CVCT WASHINGTON, DC US

Maison Française, French Embassy

17th Global Cardio Vascular Clinical Trialists Workshop

Course Directors:

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

DECEMBER 2014

SUNDAY 7 & MONDAY 8

www.globalcvctworkshop.com

Inserm

UNIVERSITÉ DE LORRAINE

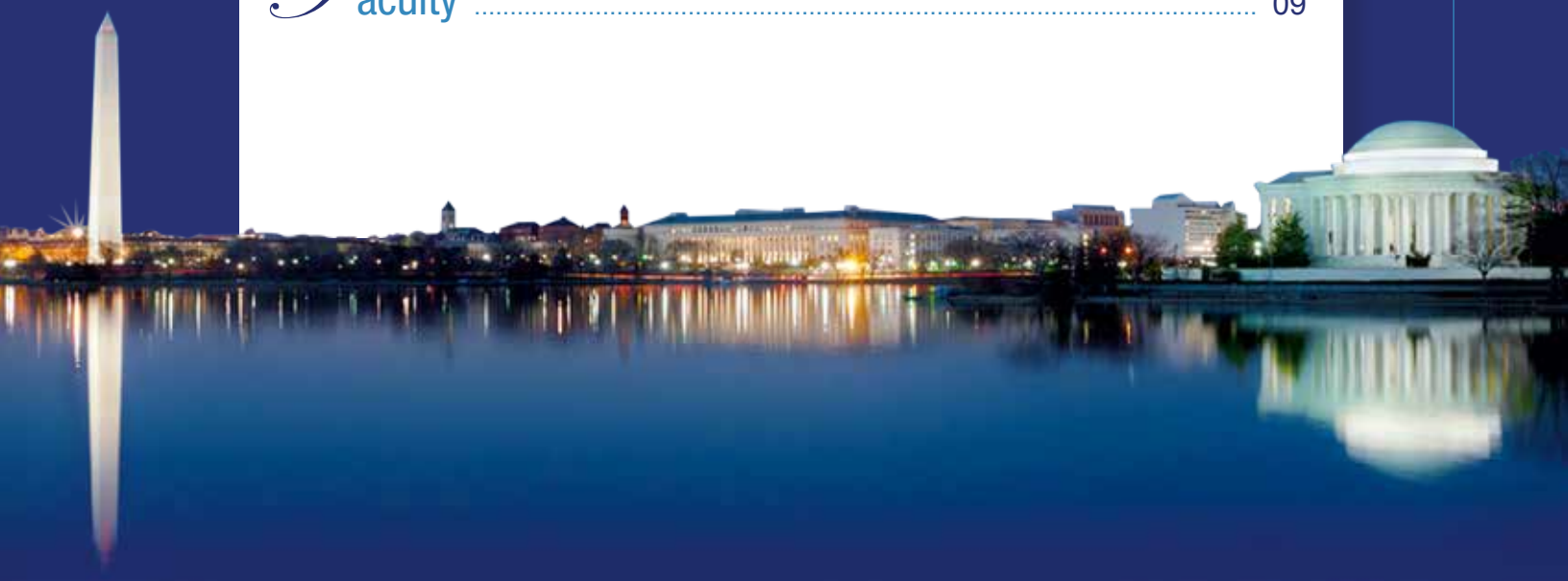
NIH National Heart, Lung, and Blood Institute

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

FDA

17th Global Cardio Vascular Clinical Trialists Workshop

Summary



CVCT WASHINGTON, DC US

17th CardioVascular
Clinical Trialists Workshop

Introduction

7 December 2014
French Embassy, 4101 Reservoir Rd NW, Washington, DC

Dear all

Welcome to Washington, DC, for a special US edition of the Global CardioVascular Clinical Trialists Workshop.

CVCT Workshop brings together a highly selected, on invitation only, exclusive faculty of up to 45 truly global leading experts involved in the science of cardiovascular clinical trials, with a unique mix of backgrounds: Academy, Industry R&D, regulatory agencies (FDA, EMA, Others), major journal editors and international science institutions (NHLBI, European Commission, Inserm).

CVCT Workshops have become the authoritative meeting place for cardiovascular trial principal investigators, statisticians, Pharma R&D experts and regulators from the major transatlantic agencies. Brainstorming topics include CV drugs, device and biomarker development and trial design, conduct, ethics, interpretation, approvability and implementation.

The ethos of the meeting is to allow ample time for discussion and brainstorming about generic CV trial science issues, not necessarily related to specific therapeutic areas. Speakers/discussants' presentations should mainly serve as prompts for lively panel discussion, aiming to move the lines and whenever possible, achieve breakthroughs. Emphasis is on interaction among highly knowledgeable experts with no lecturing. Importantly, presentation time should be strictly adhered to, i.e. 10 mins max for speakers and 5 mins max for each discussant.

Moderators have the critical task to keep time and give each panelist a chance to be involved.

With your full engagement over the next two days, we hope to foster an international exchange of ideas – and perhaps innovative thought leadership – rather than the creation of any specific guidelines or rule-making.

Please note that in order to achieve an optimal think tank dynamic, attendance at the entirety of the Workshop (all day Sunday and Monday) is kindly requested from each faculty member.

