CVCT

15th CardioVascular Clinical Trialists Workshop

PARIS CVCT 2012

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

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Sunday 2
& Monday 3
December,
2012

Pullman
Montparnasse
PARIS, France

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

CHU NANCY

UNIVERSITÉ DE LORRAINE

emea

FDA

National Heart Lung and Blood Institute

EUROPEAN SOCIETY OF CARDIOLOGY

CVCT

15th CardioVascular Clinical Trialists Workshop

SUMMARY

15th CardioVascular Clinical
Trialists Workshop

Paris, December 2nd, 2012

Dear All,

We are most delighted to welcome you in Paris.

We hope that you have had a safe trip.
This is the 15th time that the Workshop on cardiovascular clinical trials is organized. There will be several participants familiar with the workshop and many new faces.

Thanks to your personal input and feedback from participants to the previous workshops we believe we have achieved an exciting program. We hope that you will enjoy the interactive format of the workshop, the variety of respective background of each participant, the science and also, hopefully, the camaraderie to which we all look very much forward. Should you need any assistance or have any query, please contact my assistant Stéphanie GROJEAN. She will attend the whole workshop.

We wish you a very successful meeting and a pleasant stay in Paris.

With our best regards,

Pr Faiez Zannad 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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15th CardioVascular Clinical Trialists Workshop

GENERAL INFORMATION

VENUE OF THE CONGRESS

PULLMAN Paris Montparnasse
19 Rue du Commandant René Mouchotte
75014 Paris

MEETING ROOM

"Soutine/Utrillo"

ON SITE CONTACTS

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TECHNICAL INFORMATION

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

DINNER

Sunday December 2nd, 2012

19:30 - Meet at the Workshop welcome desk

Private transfer by coach
Port Debilly (facing au 26 Avenue de New-York - 75016 Paris)

20:00 Aperitif on board of the "Montebello" boat,
and dinner cruise through Paris.

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15th CardioVascular Clinical Trialists Workshop

SCIENTIFIQUE PROGRAM

SUNDAY, DECEMBER 2ND, 2012

08:20-08:30 Welcome and Introduction: Faiez ZANNAD (Nancy, FRA)

08:30-10:00 Moderator: Faiez ZANNAD (Nancy, FRA)

❑ **Session 1 - New regulatory environment in human subject research**
(Streamlining RCTs, Consent form issues, Safety monitoring issues…)

Speaker: Alice MASCETTE (Bethesda, USA)
Discussant: Jerry MENIKOFF (OHRP, Rockville, USA)

10:00-10:30 **Coffee break**

10:30-12:30 Moderator: Ileana PIÑA (New York, USA)

❑ **Session 2 - How can we move beyond blinding?**

Speaker: Nancy GELLER (Bethesda, USA)
Discussant: Andrew FARB (FDA, USA)

12:30 -13:30 **Lunch**

13:30-15:30 Moderator: Janet WITTES (Washington, USA)

❑ **Session 3 - Alternatives to time-to-first event**

Speaker: Stuart POCOCK (London, GBR)
Discussant: Jeffrey BORER (New York, USA)

15:30-16:00 **Coffee break**

16:00-18:00 Moderator: Chris O'CONNOR (JACC-HF, Durham, USA)

❑ **Session 4 - Non-inferiority: Regulatory (FDA vs. EMEA) vs. sponsor vs. trialists views.**

Speaker: Rob HEMMINGS (London, GBR)
Discussant: David GORDON (Bethesda, USA)
Discussant: Scott BERKOWITZ (Bayer, USA)

MONDAY, DECEMBER 3RD, 2012

08:00-09:00 Moderator: Bertram PITT (Ann Arbor, USA)

❑ **Session 5 - How and how long should we look for long term safety of drugs that we prescribe for life?**

Speaker: Janet WITTES (Washington, USA)
Discussant: Desmond JULIAN (London, GBR)
Discussant: Armin KOCH (Hannover, GER)

09:30-10:30 Moderator: Marc PFEFFER (Boston, USA)

❑ **Session 6 - Reporting the results of randomized clinical trials in journals. Current statistical practices, consistency with regulatory files, and room for improvement.**

Speaker: John JARCHO (NEJM, Boston, USA)
Discussant: Stuart POCOCK (London, GBR)
Discussant: Christophe GAUDIN (Sanofi-Aventis, FRA)
Discussant: David GORDON (Bethesda, USA)

