CVCT

16th CardioVascular Clinical Trialists Workshop

PARIS CVCT 2013

Course Directors: Faiez ZANNAD, Nancy - FRA, Bertram PITT, Ann Arbor - USA

Pullman Montparnasse
PARIS, France

Sunday 8
& Monday 9
December
2013

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

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CVCT

16th CardioVascular Clinical Trialists Workshop

SUMMARY

16th CardioVascular Clinical Trialists Workshop

Paris, 8 December 2013

Dear All

Welcome to Paris. We are very pleased to have you with us for the 16th Global CardioVascular Clinical Trialists Workshop.

We share a long history of international exchange and discussion on the most pressing matters in the field of clinical trials today.

The CVCT Workshop has 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.

With your contribution, we aim to:

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

The interactive format of the Workshop, our participants' vast range of experiences and the long-standing friendships we have forged make this event a highlight in our agenda.

Should you have any queries, please do not hesitate to contact my scientific assistant, Stéphanie Grojean, who will be present for the duration of the Workshop.

We look forward to a rich and spirited dialogue with you over the next two days.

With our best regards

Pr Faiez ZANNAD, Nancy and Co-Chairmen: *Bertram PITT, Ann Arbor*
Gonzalo CALVO, Barcelona
Mihai GHEORGHIADE, Chicago
Wolfgang KOENIG, Ulm
Chris O'CONNOR, Durham
Marc PFEFFER, Boston
Ileana PIÑA, New-York
Janet WITTES, Washington

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16th CardioVascular Clinical Trialists Workshop

GENERAL INFORMATION

VENUE OF THE CONGRESS

PULLMAN Paris Montparnasse
19 Rue du Commandant René Mouchotte
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MEETING ROOM

Chagall/Van Dongen

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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)

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DINNER

Sunday 8 December, 2013

18:00 - Meet at the Workshop welcome desk
Private transfer by coach to the Centre Georges Pompidou (Beaubourg) for a free visit of the largest collection in Europe of modern and contemporary art

20:45 - Dinner at the restaurant “GEORGES” – 6th floor, Centre Georges Pompidou, 19 rue Beaubourg – 75004 Paris

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SCIENTIFIC PROGRAM

SUNDAY 8 DECEMBER, 2013

08:15-08:30 Welcome and Introduction: Faiez Zannad (Nancy, FRA)

08:30-11:00 Moderator: Faiez Zannad (Nancy, FRA)

❑ **Session 1 - Endpoints in device trials: Different from drug trials?**

Speaker: Jeffrey Borer (New York, USA)
Discussant: Ileana Piña (New York, USA)
Discussant: Hector Garcia (Cardialysis, NED)

❑ **Session 2 - Open access issues: Open database access timely (rapid) data publication, free availability of published data, open (unblinded) expert manuscript review**

Speaker: Stuart Spencer (London, GBR)
Discussant: Amany Elgazayerly (EMA, NED)
Discussant: David Gordon (NHLBI, USA)
Discussant: Hubert Pouleur (Pfizer, USA)

11:00-11:30 **Coffee break**

11:30-13:00 Moderator: Bertram Pitt (Ann Arbor, USA)

❑ **Session 3 - Observational studies helped or hindered? Real world vs. clinical trial data**

Speaker: Stuart Pocock (London, GBR)
Discussant: Kirkwood Adams (Chapel Hill, USA)
Discussant: Gonzalo Calvo (Barcelona, ESP)
Discussant: Norman Stockbridge (FDA, USA)

13:00-14:30 **Lunch**

14:30-17:30 Moderator: Ileana Piña (New York, USA)

❑ **Session 4 - Enrichment designs (FDA Draft guidance): Decreasing heterogeneity, predictive enrichment, and prognostic enrichment - regulatory considerations when using enrichment strategies**

Speaker: Bart van der Schueren (EMA, BEL)
Discussant: Norman Stockbridge (FDA, USA)

❑ **Session 5 - Use of data from devices as endpoints**

Speaker: Jeffrey Borer (New York, USA)
Discussant: Cecilia Linde (Stockholm, SWE)
Discussant: Norman Stockbridge (FDA, USA)

MONDAY 9 DECEMBER 2013

09:00-11:00 Moderator: Jeffrey Borer (New York, USA)

❑ **Session 6 - Comparative effectiveness: Is it simply pouring money out from real trials?**

Speaker: Denise Bonds (NHLBI, USA)
Discussant: Gonzalo Calvo (Barcelona, ESP)
Discussant: David Gordon (NHLBI, USA)

❑ **Session 7 - Trial execution issues: Site selection, operational issues -CRO vs. company management**

Speaker: Karen Wai (Quintiles, SGP)
Discussant: Yves Rosenberg (NHLBI, USA)