With 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

Aurélie STADTLER: +1 312 972 1770

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
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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 7 December 2014

6.30 pm - meet in the lobby of the **Georgetown University Hotel and Conference Center**

Private transfer by coach to Blues Alley, a Georgetown institution modeled after the jazz supper clubs of the 1920s and '30s.

Dinner and concert by Cuban artist Arturo Sandoval, former protégé of Dizzy Gillespie. Mr Zandoval is regarded as one the world's greatest musicians of jazz trumpet and flugel horn, and is also a renowned classical artist, pianist and composer.

Scientific program

SUNDAY 7 DECEMBER 2014

11.00 am ▸ **Welcome and introductory remarks**

Faiez Zannad

11.15 am - 1.00 pm ▸ **How to interpret composite outcomes?**

Moderator: Faiez Zannad (Nancy, FRA)

Speaker: Stuart Pocock (London, UK)
Discussant: Milton Packer (Dallas, USA)
Discussant: Armin Koch (EMA, GER)
Discussant: Norman Stockbridge (FDA, USA)
Discussant: Robert Cody (Janssen, USA)

1.00 pm - 2.00 pm 🍽 **Lunch break**

2.00 pm - 3.00 pm ▸ **Patient-Centered Outcomes Research Institute (PCORI)**

Evidence-based information that comes from research guided by patients, caregivers and the broader healthcare community

Moderator: Ileana Piña (New York, USA)

Speaker: Jerry Menikoff (New York, USA)
Discussant: Ileana Piña (New York, USA)
Discussant: Sebastien Roux (Actelion, CHE)
Discussant: Ellis Unger (FDA, USA)

3.00 pm - 3.30 pm 🍽 **Coffee break**

3.30 pm - 5.30 pm ▸ **Publications of trials results: how can they be improved? Discrepancies with reports to regulators**

Moderator: Jeffrey Borer (New York, USA)

Speaker: John Jarcho (NEJM, Boston, USA)
Discussant: Stuart Pocock (London, UK)
Discussant: Stuart Spencer (The Lancet, London, UK)
Discussant: David Guez (Servier, FRA)
Discussant: Karen Hicks (FDA, USA)

MONDAY 8 DECEMBER 2014

8.00 am - 10.00 am ▸ **Disagreements within and between regulatory agencies: how do we resolve them?**

Discrepancies within regulators: how internal discrepancies get resolved and discrepancies among regulatory agencies

Moderator: Norman Stockbridge (FDA, USA)

Speaker: Angeles Alonso (EMA, ESP)
Discussant: Milton Packer (Dallas, USA)
Discussant: Ellis Unger (FDA, USA)
Discussant: Robert Cody (Janssen, USA)
Discussant: Amani El-Gazayerly (EMA, NED)

10.00 am - 10.30 pm 🍽 **Coffee break**

10.30 am - 12.15 pm ▸ **Regional differences in trials: do they exist? Can we detect/avoid them?**

Consequences for trial interpretation and regulatory approval

Moderator: Bertram Pitt (Ann Arbor, USA)

Speaker: Marc Pfeffer (Boston, USA)
Discussant: Janet Wittes (Washington, DC, USA)
Discussant: Robert Temple (FDA, USA)
Discussant: Sebastien Roux (Actelion, CHE)

12.15 pm - 1.15 pm 🍽 **Lunch break**

1.15 pm - 3.00 pm ▸ **How to design personalized medicine trials investigating targeted therapies?**

Moderator: Nancy Geller (NIH, NHLBI, USA)

Speaker: Faiez Zannad (Nancy, FRA)
Discussant: Janet Wittes (Washington, DC, USA)
Discussant: Michael Lauer (NIH, NHLBI, USA)
Discussant: Pieter de Graeff (EMA, NED)
Discussant: Robert Temple (FDA, USA)

3.00 pm - 5.00 pm ▸ **The role of registries in evaluating treatments**

Registry-based trials, registries vs. trials: *post hoc* use of registries vs. prospective cohorts

Moderator: Roxana Mehran (New York, USA)

Speaker: Rob Califf (Durham, USA)
Discussant: Nancy Geller (NIH, NHLBI, USA)
Discussant: John Jarcho (NEJM, Boston, USA)
Discussant: Mary Ross Southworth (FDA, USA)
Discussant: Bram Zuckerman (FDA, USA)

Faculty

Angeles Alonso (EMA, ESP)

Honorary Senior Lecturer, Cardiovascular Sciences Research Centre. St. George's, University of London
Senior Medical Assessor, Medicines & Healthcare Products Regulatory Agency (MRHA), UK
Member of the Scientific Working Party of the European Medicines Agency (EMA)
Member of the EuroObservational Research Program (EORP). European Society of Cardiology
Member of the Regulatory Affairs Committee. European Society of Cardiology

Graduated from the School of Medicine at the Universidad Autónoma de Madrid (1979). PhD at the Medical School (1991). Staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid), since 1987. 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 Programm Committee, Registries and Pharma Working Group).

Moez Ben Ali (Villejuif, FRA)

Oncologist From Gustave Roussy Institute specialized in pharmacology and therapeutics, expert in clinical development of anticancer drugs. Dr Ben Ali has more than eight years of biopharmaceutical industry experience in senior positions in Medical Affairs, Drug Development, Business Development, clinical operation and Licensing, member of several global brand development operating Committee, Member of the global Protocol Steering Committee of many biopharmaceutical company. He is Head of the Oncologues Sans Frontieres cooperative group and a member of many cooperative group scientific committees.