10:30-11:00 **Coffee break**

11:00-12:30 Moderator: Gonzalo CALVO (Barcelona, ESP)

❑ **Session 7 - Registries and post marketing surveillance studies. How useful for complementing RCTs?**

Speaker: Michael LAUER (Bethesda, USA)
Discussant: Roxana MEHRAN (New York, USA)
Discussant: Kenneth STEIN (Boston Scientific, USA)

12:30 -13:30 **Lunch**

13:30-14:30 Moderator: Wolfgang KOENIG (Ulm, GER)

❑ **Session 8 - To adjudicate or not to adjudicate**

Speaker: Nevine ZARIFFA (AstraZeneca, USA)
Discussant: Janet WITTES (Washington, USA)
Discussant: John MC MURRAY (Glasgow, GBR)

14:30-15:00 **Coffee break**

15:00-18:00 Moderators: Faiez ZANNAD (Nancy, FRA), Mihai GHEORGHIADE (Chicago, USA)

❑ Session 9: Special Session

Hospitalized Heart Failure trials: Are we missing the unmet needs? How to align between academia, industry, regulatory agencies, payers and clinical performance measures

Heart failure is of pandemic proportion and numbers of patients afflicted will continue to grow as the prevalence of diabetes, hypertension and coronary artery disease is increasing worldwide (particularly in Asia).
Economic burden associated with this condition is enormous as cardiovascular and stroke consumed nearly $300 billion in 2008, compared to $228 billion for cancer care, in the United States alone. Of this $300 billion, heart failure plays a prominent role with 1 in 9 death certificates in the United States listing it in 2008. New and or existing therapies will have 2 goals - on one hand to improve outcomes and on the other hand reduce costs (do more with less).
Development of new therapies should meet the need of payers (consumers) who carry this economic burden. It is the responsibility of "academia" to identify hospitalizations for heart failure (HHF) as a huge medical need given the unacceptably high post discharge rate which had not changed in the last decade. Apparently there is no alignment between the industry, academia, regulatory agencies and payers. It is not clear if the development of new therapies specifically targeting HHF (drugs and devices) will "start" with the industry or specific requests from the payers. Once the importance of HHF is recognized by all involved parties including industry, regulatory agencies, payers and academia, the groups must work together to formulate an approach that has the best chance of maximizing a return on investment.

Moderator: Faiez ZANNAD (Nancy, FRA),

❑ 9.1 - Hospitalizations for Heart Failure (HHF): A Global Health and Economical Burden

Speaker: Mihai GHEORGHIADE (Chicago, USA)
Discussant: Faiez ZANNAD (Nancy, FRA)
Discussant: Robert CODY (J&J, USA)

❑ 9.2 - Developing performance measures: what level of evidence is needed?

Speaker: Robert BONOW (Chicago, USA)

❑ 9.3 - The perspective of Industry

Speaker: Kenneth STEIN (Boston Scientific, USA)
Speaker: Dan SCHABER (Medtronic, USA)

Moderator: Mihai GHEORGHIADE (Chicago, USA)

❑ 9.4 - The perspective of the payers

Speaker: Scott TAYLOR (Geisinger, USA)
Speaker: Mira PAVLOVIC (HAS, Paris, FRA)

❑ 9.5 - The perspective of the regulatory agencies

Speaker: Gonzalo CALVO (Barcelona, ESP)
Speaker: Andrew FARB (FDA, USA)

17:30-18:00 **Summary and Next Steps**

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15th CardioVascular Clinical Trialists Workshop

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Kirkwood ADAMS, Chapel Hill, USA

Kirkwood F. Adams Jr., M.D., is Associate Professor of Medicine and Radiology in the Division of Cardiology, University of North Carolina at Chapel Hill, where he founded and for many years directed the UNC Heart Failure Program and served as the first transplant cardiologist for two decades, 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.

Dr. Adams 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 also served on the data and safety monitoring boards of the DEFINITE, EMOTE, IMPACT and SADHART-CHF trials and on national advisory boards for several pharmaceutical companies. He has served on the Steering Committees for the ESCAPE, ACQUAINT-HF, ACTIV in CHF, RITZ 4, OPTIME CHF, REVERT, and HF-ACTION, ASCEND, RELAX trials and the ADHERE and STAMINA-HFP registries. 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.