11:00-11:30 **Coffee break**

11:30-12:30 Moderator: Scott Solomon (Boston, USA)

❑ **Session 8 - Role and proper use of secondary publications: Secondary trial analyses beyond the primary endpoint, subgroups**

Speaker: Stuart Pocock (London, GBR)
Discussant: Stuart Spencer (London, GBR)

12:30 -14:30 **Lunch**

14:30-17:00 Moderator: Gonzalo Calvo (Barcelona, ESP)

❑ **Session 9 - Cardiovascular safety trials: Anti-diabetic, anti-obesity, osteoporosis drug**

Speaker: Krishna Prasad (MHRA, GBR)
Discussant: Beth Anne Piper (Pfizer, USA)
Discussant: Stuart Pocock (London, GBR)
Discussant: Stuart Kupfer (Takeda, USA)

❑ **Session 10 - What has been learnt from post approval trials?**

Speaker: Fernando de Andrès-Trelles (Universidad Complutense de Madrid and SAWP of the EMA, ESP)
Discussant: Corine Bernaud (AstraZeneca, FRA)
Discussant: Angeles Alonso (EMA, ESP)

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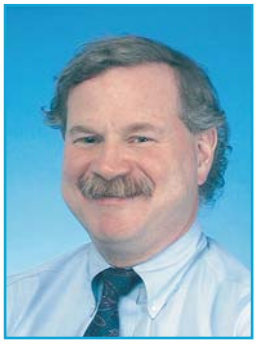

Kirkwood Adams (Chapel Hill, USA)

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 is currently involved in numerous research activities related to heart failure with particular focus on novel drug development in acute heart failure and translational research concerning the identification and clinical application of cardiovascular biomarkers and pharmacogenomics. He received his medical degree from the University of North Carolina. He did his internship and residency at North Carolina Memorial Hospital, where he also completed a fellowship in cardiology. He is a diplomate of the American Board of Internal Medicine, with subspecialty certification in cardiology.

Dr. Adams has been involved in more than 120 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 has recently been involved in three NHLBI-funded trials: ACTION (investigating outcomes of exercise training in patients with heart failure), DISCOVER (investigating stress and heart failure), and ESCAPE (role of right heart catheterization in the management of advanced heart failure).

Dr. Adams is the principal investigator for the national multicenter database group, UNITE-HF, which focuses on registries of patients with heart failure. Through his leadership, this group has published extensively on the prevalence and relationship to quality of life of anemia in heart failure, and the association of various biomarkers with anemia of heart failure.

Dr. Adams has served as editorial advisor to *American Heart Journal, Journal of Cardiac Failure,* and *TheHeart.org*.

Dr. Adams has also been a reviewer for a number of cardiovascular journals. He has published more than 150 manuscripts in refereed journals, a number of book chapters and monographs, and more than 150 abstracts.

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, UK (MHRA).
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). Ph.D at the Medical School (1991). Staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid), since 1987. Head of the Coronary Care Unit (1987-2000). Senior Consultant as a Clinical Cardiologist (involved in clinical trials on Heart Failure, Ischaemic Heart Disease and Cardiovascular Prevention) 2000-2012. Member of the Committee for Ethics and Clinical Investigation (2000-2009). Coordinator, Chairperson and speaker of several post-degree Ph D Courses at the Academic Hospital Puerta de Hierro de Madrid since 1986. Member of the Heart Failure, Ischemic Diseases, Women and CV Disease, Pharmacology Working Groups of the Spanish Society of Cardiology, General Vice-Secretary elect of the Spanish Society of Cardiology: 1999-2001, General Secretary of the Spanish Society of Cardiology: 2001-2003 and President of the International Relations Department of the Spanish Society of Cardiology and Member of the Editorial Committee of the *Spanish Heart Journal.* Fellow of the European Society of Cardiology since 2001, currently involved in several proyects with the European Society of Cardiology (Clinical Guidelines, Cardiovascular Round Table, Congress Program Committee, Registries and Pharma Working Group).

Corine Bernaud (AstraZeneca, FRA)

Corine Bernaud was appointed Medical Director France since March 2012, based in the AstraZeneca French Office, Rueil-Malmaison, France. Her role has full responsibility for Medical & Regulatory Affairs, Clinical Activities, Medical Information & Patient Safety in France.

She 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. 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 GP 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. In 2004 she became Medical Director of Sankyo France developing the Medical Department focused on CV-Metabolism & Rheumatology.

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 E. Bonds (NHLBI, USA)

Dr. Bonds receive 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), and the Health Care Systems Research Collaboratory. 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 12-019 Pilot Studies to Develop and Test Novel, Low-Cost Methods for the Conduct of Clinical Trials and a soon to be released RFA to conduct Low-Cost Pragmatic Patient-Centered Randomized Controlled Intervention Trials.