Lance Berman (Relypsa, USA)

Dr. Berman joined Relypsa in December 2011 as Senior Vice President, Commercial Strategy and Medical Affairs and was promoted in October 2012 to Senior Vice President and Chief Medical Officer. Prior to Relypsa, Dr. Berman was the Chief Medical Officer of CPEX Pharmaceuticals where he was responsible for the clinical development of the Company's late stage clinical product as well as its in-licensing and acquisition strategies. Prior to that, Dr. Berman served in various medical leadership roles at Pfizer Inc. from June 2003 to January 2009, where he was responsible for atherosclerosis, hypertension and endocrinology products serving at various times as US or Global Medical Team Leader. Previously, Dr. Berman held roles of increasing responsibility at Schering-Plough Corporation (merged with Merck) and Janssen Pharmaceuticals, Inc. (Johnson & Johnson). Dr. Berman received his Bachelor of Medicine and Bachelor of Surgery degrees at the University of Cape Town in Cape Town, South Africa, and an M.S. in Pharmaceutical Medicine from Hibernia College.

Corine Bernaud (AstraZeneca, UK)

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.

Denise Bonds (NIH, NHLBI, USA)

Dr. Bonds received her medical degree from Creighton University, completed her internal medicine residency at Alameda County Medical Center and a research fellowship and Masters in Public Health at Boston University. Dr. Bonds was a faculty member at Wake Forest University and the University of Virginia before joining National Heart Lung and Blood Institute (NHLBI) in 2009. During her time as a faculty member, she worked on cardiovascular clinical trials including the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study and the Women's Health Initiative. Since joining NHLBI, Dr. Bonds has continued to focus on clinical trials. She is a member of the project team for the Systolic Blood Pressure Intervention Trial (SPRINT), Prospective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE), the Health Care Systems Research Collaboratory, and the Best Endovascular vs. Best Surgical Therapy in Patients With Critical Limb Ischemia (BEST-CLI). Her research interests include developing new methods to stream line and reduce the cost of conducting clinical trials. She is the program officer for RFA HL-12-019 Pilot Studies to Develop and Test Novel, Low-Cost Methods for the Conduct of Clinical Trials and RFA HL-14-019 Low-Cost Pragmatic Patient-Centered Randomized Controlled Intervention Trials.

Jeffrey Borer (New York, USA)

Jeffrey S. Borer is Professor of Medicine, Cell Biology, Radiology and Surgery at SUNY Downstate Medical Center. For 4 years, was Chairman, Department of Medicine, at Downstate, a position he relinquished, but continues to serve as Chief, Division of Cardiovascular Medicine, and Director of two research institutes. His BA is from Harvard, MD from Cornell, trained at the Massachusetts General Hospital, spent 7 years at the 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. Back at NIH, he developed stress radionuclide cineangiography, the first non-invasive assessor of cardiac function with exercise. He returned to Cornell for 30 years as Harriman Professor of Cardiovascular Medicine and Chief, Division of Cardiovascular Pathophysiology. He performs clinical service, teaching and research, the latter primarily in valve diseases and in therapeutic efficacy of heart rate modification. He has been a USFDA Advisor for 37 years, chaired the CardioRenal Drugs Advisory Committee for 3 terms and the Circulatory Devices Advisory Panel for 1 term, was a life sciences Advisor to NASA for 24 years, served as officer/board member of national professional societies (currently President, Heart Valve Society of America), published almost 500 scientific papers and 6 books, participated in numerous clinical trials, is editor-in-chief of the journal, Cardiology, and received several recognitions for his work (most recently, the Lifetime Achievement Award of the joint heart valve societies (2014), and a Legend of Cardiology Award at the 10th Annual Complex Catheter-based Cardiovascular Therapeutics conference (2014).

Rob Califf (Durham, USA)

Robert M. Califf, MD, MACC, is the Donald F. Fortin, MD, Professor of Cardiology at the Duke University School of Medicine and Vice Chancellor for Clinical and Translational Research. Dr. Califf is also the director of the Duke Translational Medicine Institute (DTMI). The DTMI, which is supported by a Clinical and Translational Science Award from the National Institutes of Health, is Duke University's home for clinical and translational research activities.

Prior to assuming his role at DTMI, he served as the founding director of the Duke Clinical Research Institute (DCRI), the world's largest academic clinical research organization. An international leader in cardiovascular medicine, health outcomes, quality of care, and medical economics, he is the author or coauthor of more than 1,000 peer-reviewed articles, reviews, and editorials and is among the most frequently cited authors in medicine. Dr. Califf is the editor-in-chief of the American Heart Journal and has served on the FDA's Cardiorenal Advisory Panel, the Pharmaceutical Roundtable of the Institute of Medicine (IOM), and was the founding director of the coordinating center for the Centers for

Education & Research on Therapeutics™ (CERTs), a public-private partnership focused on research and education to advance and optimize the use of medical products.