Dr. Adams has a major interest in developing practice guidelines for congestive heart failure. He also served as chair of the Guidelines/Clinical Positions Committee of the Heart Failure Society of America from 1996 to 2006 and is a past member of the Executive Council of this society.

He led the development of the original guideline devoted to pharmacological therapy and the first comprehensive guideline for heart failure developed by this society.

In addition to heart failure drug development, his current research interests are heavily focused on personalized medicine with ongoing projects related to novel biomarkers for heart failure, pharmacogenomics of heart failure therapeutics, and biomarker guided therapy for improving outcomes in CHF.

He is very actively involved on the Executive Committee for the NHLBI sponsoredtrial of NT-proBNP guided therapy know as GUIDE-IT.

Angeles ALONSO, Madrid, ESP

Senior Consultant. Cardiology Dpt. Hospital Universitario Puerta de Hierro. Madrid. Spain
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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 Programm Committee, Registries and Pharma Working Group)

Yuki ANDO, PMDA, Tokyo, JAP

Ms. Yuki Ando is a senior scientist for biostatistics of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan.

She received a master's degree in engineering from Tokyo Science University. Then she joined the Pharmaceuticals and Medical Devices Evaluation Center, which was subsequently transformed into the current PMDA.

Currently she is the leader of Biostatistics Group and is responsible for the statistical review and consultation in the new drug review offices in the PMDA. She is also the leader of "Innovative Statistical Strategies for New Drug Development" project team which is one of the projects across multi-offices in PMDA, and is involved in the research of design and evaluation of multi-regional clinical trials.

Scott BERKOWITZ, Bayer, GER

Scott D. Berkowitz, MD, FACP, FACC is currently Vice President and Head, Thrombosis and Hemostasis Group, Cardiovascular and Coagulation Therapeutic Area, Global Clinical Development at Bayer Healthcare Pharmaceuticals. He oversees the clinical development of the oral direct Factor Xa inhibitor rivaroxaban, the antithrombotic known as Xarelto®. Prior to this he worked at AstraZeneca LP on the clinical development of the first oral direct thrombin inhibitor, ximelagatran. His pharmaceutical clinical trial experience includes protocol development, trial medical oversight, data interpretation, synthesis, and presentation, IND and NDA/CTD authoring, health regulatory authority interactions with the FDA, EMA, and those of many other countries, and preparations for and representation to four FDA Advisory Committee meetings. Dr. Berkowitz has over 12 years of pharmaceutical industry experience and has been involved in clinical studies of coagulation medications for 22 years. Prior to joining industry, from 1993 – 2000 Dr. Berkowitz was Associate Professor of Medicine and Pathology at Duke University Medical Center, where he held dual appointments in Hematology and Cardiology of the Department of Medicine, and at the Duke Clinical Research Institute, where he provided coagulation and hematologic expertise to the Cardiology clinical trials 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 Research, Medical Information & Patient Safety in France.
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. In these roles she delivered innovative life cycle clinical programmes and established important scientific partnerships. Corine Bernaud is a physician with a post doctorate degree in Biology, Sports Medicine and Medical Science & Biology from the University of Franche-Comté, Besançon and a degree in Statistics & Clinical Research from the University of Paris VI in Paris, 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.

Robert O. BONOW, Chicago, USA

Dr. Robert O. Bonow is the Goldberg Distinguished Professor of Cardiology at the Northwestern University Feinberg School of Medicine and Director of the Center for Cardiovascular Innovation. He has authored or co-authored more than 450 published papers and 100 book chapters. He serves on the editorial boards of 10 medical journals and is one of the four editors of Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine.
Dr. Bonow is past-President of the American Heart Association, a Master of the American College of Cardiology and a Master of the American College of Physicians. He has chaired the Task Force on Performance Measures of the ACC/AHAAmong his honors are the NIH Director's Award, the U.S. Public Health Service Commendation Medal and Outstanding Service Medal, and elected membership in the American Society for Clinical Investigation and the Association of American Physicians. He is the recipient of the Distinguished Leadership Award, Distinguished Achievement Award, Gold Heart Award, and James B. Herrick Award of the AHA; the Distinguished Fellowship Award and Distinguished Service Award of the ACC; the Denolin Award of the ESC; and the John Phillips Memorial Award of the ACP. An endowed chair was established in his name at Northwestern University in 2012.