Jeffrey S. Borer (New York, USA)

Jeffrey S. Borer, M.D., is Professor of Medicine, Cell Biology, Radiology and Surgery at the State University of New York Downstate Medical Center. From 2009 through 2013 he served as Chairman, Department of Medicine, at SUNY Downstate, and now continues as Chief, Division of Cardiovascular Medicine, and Director of two research institutes at Downstate. Dr. Borer received a BA from Harvard, M.D. from Cornell, trained at the Massachusetts General Hospital, spent 7 years in the Cardiology Branch, NHLBI, and a year at Guy's Hospital (London) as Senior Fullbright Hays Scholar and Glorney-Raisbeck Fellow in the Medical Sciences, returned to Cornell for 30 years as Gladys and Roland Harriman Professor of Cardiovascular Medicine and Chief, Division of Cardiovascular Pathophysiology. He has been an Advisor to the USFDA for 36 years, chaired the CardioRenal Drugs Advisory Committee for 3 terms, and the Circulatory Devices Advisory Panel for one term, was a life sciences Adviser to the US National Aeronautics and Space Administration for 24 years, has served as officer/board member of several national professional societies (currently President, Heart Valve Society of America), has published almost 450 scientific papers and 5 books, primarily related to heart valve diseases, chronic stable coronary artery disease and cardiac imaging, has participated in various roles in numerous clinical trials, is editor-in-chief of the journal, *Cardiology*, and has received several awards and other recognitions for his work.

Gonzalo Calvo (Barcelona, ESP)

Gonzalo Calvo, MD, PhD, is Consultant in Clinical Pharmacology at Hospital Clinic of Barcelona. He has a vast regulatory experience, having served as member of the EMA- Committee for Human Medicinal Products (CHMP) from 2002 to 2011. For more than 10 years he chaired the CHMP CV Working Party, the EMA policy-making body in cardiovascular diseases from 2000 to 2011. He is the acting chair of the European Association for Clinical Pharmacology and Therapeutics (EACPT). On 24 September 2013 he was elected as co-chair of the EMA-Healthcare Professionals Working Party (HCPWP).

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Fernando de Andrès-Trelles (Universidad Complutense de Madrid and SAWP of the EMA, ESP)

Fernando de Andres-Trelles MD, PhD, is Professor of Pharmacology at Madrid's Universidad Complutense (Spain). Involved in evaluation of new medicines since 1993. Currently a member of the Paediatric Committee (PDCO) and of the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA). Also a member of the Medicines Evaluation Board (CMH) of The Spanish Medicines Agency (AEMPS).

Amany Elgazayerly (EMA, NED)

Amany Elgazayerly 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.

Carola Friedman (Novartis, USA)

Carola Friedman is a Vice President and Senior Global Program Medical Director in the Novartis Critical Care Franchise. She joined Novartis in 2004, and has had responsibility for large development programs as well as the transition of cardiovascular drugs from Translational Medicine to Development. She has extensive pharmaceutical industry experience in Clinical Development and Medical Affairs in the areas of thrombosis, ischemia, heart failure and lipids.

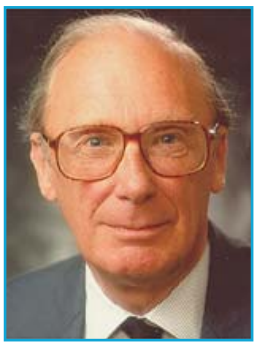
Carola Friedman joined the industry following a cardiology practice, and is a Board Certified cardiologist and a Fellow of the American College of Cardiology.

Nancy Geller (NHLBI, USA)

Nancy L. Geller has been the Director of the Office of Biostatistics Research at the National Heart, Lung and Blood Institute of the National Institutes of Health since 1990. She directs a group of 12 statisticians who collaborate in the design, implementation, monitoring and analysis of multicenter clinical trials in heart, lung and blood diseases and sleep disorders and administers all statistical activities of the National Heart, Lung and Blood Institute. She has been or is involved in the design and analysis of a number of cardiovascular trials, including PEACE, AFFIRM, WHI (Women's Health Initiative), FREEDOM, ACCORD, the ongoing Ranolazine ICD trial (RAID), the recently completed COAG (Clarification of Optimal Anticoagulation through Genetics) trial and a recently completed trial of repair versus replacement of the mitral valve in severe ischemic mitral regurgitation. She has published over 200 papers in the statistical and medical literature. She is an Associate Editor of *Biometrics* and a member of the Editorial Board of *Clinical Trials.* She is a Fellow of both the International Statistics Institute and the American Statistical Association. She was the winner of the 2009 Janet L. Norwood Award for outstanding achievement by a woman in the statistical sciences and was 2011 President of the American Statistical Association.