Dr. Califf is currently a member of the IOM Forum in Drug Discovery, Development, and Translation and the IOM Policy Committee. He also co-chairs the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke and the FDA, and serves as chair for the Clinical Research Forum (CRF), an organization of academic health system leaders; both CTTI and the CRF are devoted to facilitating systemic improvements to the clinical research enterprise. Most recently, Dr. Califf is the principal investigator for the coordinating center of the NIH Health Care Systems Research Collaboratory, an NIH Common Fund program that develops, tests, and disseminates innovative methodologies for pragmatic clinical research. He is also a co-director of the coordinating center for the Patient-Centered Clinical Research Network (PCORnet), an innovative nationwide initiative funded by the Patient-Centered Outcomes Research Institute (PCORI) that supports large-scale patient-centered trials and comparative effectiveness research.

Gonzalo Calvo (Barcelona, ESP)

Gonzalo Calvo is a consultant in Clinical Pharmacology at the Hospital Clinic of Barcelona and Associate Professor of Pharmacology at the University of Barcelona (UB). After receiving his medical degree, he specialized in Clinical Pharmacology at CSU Vall d'Hebron (1993) and became a doctor of medicine in 1997.

Pr. Calvo's main area of expertise is drug regulation, with particular interest in cardiovascular and onco-haematology. He has been principal investigator of around 50 clinical trials and has co-authored 85 peer-reviewed papers and 2 books.

From 2002 to 2011, he represented the Spanish Agency on Medicines and Healthcare Products (AEMPS) at the EMA Committee for Human Medicinal Products (CHMP) as rapporteur of more than 60 new drug applications.

Pr. Calvo has been the chair of the CHMP Cardiovascular Working Party since 2002.
He was elected President of the European Association of Clinical Pharmacology and Therapeutics (EACPT) in 2011.

James Carr (Stealth Preptides, USA)

Jim Carr is Vice President of Cardiovascular and Renal Clinical Development at Stealth Biotherapeutics. Jim received his Doctor of Pharmacy degree at the University of Minnesota in 1990 and did a fellowship focusing on cardiovascular pharmacology and clinical toxicology at the same institution. For many years, prior to joining the pharmaceutical industry, Jim was on the clinical faculty of the University at Buffalo where he led a clinical pharmacology consulting service and also taught clinical pharmacokinetics. After joining the Medical Affairs group at GSK in 1996, Jim soon became involved in supporting the launch of carvedilol and was instrumental in guiding the clinical development of the compound in pursuit of additional indications. Jim subsequently pursued other roles within industry, which included leading the clinical development of bucindolol for heart failure for Arca biopharma. After leaving Arca biopharma in 2010, Jim resumed his career at GSK working in the Global Cardiovascular and Metabolism group. Recently, Jim left GSK to assume his current role at Stealth Biotherapeutics with a goal of developing a novel peptide for the treatment of heart failure.

Robert Cody (Janssen, USA)

Dr. Cody is currently Cardiovascular Franchise Development Lead in the Cardiovascular/Metabolism Therapeutic Area, of Janssen Pharmaceuticals, / Johnson and Johnson. He previously was Global Director for Scientific Affairs-Cardiovascular at Merck & Co. Prior to Merck, Dr. Cody was Vice-President for Medical Affairs and Chief Medical Officer of CVRx, Inc., a medical device company in Minneapolis, MN, (while on leave from the University of Michigan). At the University of Michigan Health System, Dr. Cody was a Professor of Internal Medicine and Associate Chief of the Division of Cardiovascular Disease. He was also Director of the Heart Failure & Transplant Management Program, and co-chair of the Institutional Review Board.

Dr. Cody has previously held faculty/clinical positions at the Ohio State University Medical Center and Weill Cornell Medical School, New York-Presbyterian Hospitals. Dr. Cody has led the design and execution of international clinical trials in heart failure, and served as Chair of numerous Data and Safety Monitoring Boards for cardiovascular trials. Dr. Cody received his M.B.A.

degree from the University of Michigan, and his MD degree from Penn State University. Dr. Cody completed a Residency in Internal Medicine at the Cleveland Clinic Foundation, and his Cardiovascular Fellowship at Massachusetts General Hospital and Harvard Medical School.

Virginija Dambrauskaite (EU, BEL)

Virginija Dambrauskaite is a scientific officer working in the unit of «Medical research and the challenge of ageing» of the «Health» Directorate in the Directorate General for Research and Innovation of the European Commission in Brussels. Since 2006 she is in charge of the FP7 Collaborative programme section on research into cardiovascular disease. Since 2014, she is engaged in collaborative efforts of implementing societal challenge of «Health, demographic change and wellbeing» of the new EU Research and Innovation programme HORIZON 2020.

After receiving her medical degree at Vilnius University, Lithuania in 1997 and completing her cardiology training at Vilnius University Hospital, she served as a clinical research fellow in the Cardiac Ultrasound research group at the Catholic University of Leuven, Belgium, where in 2002 she obtained a Masters degree in Medical Imaging. In 2008 she obtained a PhD in Biomedical Sciences at Vilnius University, Lithuania. From 2004 till 2006 she already worked as a national seconded expert for the European Commission in cardiovascular disease research area.

Pieter de Graeff (EMA, NED)

Following medical training at the University of Groningen, Pieter de Graeff graduated in 1975. On completion of 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. 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 100 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.

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.

