpToDate and Associate Editor at Circulation.

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.

Stuart's background is in research which started at the Brompton Hospital, London, looking at spinal curvature in children before moving to the Veterinary School site at Bristol University. During this period he was invited to establish a research unit in The Netherlands. Later he set up a research team for a major pharmaceutical company in Switzerland for a year, and then spent 9 years as a senior researcher in New Zealand. He has also had two senior research fellowships at Leuven University, Belgium, and visiting professorships at King's College, London and Hong Kong University, and an honorary doctorate of medicine from Umea University, Sweden. A broad biomedical research base in different settings (Universities, government and industry) in front-line research has given a clear understanding of principles in research and publications applicable across disciplines. Stuart is also a Trustee of the Scoliosis Association (UK), is on the British Scoliosis Research Fund grants committee and the steering Committee of the Swedish national GP Research School.

Kenneth Stein (Boston Scientific, USA)

Bertram Pitt is a professor of medicine emeritus at 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 (Montréal, CAN)

Jean-Claude Tardif, Director of the Research Centre at the Montreal Heart Institute and Professor of Medicine at the University of Montreal (UdeM). He graduated from UdeM with his MD in 1987 and completed his training in cardiology and research in Montreal and Boston (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, more than 30 book chapters and has edited several books. Dr Tardif is or has been the international principal investigator 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).

Dr Tardif has won 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 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. Dr Tardif was named Fellow of the Canadian Academy of Health Sciences (FCAHS) and recently inducted into the Order of Canada, the highest distinction in the country.

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.

Aliza Thompson (FDA, USA)

Aliza Thompson, MD, MS is a Clinical Team Leader in the Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research, at the US Food and Drug Administration.

Dr Thompson joined the Division of Cardiovascular and Renal Products in 2007. She received her medical degree from Johns Hopkins School of Medicine 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.

Rick Turner (Quintiles, USA)

Rick Turner, PhD, DSc, FASH, FACC, is an experimental research scientist, clinical trialist, author, editor, and educator. He spent the first part of his professional career in the field of Cardiovascular Behavioral Medicine, detailing the individual differences in cardiovascular responses to behavioral and psychological stressors. He received two international awards for his research, and is Co-Editor of the 2013 Springer volume "Encyclopedia of Behavioral Medicine," the definitive work in this field. He has now taken his research skills into the biopharmaceutical industry.

Dr Turner is currently Chief Scientific Advisor, Cardiac Safety Services, and Senior Scientific Director, Clinical

Communications, QuintilesIMS. He is the author and co-author of over 120 publications in peer-reviewed journals, and the author, co-author, and editor of 15 books, including the recent Springer volume "Cardiovascular Safety in Drug Development and Therapeutic Use: New Methodologies and Evolving Regulatory Landscapes." Additionally, he holds the positions of Adjunct Professor of Pharmacy Practice, Campbell University, and President and Chief Scientific Officer, Turner Medical Communications.

Ellis Unger (FDA, USA)

Dr Ellis F. Unger 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 promoted to Director in July, 2012.

Martin Unverdorben (Daiichi Sankyo, USA)

Martin Unverdorben, MD, PhD, FACC, Professor of Medicine earned his medical and doctoral degrees from the University of Frankfurt/Main, Germany, where he also serves a faculty member. He is the owner of several patents. He publishes animal and clinical research in such areas as cardiovascular and pulmonary medicine, inflammation, biomarkers, catheter-based drug delivery, and is the co-editor of a textbook on cardiac rehabilitation. He is a regular reviewer to international journals and of conference abstracts mainly in cardiovascular and internal medicine. He has been contributing to international congresses in various roles. Following more than 20 years of clinical practice with board certification in Cardiology, Internal Medicine, and Sports Medicine he joined the medical device and the pharmaceutical industry. Currently, he is responsible for strategizing and executing the global life cycle management program and its publication of Daiichi Sankyo's anticoagulant. He is the global medical affairs member on the R&D team for new product development and insourcing within the cardiovascular franchise. He also serves in other strategic roles within Daiichi Sankyo.