David Gordon (NHLBI, USA)

David Gordon, MD, PhD, MPH, is a cardiovascular clinical trialist and epidemiologist, who has served since 2002 as Special Assistant for Clinical Studies in the NHLBI's Division of Cardiovascular Sciences (DCVS). 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, 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, and on data and safety monitoring in clinical trials. He has also participated in all four National Cholesterol Education Program Adult Cholesterol Treatment panels. In June 2013, Dr. Gordon assumed the position of Acting Associate Director of the DCVS Prevention and Population Sciences Program.



Desmond Julian (London, GBR)

Professor Desmond Julian undertook his undergraduate medical education in Cambridge and London, and trained in cardiology at the National Heart Hospital, London, Harvard Medical School, and Edinburgh. In 1961 he was the first to put forward the concept of the coronary care unit in an article in *The Lancet* and went to Sydney, Australia to set up the first coronary unit. He was Cardiologist in the Royal Infirmary Edinburgh from 1964 to 1975 and Professor of Cardiology in the University of Newcastle-upon-Tyne from 1975 to 1986, and subsequently Medical Director of the British Heart Foundation from 1986 to 1993.

He was awarded the Gold Medal of the European Society of Cardiology in 1998, the Mackenzie Medal of the British Cardiac Society in 2003 and the International Service Award of the American College of Cardiology in 2005.

He was Editor of the *European Heart Journal* from its inception in 1979 to 1988. He is the author or editor of some 20 books on cardiological topics. He has been involved in the design, monitoring and analysis of many of the major clinical trials in cardiology including the ISIS trials, Consensus and 4S.

Joerg Koglin (Merck, USA)

Joerg Koglin, MD, PhD, is Executive Director, Section Head, Cardiovascular Clinical Research, at Merck Research Laboratories. He is board-certified in Internal Medicine and Cardiology. After more than 10 years as an academia-based physician with a junior faculty position at the Department of Cardiology, University of Munich, Germany, Dr Koglin has worked in corporate R&D for over 10 years. Since joining Merck Research Laboratories in 2007 in the Late Stage Global Clinical Development organization, Dr Koglin has been involved as the Clinical Lead and Development Team Lead in various early and late development programs for atherosclerosis, hypertension, ischemia/reperfusion, thrombosis and atrial fibrillation compounds and supporting the development of novel biomarker platforms to further enhance clinical development of cardiovascular drugs.

In his current role, Dr. Koglin is Section Head in the Cardiovascular Clinical Research Team providing clinical and medical oversight for all development programs around heart failure, pulmonary hypertension, and atrial fibrillation, and supports overall cardiovascular strategy development.

Stuart Kupfer (Takeda, USA)

Stuart Kupfer, MD, 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 M.D. 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.

Carolyn Lam (Singapore, SGP)

Dr Carolyn Lam, MBBS, MRCP, MS, FACC, FESC, is an Associate Professor of the Yong Loo Lin School of Medicine, Singapore; a Consultant Cardiologist at the National University Heart Centre, Singapore; and the Director of the first Women's Heart Health Clinic in Singapore. She graduated from the Faculty of Medicine, National University of Singapore, did her Cardiology Fellowship at the Cardiac Department of NUH, 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 returned to Singapore in 2010 on the National Medical Research Council's Clinician Scientist Award, concurrently holding appointments as Assistant Professor of Medicine, College of Medicine, Mayo Clinic, and Adjunct Assistant Professor, Section of Preventive Medicine & Epidemiology, Boston University School of Medicine.

Dr Lam is the principal investigator of an ongoing nation-wide heart failure study in Singapore (the Singapore Heart Failure Outcomes and Phenotypes [SHOP] study) and a multinational Asian study of patients with heart failure across 11 Asian countries (Asian Sudden Cardiac Death in Heart Failure [ASIAN-HF] study). She is on the Executive Committees of several global heart failure trials. She 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, was named an InterAcademy Medical Panel Young Physician Leader at the World Health Summit in Berlin (2012), and is currently recipient of the Senior Investigator Clinical Scientist Award (2013). She is the editor-in-chief of the *ASEAN Heart Journal*.

Andrea Laslop (EMA, AUT)

Andrea Laslop joined AGES, the Austrian Agency for Health and Food Safety, on January 1st, 2006. She is heading there the Scientific Office, which constitutes the link to the European Medicines Agency (EMA) with a focus on the different types of centralised European procedures during drug development, marketing authorisation applications and life-cycle management. Since 2003 she is a member of the EMA Scientific Advice Working Party, in 2007 she also became alternate member of the Committee for Human Medicinal Products of the EMA, where she is representing Austria now as the full member since 2009.