Nancy Geller (NIH, NHLBI, USA)

Nancy L. Geller has been the Director of the Office of Biostatistics Research at the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health for over 20 years. She directs a group of 12 statisticians who collaborate in the design, implementation, monitoring and analysis of clinical

studies in heart, lung and blood diseases and sleep disorders and she administers all statistical activities of the NHLBI. Dr. Geller has been involved in the design and analysis of a number of cardiovascular clinical trials, including ACCORD, COAG, FREEDOM and the upcoming Chronic Hypertension in Pregnancy (CHAP) trial. 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 Statistical 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 the 2011 President of the American Statistical Association.

Robert Golub (JAMA, Chicago, USA)

Robert M. Golub, MD, is Deputy Editor, JAMA. His roles include oversight of the JAMA scientific content and managing the peer review process; he is also responsible for directing JAMA educational activities. He is Associate Professor of Medicine at the Feinberg School of Medicine at Northwestern University, with academic appointments in the Division of General Internal Medicine and the Department of Preventive Medicine. Dr. Golub developed the Northwestern University medical school curriculum on medical decision making, which began in 1992, and received the Society of General Internal Medicine National Clinician-Educator Award for Teaching Innovation. He served as chair of the Northwestern University Medical School Curriculum Committee. Areas of research are in medical decision making (decision analysis, cost-effectiveness analysis, psychology of decision making, and assessing patient preferences). He has served on the Board of Trustees for the Society for Medical Decision Making and as visiting faculty for the Stanford University Faculty Development Program and the University of Buenos Aires Program in Clinical Effectiveness. Dr. Golub received his undergraduate degree from Princeton University, and his MD from Columbia University College of Physicians and Surgeons. He completed his internship and residency at Northwestern University School of Medicine/Northwestern Memorial Hospital, where he also served as chief resident. He is board certified in internal medicine.

David Gordon (NIH, NHLBI, USA)

Dr. Gordon 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.

David Guez (Servier, FRA)

David Guez is Director of R/D Innovative Special Projects at Servier Group. He was trained as a medical doctor in Paris (France) and as a specialist in cardiology and internal medicine (mainly geriatry) between 1977 and 1985.

He joined Servier in 1985 and was responsible for drug development in cardiovascular and neurological diseases ; from 2002-2006 he served as Director of Therapeutic Research responsible for conception and management of strategy and development plan in cardiovascular, neuropsychiatry, oncology, rheumatology, endocrinology and metabolic diseases for all medicines and for their life—cycle management; from 2006-2010 he served as Director of Medical Innovation and R&D Coordination (Strategic Planning, project and portfolio management).

He also participates in several R&D processes as a member of the Company and R&D Boards, Project Management Committees and Strategic Transverse Initiatives.

Karen Hicks (FDA, USA)

Dr. Karen Hicks 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 her Master of Science degree in Physiology from Georgetown University. She obtained her 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. She is board certified in Cardiovascular Disease and Interventional Cardiology. She remains clinically active at the Walter Reed National Military Medical Center in Bethesda, MD and created a Memorandum of Understanding between the institutions so cardiology fellows can perform rotations at the FDA. On behalf of the FDA, Dr. Hicks is a frequent speaker on regulatory policy at national meetings. She leads two large multi-stakeholder Initiatives to Standardize Data Collection for Cardiovascular Trials. Dr. Hicks was chair of the writing committee for the 2014 ACC/AHA Key Data Elements and Definitions for Cardiovascular Endpoint Events in Clinical Trials and has participated in other ACC/AHA writing committees. Her interests include interventional cardiology, definition and harmonization of cardiovascular endpoints, clinical trial design, and cardiovascular risk factor modification.

Nisha Jain (FDA, USA)

After Dr. Jain's training in Pediatric Hematology and Oncology, she joined the FDA in 2000, as a visiting scientist in the Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration. In her current position, as the Chief of the Clinical Review Branch, she oversees the clinical development program of diverse class of products that include coagulation factors, anti-coagulants and their antidotes, plasma proteins, immunoglobulins, blood substitutes and other plasma derived products and their analogues. Dr. Jain provides advice on clinical study design of pre and post-market clinical studies to evaluate safety and efficacy of biologic products. She serves on numerous national and international committees on clinical trials, safety and efficacy evaluation such as International Society of Thrombosis and Hemostasis, International anti RhD allo-immunization working group, Interagency Factor VIII inhibitor committee etc. Dr. Jain also serves as FDA liaison for various patient advocacy groups such as National Hemophilia Foundation, National Organization of Rare Disease, Alpha one foundation etc. Her special interest is clinical development of products intended for rare diseases. She has received FDA Commissioner's Special Achievement Award for her efforts to help design clinical trials that led to approval of products intended for rare diseases including the first transgenic product, ATryn (recombinant antithrombin III) approved by the FDA.

John Jarcho (NEJM, Boston, USA)

John Jarcho is a deputy editor at the New England Journal of Medicine and a cardiologist on the staff of the Brigham and Women's Hospital in Boston, Massachusetts, USA. He attended medical school at the University of Utah and received his training in medicine and cardiology at Brigham and Women's Hospital. His area of clinical interest is heart failure, ventricular assist, and cardiac transplantation.