Xingli Wang (Novartis, USA)

Xing Li Wang, MD, PhD, FAHA, FACC, cardiologist by training, joined Novartis in 2010 and is now working as a Global Program Medical Director for the heart failure clinical development programs. Prior to joining Novartis, Dr Wang worked in Merck/Schering-Plough as a lead project physician/director for the Phase IIIb Early ACS integrilin trial in the treatment acute coronary syndrome patients and the Phase III global RED-CABG acadesine trial for myocardial protection against ischemia reperfusion injury.

Through more than 8 years industry experience, he has also established experience in business development and licensing, disease segmentation and transition of early to late drug development programs. Before joining industry, Dr Wang was a tenured Professor in Michael E. DeBakey Department of Surgery, Baylor College of Medicine/Texas Heart Institute, Houston, and Scientist in Department of Genetics, Southwest Foundation for Biomedical Research, San Antonio, Texas, where he was responsible for 5 NIH sponsored basic and clinical studies. He is a past recipient of AHA Established Investigator Award from the American Heart Association in 2002. After graduating from Shandong Medical College in 1985, Dr Wang had a PhD from University of New South Wales in cardiovascular medicine in 1991, and completed his clinical rotation in Prince of Wales Hospital, Sydney, Australia through 1999.

His academic research has been focused on cardiovascular diseases, genetics, endothelial biology and stem

cells. He has a career publication of more than 200 peer-reviewed papers.

Scott Wasserman (Amgen, USA)

Dr Wasserman is the Vice President, Cardiovascular and Metabolic Therapeutic Area Head and Head of the Development Design Center at Amgen. In these roles, he is responsible for the development and execution of the cardiovascular and metabolic strategy and the optimization of clinical development programs across Amgen, respectively. Since joining Amgen in June 2005, Scott set strategy and executed critical global programs in heart failure, anemia, osteoporosis, fracture healing, and lipid metabolism. Over the last 5 years, Scott led the global Repatha clinical program and registration. As Amgen's first cardiologist, Scott developed the company's cardiovascular capabilities, shaped its portfolio, and built its Therapeutic Area team.

Prior to joining Amgen, Scott was on faculty at Stanford University in the Division of Cardiovascular Medicine. At Stanford, he performed research on flow-mediated endothelial gene expression and served as a non-interventional academic cardiologist with expertise in heart failure and echocardiography. He received his MD, Magna Cum Laude from Harvard Medical School and his BS, Magna Cum Laude from Haverford College. He completed his postgraduate training in Internal Medicine and Cardiovascular Medicine at Stanford University and did post-doctoral cardiovascular research at COR Therapeutics and Millennium Pharmaceuticals.

Janet Wittes (StatCollaborative, USA)

Janet Wittes, PhD is President of Statistics Collaborative, Inc. which she founded in 1990. One of the main activities of Statistics Collaborative is to serve as the statistical reporting group for independent data monitoring committees. Previously, she was Chief, Biostatistics Research Branch, National Heart, Lung, & Blood Institute (1983 to 1989). 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, and NCI) and industry. For the FDA, she is currently a member of the Gene Therapy Advisory Panel.

She was formerly Editor in Chief of Controlled Clinical Trials (1994 to 1998). She received her Ph.D. 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, 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 160 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 is Professor of Therapeutics at the University of Lorraine in Nancy, France. He earned his MD degree and cardiology specialty at the University of Lorraine in 1979 and PhD degree in clinical pharmacology at the University of Lyon in Lyon, France, in 1984. During his PhD study, he also completed a fellowship at the MRC Clinical Pharmacology unit, Oxford, UK. Pr Zannad is currently Head of the Division of Heart Failure and Hypertension and Director of the Inserm Clinical Investigation Center at "Institut Lorrain du Coeur et des Vaisseaux" in the Centre Hospitalier et Universitaire of Nancy.

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

Bram Zuckerman (FDA, USA)

Dr 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.

Notes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