Prior to this, Andrea Laslop worked as an associate professor of pharmacology and toxicology at the Medical University of Innsbruck, Austria, where she earned her MD and later on specialized as a pharmacologist. Her professional career included several sojourns for joint research projects at the NIMH in Bethesda, the Albert Einstein College of Medicine in New York and the Clinical Research Institute of Montreal.

Cecilia Linde (Stockholm, SWE)

Cecilia Linde, MD, PhD, is Professor and former Head of Cardiology of the Karolinska University Hospital in Stockholm, Sweden. Her research focuses CRT in heart failure. She was a co-chairman in the MUSTIC study, the first randomized controlled study ion CRT in severe to moderate heart failure, and is the principal investigator of the REsynchronization reVErses Remodeling in Systolic left vEntricular dysfunction (REVERSE) study, which was the first to show a benefit of CRT in mild heart failure. She is presently the PI of the ongoing MiracelEF study focusing on CRT in mild to moderate heart failure and LVEF 36-50%. Dr Linde is the author of more than 200 papers, reviews and meeting abstracts in a wide variety of fields including CRT, haemodynamic monitoring and the molecular biology of arrhythmias, and she serves on the editorial board of several journals. She has been a board member of the European Heart Rhythm Association (EHRA), an official branch of the European Society of Cardiology. She has been involved in the EHRA Task Force for guidelines in pacing and CRT published 2007 updated 2010 and is a member of the scientific committee of the European cardiac resynchronization therapy survey. She is chair of the scientific program committee for EHRA Europace Cardiostim in Milan 2015 and a member of the Board EHRA.

Patricia Maillère (Servier, FRA)

Patricia (Pharm. D.) is Director Worldwide Regulatory Affairs (Pharmacien Responsible) at Les Laboratoires Servier. She is responsible for worldwide development support, registration procedures and product maintenance, as well pharmaceutical affairs in France, scientific information management and clinical quality assurance. Among her areas of expertise are centralized and decentralized European procedures, registration in key emerging countries, scientific advice, PIP, orphan designation and HAS filing. She has worked at Servier since 1984, specialising in regulatory affairs and R&D coordination. She is a member of AFAR, IPEC, DIA and EFPIA.

Kiyoshi Nobori (PMDA, JAP)

Kiyoshi Nobori, MD, PhD, is currently a Reviewer of Pharmaceuticals and Medical Devices Agency (PMDA), Japan. Prior to joining PMDA, he served as an Assistant Professor in Cardiology Division at Akita University in Japan (2006-2011). Dr. Nobori received his MD from Shinsyu University in Japan. He received his PhD from Tokyo Medical and Dental University, and his postdoctoral fellowship at Center for Cardiovascular Development, Baylor College of Medicine, Houston, TX.

Gunnar Olsson (previously AstraZeneca, SWE)

Graduated from Karolinska Institutet (medical school) in 1978 for medical degree. Licence to Practice Medicine 1980 (post-internship), Registrar 1980-86, Consultant 1986-1989.

PhD 1984, Specialist in Cardiology and Internal Medicine 1985, Associate Professor in Cardiology 1986, Adjunct Professor at Karolinska Institutet, Stockholm 1998-2010.

Honorary Doctorate in Medicine (honoris causa) at Gothenburg University 2004.

Medical Director (Cardiovascular) in Astra 1989, Various leadership roles in Astra/AstraZeneca R&D, and Vice President & Head of Cardiovascular and Gastro-intestinal in Global R&D 2003-2013. Approximately 125 publications in the field of cardiovascular medicine.

Ileana Piña (New York, USA)

Ileana L. Piña, MD, MPH, received her Doctor of Medicine from University of Miami in 1976, followed by an internal medicine residency (University of South Florida) and cardiology fellowship (University of Miami). Between 1982 and 2006, Dr. Piña served as a director at several institutions, in which she initiated cardiopulmonary testing of heart failure patients and established a cardiac rehabilitation program. From 2006 to 2009 she completed a Quality Fellowship at the Cleveland VA and, in 2010, obtained a Masters in Public Health.

Dr. Piña served as principal investigator in multiple heart failure trials, including PRECISE, ELITE and ATLAS, co-investigator for VEST and Val-HeFT, and served on the DSMB of WARCEF. She is a former member of the Heart Failure Society of America Executive Council and former Chair of NHLBI, via the HF-ACTION study and Clinical Trials Committee. A recent recipient of the prestigious AHA Chairman's Award (November 2013), Dr. Piña continues in her efforts to further AHA's strategic goals. She is currently on the Get With the Guidelines and Target HF committees and the Go Red for Women committee (AHA).