Armin Koch (EMA, GER)

Professor Armin Koch studied mathematics and chemistry at Heidelberg University, has been a research assistant at the German Centre for the Research on Cancer (DKFZ) between 1984 and 1991. Thereafter he has been an employee at the Institute of Medical Biometry at Heidelberg University until in 1999 when he joined the Federal Institute for Drugs and Medical Devices (BfArM) in Germany. From 2001 to 2008 he was head of the unit „Biostatistics and Experimental Design". Since 2008 he is Director of the Institute for Biostatistics at Hannover Medical School. Pr. Koch is a member of the Scientific Advice Working Party (SAWP) and the Biostatistics working party (BSWP) at the European Medicines Agency (EMA).

Stuart Kupfer (Takeda, USA)

Stuart Kupfer serves as Global Therapeutic Area Head of Cardiovascular and Metabolic Diseases at Takeda Pharmaceuticals International and is based in Deerfield, IL, USA. His areas of research include heart failure, hypertension, thrombosis, diabetes, obesity, and dyslipidemia. Dr. Kupfer previously served on the medical school faculty of Washington University in St. Louis, MO, USA where he conducted basic research in gene regulation of steroid hormone receptors and bone metabolism. Dr. Kupfer received his MD at the University of Florida in Gainesville, FL, USA and conducted his residency training at Yale-New Haven Hospital, New Haven, CT, USA and endocrinology fellowship at the University of North Carolina in Chapel Hill, NC, USA.

Marty Lefkowitz (Novartis, USA)

Martin Lefkowitz, MD, is currently Cardiovascular Therapeutic Area Head at Novartis Pharmaceuticals Corporation. Over his 15-year career with Novartis, Dr. Lefkowitz has been involved in the clinical development of compounds primarily in cardiovascular medicine, including the design and execution of major outcome trials such as ACCOMPLISH and PARADIGM-HF. He has largely worked in cardiovascular medicine with a focus on heart failure, hypertension and coronary artery disease. He received a medical degree from New York University and did his internal medicine training at the University of Michigan. Subsequently he completed a fellowship in nephrology at the University of Pennsylvania. Dr. Lefkowitz was in the clinical practice of nephrology prior to joining the pharmaceutical industry.

Michael Lauer (NIH, NHLBI, USA)

Michael Lauer, MD, is Director of the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute, where he leads the Institute's program for research on the causes, prevention, and treatment of cardiovascular diseases. 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. Since coming to the NHLBI in 2007 he has promoted efforts to leverage big data infrastructure to enable high-efficiency epidemiology, comparative effectiveness research, and clinical trials. 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.

Jerry Menikoff (FDA, USA)

Jerry A. Menikoff, MD, JD, is the Director of the Office for Human Research Protections (OHRP), an office within the US Department of Health and Human Services. That office is one of the lead units of the US government responsible for protecting research subjects. Prior to joining OHRP, Dr. Menikoff served as the director of the NIH Office of Human Subjects Research, responsible for protecting subjects enrolled in NIH intramural research. Prior to that, he was Associate Professor of Law, Ethics and Medicine at the University of Kansas. Among the books he has authored or co-authored are Law and Bioethics: An Introduction (Georgetown University Press) and What the Doctor Didn't Say: The Hidden Truth about Medical Research (Oxford University Press).

Milton Packer (Dallas, USA)

Dr. Packer is an internationally recognized clinical investigator, who has made seminal contributions to the field of heart failure, both in understanding its mechanisms and defining its management. His work has spanned more than 30 years and has been supported by numerous investigator-initiated grants from the NIH and from industry. He led the Division of Circulatory Physiology at Columbia University for 12 years and has been the principal investigator of more than 12 large international multicenter trials. He has served frequently as a member of government advisory committees, study sections, task forces or Data and Safety Monitoring Boards for the NIH. He served as a member of the Cardiac and Renal Drugs Advisory Committee to the US Food and Drug Administration from 1986-1992 and then as its Chair from 1997-2001. He was President of the Heart Failure Society of America from 2000-2002 and has served on numerous guidelines and standards committees for the American Heart Association and American College of Cardiology. He has received many teaching awards and has mentored dozens of young clinical investigators, many of whom have become leaders in research. He is currently the Stoffel Distnguished Chair in Cardiology and Professor and Chair of the Department of Clinical Sciences at the University of Texas Southwestern Medical Center in Dallas.

Marc Pfeffer (Boston, USA)

Dr. Marc Pfeffer 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 and RED-HF. He is currently a leading investigator in TOPCAT and ELIXA, trials in patients with heart failure with preserved ejection fraction and diabetes, respectively.

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, as well as, the James B. Herrick Award, both from the American Heart Association. Dr. Pfeffer is an Honorary Fellow of the Royal College of Physicians and Surgeons of Glasgow.

Ileana Piña (New York, USA)

Ileana L. Piña 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 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 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, UK)

Stuart J. Pocock is Professor of Medical Statistics at the London School of Hygiene and Tropical Medicine.

His primary research interest concerns clinical trials, both as regards methodological developments and applied collaboration in major trials. He also has interests in observational epidemiology especially pharmaco-epidemiology. His particular methodological areas of expertise include: standards for the statistical reporting of trials and epidemiological studies, the statistical ethical and organizational principles for data monitoring including early stopping guidelines, the presentation of time-to-event (survival) data, the pros and cons of non-inferiority trials, problems of multiplicity in trial reporting, eg, subgroup analyses, multiple outcomes and covariate adjustment, the development of prognostic risk scores, and the use/interpretation of meta-analyses.