Jeffrey 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. He is Chairman, Department of Medicine and Chief, Division of Cardiovascular Medicine, and Director of two research institutes at Downstate. Dr. Borer received his BA from Harvard, his M.D. from Cornell, trained at the Massachusetts General Hospital, spent 7 years in the Cardiology Branch of the NHLBI and a year at Guy's Hospital in London as a Senior Fullbright Hays Scholar and Glorney-Raisbeck Fellow in the Medical Sciences, where he completed the first clinical demonstration nitroglycerin's utility in acute myocardial infarction. Upon returning to the NIH, he developed stress radionuclide cineangiography, enabling non-invasive assessment of cardiac function with exercise. He returned to Cornell for 30 years as Gladys and Roland Harriman Professor of Cardiovascular Medicine and Chief of the Division of Cardiovascular Pathophysiology. At Cornell and now at SUNY Downstate, in addition to teaching and clinical service, his research primarily has involved developing prognosticators for regurgitant valve diseases, exploring the cellular/molecular myocardial biology of valve diseases, and assessing the effects of heart rate modification on clinical outcomes, with trials in coronary artery disease and heart failure. He has been an Advisor to the USFDA for 34 years, was a life sciences Advisor to NASA for 24 years, has served as officer or board member of several national professional societies, has published more than 400 scientific papers and 4 books, is editor-in-chief of the journal, Cardiology, and has received several awards/recognitions for his work.

Gonzalo CALVO, Barcelona, ESP

Gonzalo Calvo is consultant in Clinical Pharmacology at Hospital Clinic of Barcelona, and Associate Professor of Pharmacology at the University of Barcelona (UB).

He represented the Spanish Agency on Medicines and Healthcare Products (AEMPS) in the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) from 2002 to 2011.

He was chair of the Cardiovascular Working Party and the Respiratory Drafting Group. He was elected President of the European Association of Clinical Pharmacology and Therapeutics in 2011.

Robert CODY, J&J, USA

Dr. Cody is Vice-President, and Heart Failure Disease Area Leader in the Cardiovascular and Metabolism franchise of Janssen Pharmaceuticals.LLC, of Johnson and Johnson. He previously was Executive Director, Merck & Co., and Global Director for Scientific Affairs-Cardiovascular. 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 M.D. 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.

Efthymios DELIARGYRIS, The Medicines Company, GER

Dr. Deliargyris completed his medical studies at the Kapodistrian University of Athens School of Medicine and subsequently completed his post-doctoral studies in the United States where he obtained triple board certification in Internal Medicine, Cardiovascular Medicine & Interventional Cardiology. He was subsequently Assistant Professor of Medicine/Cardiology at Wake Forest University, NC, USA where he also served as Director of the Intravascular Ultrasound Laboratory.

In 2004 he returned to Athens, GREECE and served as Chief of Cardiology at Athens Medical Center. In 2010 Dr. Deliargyris joined The Medicines Company where he now serves as the Global Medical Director at of Munich, GERMANY. Dr. Deliargyris has been the recipient of multiple research awards including the 1997 Merck Young Lipid Investigator Award, the 1999 Society of Cardiac Angiography and Interventions Research Competition - 1st Prize, the 2001 David A. Hack Excellence in Cardiovascular Research Competition - 1st Prize and the 2003 Vascular Biology Working Group Research Award. His primary research interests are in thrombosis and antithrombotic agents, including the pathophysiology of anti-PF4/heparin complex antibodies and their significance, also in imaging and treatments of vulnerable atherosclerotic plaques, and in novel risk factors for cardiovascular events with extensive prior research in the link between periodontal disease and atherosclerosis

Jeffrey FRIEDMAN, Boehringer, GER

Physician with U. S. board certification in paediatrics and paediatric nephrology following training at Cornell University Medical College-The New York Hospital, with an additional research fellowship in paediatric nephrology at Harvard University.
Prior academic appointment at Cornell University Medical College.
Thirty years experience in the clinical development of cardiovascular products for the following indications: hypertension, cardiovascular outcomes (MACE) prevention, heart failure, acute stroke outcomes improvement and chronic stroke prevention, prevention of cardiovascular outcomes associated with cardiac and non-cardiac surgery, diabetic nephropathy, acute coronary syndromes
Major Accomplishments include management of all clinical development of Pradaxa (dabigatran etexilate) from Phase II through registration in multiple indications

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Christophe GAUDIN, Sanofi-Aventis, FRA

After a 3-year post-doctoral training in US as a fellow from Harvard Medical School, then Columbia University in a research program of transgenic mice overexpressing the Gsalpha protein in the cardiomyocytes, Christophe Gaudin first joined the pharmaceutical industry in France as a Clinical Pharmacologist and was then appointed by Sanofi in 1997.