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

Bertram Pitt (Ann Arbor, USA)

Bertram Pitt is a professor of medicine emeritus at the University Of Michigan School Of Medicine. Dr. Pitt obtained his MD degree from the University of Basel in Switzerland in 1959. He subsequently did a fellowship in cardiology at the Johns Hopkins University School of Medicine and remained on the faculty there until 1977 when he left to direct the division of cardiology at the University of Michigan School of Medicine. He has been chairman or co-chairman of a number of clinical trials in cardiology including: SOLVD; ELITE I and II; Prevent; Rales and Ephesus. He is currently chairman of the steering committee of the NHLBI TOPCAT trial examining the effect of spironolactone in patients with HF and preserved LV systolic function; co-chairman of the Emphasis-HF trial examining the role of eplerenone in patients with NYHA Class II HF; chairman of Break-DHF; co-chairman of STOP-CKD; co-chairman of Exceed; 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 numerous medical journal editorial boards. He has also been a member of a number of medical organizations and has served as an advisor to the clinical trials branch of the NHLBI and a member of the FDA cardio-renal advisory board. He has been awarded the James B. Herrick Award by the Council of Clinical Cardiology of the American Heart Association and has been elected to the Society of Scholars of the Johns Hopkins University.

Stuart Pocock (London, GBR)

Stuart 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.

Professor 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.

Hubert Pouleur (Pfizer, USA)

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

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

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

Krishna Prasad (MHRA, GBR)

Manager, CV team, Expert Assessor/Cardiologist

MHRA, DoH UK, and St Thomas Hospital, London

Dr Prasad MB, BS, MD, FRCP, has a dual role at the MHRA, the UK regulatory agency, as a unit manager and an assessor. He is also a practicing cardiologist with a special interest in cardiovascular genetics and personalized medicine. He is a member of the Cardiovascular Working party of the CHMP/EMEA and the Co-rapp (EU/CHMP representative) for the ICH process relating to the E-14 guidance document. He has also been member of the pharmacogenomics working party of CHMP since its formal inception. In addition, prior to joining the MHRA, he worked as a BHF supported Research Fellow and Lecturer in Cardiology. His special areas of interest are heart failure, arrhythmias and sudden death where he was involved in research as an academic, with a number of publications. Dr Prasad's areas of special interest outside of cardiology are Pharmacogenetics/ pharmacogenomics, stratified medicine and drug innovation and he has been author on abstracts, publications including peer review papers, book chapters and editorials. He has an interest in development of regulatory guidance and in enhancing the interaction between academia, regulators and the other stakeholders.

Yves Rosenberg (NHLBI, USA)

Dr. Rosenberg, MD, M.P.H. is Chief of the Atherothrombosis and Coronary Artery Disease Branch, Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute, National Institutes of Health, in Bethesda, Maryland. Dr. Rosenberg obtained his MD from the University of Lyon, France, and is Board certified in Preventive Medicine. He also has an MPH from the Johns Hopkins School of Hygiene & Public Health, and a MS in Clinical Pharmacology. Dr. Rosenberg's main research interests are the design and conduct of large multicenter phase III clinicaltrials; the methodology of trials of treatment strategies and comparative effectiveness trials. As a Program Director at NHLBI for the last 18 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 NIH Project Scientist for a randomized trial of genotype-guided warfarin therapy (COAG), the first large scale (1,015 participants) NIH trial of genotype-guided therapy 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 a Nephrologist and Vascular medicine specialist, Professor of Therapeutics at the University of Lorraine, France. Since 2007, he is deputy Director in Nancy University Hospital Inserm Clinical Investigation Center, which is headed by Professor Faiez Zannad, researcher in Inserm UMR_S1116, and is consultant in the University Hospital Heart Failure and Hypertension Unit (ESH excellence Centre) as well as in hemodialysis clinics within a Disease Management program. He is mainly involved in clinical research, especially concerning circulating biomarkers, in the settings of heart failure, hypertension, hemodialysis and vascular diseases. He is also involved in translational basic research studies on the mechanisms of transition of hypertension and metabolic disorders to the cardiorenal syndrome. He is a EURECA-m (cardiorenal working group of ERA-EDTA) member since its creation in 2009 and was elected as board member in 2013. He is the PI of a doubleblind (spironolactone vs. placebo) CV outcome RCT in hemodialysis (ALCHEMIST), funded by the French Ministry of Health, and steering committee member of four international randomized clinical trials, including one led by EURECA-m.