Pr. Pocock runs a statistical centre for the design, conduct, analysis and reporting of major clinical trials, especially in cardiovascular diseases. He is also a consultant statistician for a wider range of clinical trials in which expert statistical advice is needed, and serves as a statistical member of many trial data monitoring and steering committees.
He collaborates internationally especially with the Centro Nacional de Investigaciones Cardiovasculares in Madrid, and the Cardiovascular Research Foundation

and Mount Sinai School of Medicine in New York. He is a frequent lecturer on a variety of clinical trials issues.

Yves Rosenberg (NIH, 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, National Institutes of Health, inBethesda, 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 the ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) an 8,000 participants, 400 sites 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) since 2014. 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.

Sébastien 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.

Arantxa Sancho (EMA, ESP)

Arantxa Sancho obtained her medical degree in Madrid, by the Autonomous University in 1997, and then made a 4-year medical specialty in Clinical Pharmacology at Hospital La Paz, Madrid. She was granted a training stay and in 2002 joined the Spanish Agency on Medicines and Healthcare Products (AEMPS) where she worked as a clinical

assessor mainly in the context of European procedures. In 2005 she moved to Hospital Puerta de Hierro, Majadahonda, where she has been working at the Clinical Pharmacology Department developing assistance and research activities at the hospital clinical research unit in collaboration with different medical departments. Her collaboration with the AEMPS-EMA continued during this time, focusing on the centralised scientific advice and marketing authorisation procedures for CNS, cardiovascular, endocrinology and ophthalmology medicinal products. She has been member of the EWP (2006-10), the CNS-WP (2007-10) and the RIWP since 2010. In 2011, she was nominated Alternate member of the CHMP- EMA. Since then, she has been rapporteur of more than 15 new drug applications, including haematologic, oncologic and cardiologic medicinal products. Her areas of interest include drug regulation, drug place in therapeutics, with particular interest in CNS, rheumatology, viral diseases and onco-haematology. She is also member of a Research Ethics Committee since 2005.

Kaori Shinagawa (PMDA, JAP)

Dr. Kaori Shinagawa, MD, PhD, majored in internal medicine, with an emphasis on cardiology. After graduating from National Saga Medical School in 1992, she conducted medical examinations and patients treatments including clinical electrophysiological studies as a cardiologist. She received her doctoral degree of Medical Science in 2000. Her main research field was to investigate the electrophysiological mechanisms and pharmacological treatment of atrial fibrillation, and she was a postdoctoral fellow of Dr. Stanley Nattel's laboratory at Montreal Heart Institute from 1999 to 2002. She worked as a cardiologist at Eiju general hospital from 2002 to 2005. Since March 2005, she has been working at the Pharmaceuticals and Medical Devices Agency (PMDA). She is currently Senior Scientist for Clinical Medicine, PMDA. She has been involved mainly in the review and consultation of new cardiovascular drugs, and creating new guidelines for Japanese drug application. She has also been involved in International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use□ICH□activities since 2005 including E14 topic. She has authored over six papers for a variety of cardiovascular journals. Dr. Shinagawa's findings have been featured in Circulation, J Am Coll Cardiol, PACE, and Cardiovascular Res.
She also received Kimura Memorial Award from the Japanese Heart Rhythm Society in 2000.

Mary Ross Southworth (FDA, USA)

Mary Ross Southworth is the Deputy Director for Safety in the Division of Cardiovascular and Renal Drug Products in the Office of New Drugs, Center for Drug Evaluation and Research at FDA. Her responsibilities include managing postmarketing safety activities such as postmarketing studies and clinical trials, Risk Evaluation and Mitigation Strategies, and safety labeling changes and communications. Previously, she was a safety reviewer in the Office of Surveillance and Epidemiology at FDA. She received a Bachelor of Pharmacy Degree from the Virginia Commonwealth University/Medical College of Virginia and went on to obtain a PharmD degree from the University of Toledo. Prior to joining FDA, she held a faculty position in the College of Pharmacy at the University of Illinois at Chicago.

Stuart Spencer (The Lancet, London, UK)

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.

Dr. Spencer'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.

Norman Stockbridge (FDA, USA)

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

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 is a Medical Officer and 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 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.

Ellis Unger (FDA, USA)

Dr. Ellis Unger is the Director of Office of Drug Evaluation-I, Office of New Drugs, Center for Drug Evaluation and Research (CDER) at FDA. Dr. Unger obtained his medical degree from the University of Cincinnati. He completed internal medicine training at the Medical College of Virginia and a fellowship in cardiology at Johns Hopkins Hospital. From 1983 to 1997, Dr. Unger directed a translational research program in angiogenesis at the National Institutes of Health, where he worked to develop new approaches for the treatment of coronary artery disease and peripheral vascular disease. In 1997, Dr. Unger joined FDA's Center for Biologics Evaluation and Research, serving as a Medical Officer, Team Leader, and subsequently Branch Chief in the Office of Therapeutics Research and Review. With reorganization of CDER in 2005, Dr. Unger became Deputy Director of the Division of Cardiovascular and Renal Products. From 2007 to 2008, he served as the Acting Deputy Director of CDER's Office of Surveillance and Epidemiology. Dr. Unger became Deputy Director, Office of Drug Evaluation-I, in July, 2009, and became its Director in July, 2012. Dr. Unger has served on numerous working groups, including CIOMS Working Group VII, and the ICH Expert Working Groups on E2F and E2C (R2). He has authored and co-authored numerous scientific articles, and is a co-holder of two patents.

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 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 (1983–89). Her 2006 monograph, "Statistical Monitoring of Clinical Trials – A Unified Approach" by Proschan, Lan, and Wittes, deals with sequential trials. Her research has focused on design of randomized clinical trials, capture recapture methods in epidemiology, and sample size recalculation. She has served on a variety of advisory committees and data monitoring committees for government (NHLBI, the VA, and NCI) and industry. For the FDA, she has been a regular member of the Circulatory Devices Advisory Panel and has served as an ad hoc member of several other panels. Currently, she is a regular member of the Gene Therapy Advisory Committee. She was formerly Editor in Chief of Controlled Clinical Trials (1994-98). She received her PhD in Statistics from Harvard University.

Faiez Zannad (Nancy, FRA)

Pr. Faiez Zannad is Professor of Therapeutics and Cardiology, Université de Lorraine, France and Director of the Clinical Investigation Center, Inserm-CHU of Nancy.
www.cic-nancy.fr/cic
He is currently on annual sabbatical leave, acting as advisor to the Tunisian Ministry of Health, with a mission to structure health research.
In the last five years, his main professional activities have been in the following areas:

- Structuring of the clinical research infrastructure in France
- Roadmap of health research in Tunisia
- Contribution to clinical trial science and methodology in CV disease
- Significant contribution in advances in heart failure treatment, through major clinical trials, mainly with mineralocoticoid receptor antagonists (RALES, EPHESUS, EMPHASIS-HF, REMNDER, ARTS), but also with beta-blockers (CIBIS, CAPRICORN), Angio2 receptor blockers (VALIANT, HEAAL); Direct Renin Inhibitors (ASTRONAUT) and vasopressin antagonists (EVEREST), which has led to the approval of new drugs in this area and change in international guidelines.
- Specific interest in mechanistic biomarkers in heart failure Results show that fibrosis biomarkers may predict outcome and describe one target mechanism of action of mineralocoticoid receptor antagonists.
- First randomized controlled trial of CV prevention in haemodialysis patients (FOSIDIAL). Results show a potential benefit of ACE inhibitor therapy to decrease CV morbidity and mortality in patients with ESRD and left ventricular hypertrophy. Follow up with the statin trial AURORA, which did not show benefit of Rosuvastatin in haemodialysis patients. On-going ALCHEMIST trial of spironolactone in haemodialysis high-risk patients (FOSIDIAL).

Pr. Zannad is involved in a number of major cardiovascular clinical trials, as a Principal Investigator and/or as a chair or member of several Steering Committees, Critical Event Committees and Data Safety and Monitoring Boards:

- Chairman: FOSIDIAL, EMPHASIS-HF, NECTAR-HF; ARTS, COMMANDER-HF
- Member: CIBIS II, RALES, VALIANT, RECOVER, MOXCON, EPHESUS, EVEREST, AURORA, ASTRONAUT, AXIOM-ACS, HF-ACTION; PEARL-HF, ALBATROSS, REMINDER, SERVE-HF, ALCHEMIST; EXAMINE; PARAGON, STAR-HF, DENER-HTN, ESTIM-HTN
- Steering Committee: APSI, FIRST, CIBIS I, CAPRICORN, ASCEND-HF,
- Critical Event Committee: CAPRICORN, RESPECT, SCOUT, EchoCRT
- Data and Safety Monitoring Board: HEAAL, ASPIRE
- Among Pr Zannad's current and anticipated research grant support
- 2006-10: EU 6th FP: Network of excellence Integrating Genomics, Clinical Research and Care in Hypertension (InGenious HyperCare). Coordination of Joint Research Program on Transition from hypertension to heart failure.
- 2007-10: Inserm CIC translational research grant Biomarkers of Mineralocoticoid receptor activation.
- 2007-13 and 2014-2020. French Government and Lorraine region: Contrat de Plan Etat Région Lorraine: Therapeutic Innovation and Health Technology.
- 2009-11: Agence Nationale de la Recherche, France. Biomarkers of MR receptor activation
- 2009-13: EU 7th FP large scale integrating. A systems BIOlogy Study to TAilored Treatment in Chronic Heart Failure (BIOSTAT), Lead Country Investigator, France.
- 2010-14: EU 7th FP. Large scale integrating project The MEtabolic Road to DIAstolic Heart Failure (MEDIA) coordinating workpackage on biomarkers)
- 2013-2019 EU 7th FP Heart failure Omics and AGEing (HOMAGE), General Coordinator
- 2013-2017 EU 7th FP FIBRosis as a TARGET in Heart Failure (FIBROTAGERTS), General coordinator

He is chairman and organizer of several international meetings: "CardioVascular Clinical Trialists (CVCT) Forum and Workshop" (since 1998 in Cannes and Paris, with Bertram Pitt); "Heart Failure Trialists Workshop" (since 2010, for the ESC Heart Failure Association) and "Biomarkers in Heart Failure" (Since 2005 in Cannes, with Kirkwood Adams).

Pr. Zannad has received many honors during his career, the most recent in 2014, the Paul Milliez Award of the European Society of Hypertension.

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.


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