Patrick Serruys (Rotterdam, NED)

Prof. Patrick W. Serruys, with respected *h-index – 118* is a professor of Interventional Cardiology at the Interuniversity Cardiological Institute of the Netherlands (1988-1998), and Erasmus MC. Since 1980 he was a Director of the Clinical Research Program of the Catheterization Laboratory, ThoraxCenter atErasmusUniversity, and since 1997 the Head of the Interventional Department, ThoraxCenter, Erasmus MC (University Medical Center Rotterdam), Rotterdam, The Netherlands.

He is a Fellow of the American College of Cardiology and a Fellow of the European Society of Cardiology and scientific council of the International College of Angiology.

In 1996 he received the TCT Career Achievement Award and in 1997 he was awarded the Wenkebach Prize of the Dutch Heart Foundation. In 2000 he was awarded the Gruentzig Award of the European Society of Cardiology. In 2001 he held the Paul Dudley White Lecture at the American Heart Association in the USA. In 2004 he received the Andreas Gruentzig Award of the Swiss Society of Cardiology. In 2005 he held the 4th International Lecture at the AHA and Mikamo Lecture at the Japanese heart Association. In 2006 he received the highest award of the Clinical Council of the American Heart Association: the James Herrick Award. In 2007 he received the Arrigo Recordati International Prize (Italy) and the ICI Achievement Award (bestowed by the President of Israel – Shimon Perez). In 2008 he received the Einthoven Penning (Leiden). In 2009 he became Doctor Honoris Causa from the University of Athens. In 2011 he received the Lifetime Achievement Award, bestowed by the American College of Cardiology, in recognition of many years of service and invaluable contributions to the ACC. At the end of 2011 Prof. Serruys received the Ray C. Fish Award, bestowed by the Texas Heart Institute, for outstanding achievement and contribution to cardiovascular medicine. In 2012 he received a Golden Medal of the European Society of Cardiology.

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.

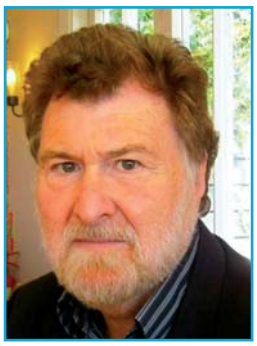
She worked as a cardiologist at Eiju general hospital from 2002 to 2005. Since March 2005, she has been working at the Pharmaceuticals and Medical Devices Agency (PMDA). She is currently Senior Scientist for Clinical Medicine, PMDA. She has been involved mainly in the review and consultation of new cardiovascular 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.

Scott Solomon (Boston, USA)

Scott D. Solomon, MD, is Professor of Medicine at Harvard Medical School, and Director of Noninvasive Cardiology and Senior Physician at Brigham and Women's Hospital. He also directs the Cardiac Imaging Core Laboratory and the Clinical Trials Endpoints Center at Brigham and Women's Hospital, and directs the Cardiac Imaging Center for the NHLBI sponsored Atherosclerosis Risk in Communities (ARIC) study and Hispanic Community Health Study – Study of Latinos (HCHS-SOL).

Dr. Solomon's research interests have focused on changes in ventricular structure and function following myocardial infarction, modifiers of risk and influences of outcome in patients following myocardial infarction and with chronic heart failure, cardiovascular safety of non-cardiovascular therapies, and factors that influence the transition from hypertension to heart failure. He has combined clinical trials with cardiac imaging, and has played a leading role in many international clinical trials in heart failure, hypertension and myocardial infarction, including the SAVE, HEART, VALIANT, CHARM, PEACE, OVERTURE, MADIT-CRT, ALOFT, ALLAY, TREAT, RED-HF, ALTITUDE, PARADIGM, FREEDOM, TOPCAT trials. He chaired the VALIDD, EXCEED, ASPIRE, PARAMOUNT trial. Dr. Solomon has directed the Harvard Medical School Cardiovascular Clerkshipand the echocardiography training program at Brigham and Women's Hospital for a decade. He has authored more than 250 original peer-reviewed articles, review articles and editorials, two textbooks of cardiac imaging, an iphone atlas of echocardiography, and the echocardiography sections for the next edition of *Braunwald's Heart Disease* and Harrison's *Principles of Internal Medicine.* He is Cardiology Section Editor at *UpToDate* and serves as Associate Editor at *Circulation*.



Stuart Spencer (London, GBR)

Stuart Spencer joined *The Lancet* in 1999 and throughout his time there has led the *Fast Track* team that aims to select, review and publish prestigious manuscripts within 4 weeks of receipt. Although dealing with all areas of research, he deals with most of the cardiology submissions.

His background is in research which started at the Brompton Hospital, London, looking at spinal curvature in children before moving to Bristol. During this period he was invited to work in The Netherlands to set up a research unit. Later he spent a year setting up a research team for a major pharmaceutical company in Switzerland, 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 Spencer is also a Trustee of the Scoliosis Association (UK) and is on the British Scoliosis Research Fund grants committee.

Norman Stockbridge (FDA, USA)

Norman Stockbridge received his MD and PhD (Physiology) from Duke University. He did research in basic cellular electrophysiology before joining in 1991 what is now the Division of Cardiovascular and Renal Products in FDA's Center for Drug Evaluation at Research. He has served as the Division Director since 2004.

Bart van der Schueren (EMA, BEL)

Bart van der Schueren is currently an assistant professor in Endocrinology at the University of Leuven, Belgium. He obtained his medical degree from the same University in 2002. In 2009 he successfully defended his PhD on the topic of drug development for migraine treatment. The emphasis of this work was on developing techniques to assess cardiovascular effects of new drugs early in their clinical development. In the same year he was recognized as a Clinical Pharmacologist by the Dutch Society of Clinical Pharmacology and Biopharmacy. Following his PhD, he finished his internship and graduated in 2010 as a Specialist in Internal Medicine and Endocrinology. Subsequently, he left for a post-doctoral scholarship at Columbia University College of Physicians and Surgeons, New York, USA to study the endocrinological and metabolic effect of bariatric surgery. He returned to Belgium in September 2011 and is now responsible for the obesity clinic at the University Hospital in Leuven. He is also an alternate member of both the scientific advice working party and the committee for medicinal products for human use at the European Medicines Agency.

Karen Wai (Quintiles, SGP)

Dr. Karen Wai is currently Senior Director, Integrated Site Services and Head of Feasibility and Site Identification Asia at Quintiles in Singapore. She leads a team responsible for feasibility, site identification and KOL mapping across Asia Pacific. She is a physician by training, acquiring a MB,BCh,BAO degree from Trinity College Dublin, Ireland. She also obtained her Masters in Business Administration from UCD Michael Smurfit Graduate Business School, Ireland. Prior to joining Quintiles she was working as a physician in both the public and private healthcare sector. Karen Wai has direct management and operational experience in European, African and Asian environments. She has served as Medical and Scientific Advisor on over 60 different clinical trial protocols in the following indications: oncology, neurology, cardiovascular, anti-infectives and rheumatoid arthritis. During this time her focus was in drug safety with experience in signal detection and risk management planning. Using her medical and safety background she is now focused on ensuring efficiency and quality during the initial planning of a clinical trial with regards to sites and investigators.

Janet Wittes (Washington, 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... She was formerly Editor in Chief of *Controlled Clinical Trials* (1994-98). She received her Ph. D. in Statistics from Harvard University. She looks forward each year to the CVCT Workshop.

Faiez Zannad (Nancy, FRA)

Faiez Zannad, MD, PhD, is Professor of Therapeutics at the Medical Faculty of the Henri Poincaré University of Nancy. He obtained his MD as a Cardiology specialist in 1979 from the Faculté de Médecine de Nancy. He is currently Head of the Division of Heart Failure, Hypertension and Preventive Cardiology/department of Cardiovascular Disease of the academic hospital of Nancy, and Director of the Clinical Investigation Center (CIC), mutually funded by the academic hospital and the INSERM and of a research group at an INSERM Unit (U961, Cardiac Fibrosis, Stiffness and cardiovascular risk) at the Faculté de Médecine. He is national coordinator of the network of 15 Clinical Investigation Centres working in the cardiovascular field in France. He is coordinating a Joint Research Program on transition from Hypertension to Heart Failure, in the 6th FP EU funded Network Excellence "InGeniousHyperCare". He conducts his research, in the area of physiopathology and pharmacotherapeutics of hypertension and heart failure.

Dr Zannad is currently Co-Editor in chief of *Fundamental and Clinical Pharmacology,* the official journal of the European Federation of Pharmacological Societies (EPHAR) and a member of the Editorial boards of a number of journals in the field of Cardiology, Hypertension and Cardiovascular Pharmacology.

He has contributed more than 300 scientific publications and published several books on cardiovascular pharmacotherapy and on Heart Failure. He is chairman and organizer of several international meetings: "CardioVascular Clinical Trialists (CVCT) Forum and Workshop" (Cannes and Paris, with Bertram Pitt and Desmond Julian); "Acute Heart Failure Syndromes" (Cannes and Chicago, with Mihai Gheoghiade) and "Biomarkers in Heart Failure" (Cannes, with Kirkwood Adams).

Dr. 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 of Executive Steering Committee: 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.
- Steering Committee Member: APSI, FIRST, CIBIS I, CAPRICORN, ASCEND-HF.
- Critical Event Committee: CAPRICORN, RESPECT, SCOUT, EchoCRT.
- Data and Safety Monitoring Board: HEAAL, ASPIRE.

16th CardioVascular Clinical Trialists Workshop

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