As a Clinical Research Director, he was responsible for the clinical development of clopidogrel in acute coronary syndrome, and then extended his responsibilities as Vice President Head of Cardiovascular and Thrombosis Clinical Investigations to lead the clinical development of a large portfolio of phase 2 and phase 3 projects.

Over 15 years in Sanofi, he led successful registration programs including the worldwide extension of clopidogrel indications and the dronedarone program.

Studies conducted under his responsibility at Sanofi included among others the CURE, CLARITY, CHARISMA, ACTIVE, STRADIVARIUS, CRESCENDO and ATHENA trials. His current role is focused in the phase 3 development of a new intravenous anticoagulant for patients with an acute coronary syndrome.

Nancy GELLER, NHLBI, Bethesda, USA

Nancy L. Geller has been the Director of the Office of Biostatistics Research at the National Heart, Lung and Blood Institute of the National Institutes of Health since 1990.

She directs a group of 12 statisticians who collaborate in the design, implementation, monitoring and analysis of multicenter clinical trials in heart, lung and blood diseases and sleep disorders and administers all statistical activities of the National Heart, Lung and Blood Institute.

She has been or is involved in the design and analysis of a number of cardiovascular trials, including PEACE, AFFIRM, WHI (Women's Health Initiative), FREEDOM, ACCORD, COAG (Clarification of Optimal Anticoagulation through Genetics) and the Ranolazine ICD trial (RAID).

She has published nearly 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.

Mihai GHEORGHIADE, Chicago, USA

Dr. Gheorghiade currently serves as Professor of Medicine and Surgery, Director of Experimental Therapeutics at the Center for Cardiovascular Innovation, Division of Cardiology, at Northwestern University's Feinberg School of Medicine and Northwestern Memorial Hospital.
He was recently appointed Adjunct Professor of Medicine and Co-Director of the new Cardiovascular Center for Drug Development at Duke University.

He graduated Magna Cum Laude from the University of Rome Medical School in 1972 and did his residency and fellowship in cardiology at Brown University. He then moved to Virginia, where he was Chief of Cardiology at the Salem VA Medical Center and Associate Professor of Medicine at the University of Virginia.

In 1985, Dr. Gheorghiade became Chief of the Cardiac Care Unit at the Henry Ford Hospital in Detroit and Associate Professor of Clinical Medicine at the University of Michigan. During his tenures in Virginia and Michigan, he received numerous teaching awards from both medical students and residents.

In 1992, he joined Northwestern University as Associate Chief of the Division of Cardiology, Chief of the Cardiology Clinical Service, and Director of the Telemetry Unit at Northwestern University Feinberg School of Medicine until 2010

Dr. Gheorghiade has served as a visiting professor in the United States and abroad. He has chaired or co-chaired more than 200 national and international meetings and has given more than 500 invited lectures. He has served or is currently serving on the editorial board of several journals including The American Heart Journal, The American Journal of Cardiology, Journal of the American College of Cardiology, and Circulation Heart Failure Journal, and is an associated editor of the Journal of Cardiovascular Medicine.

He has also served as guest editor on several occasions for The American Journal of Cardiology, The American Heart Journal, and The American Journal of Medicine.

He has chaired many international trials in heart failure including OPTIME-HF, ACTIV-HF, IMPACT, PRESERVD, HORIZON and COMPOSE Trials. He also co-chaired the global EVEREST Trial and the ECLIPSE Trial, and was a member of the Steering Committee of RADIANCE, FIRST, CARS, RITZ 4, and EPHESUS Trial. In addition, Dr. Gheorghiade was an active member of the Steering Committee in the OPTIMIZE-HF and IMPACT-HF registries. He currently serves as Chair of the international ASTRONAUT, RENO-DEFEND, and IMPROVE-HF Bridge.

Dr. Gheorghiade has authored more than 500 peer-reviewed publications and more than 300 abstract presentations at national and international meetings. He is the co-editor for two comprehensive textbooks on acute heart failure syndromes and has written several chapters in many textbooks including Kelley's Textbook of Internal Medicine, and Heart Failure: A Companion to Braunwald's Heart Disease, and most recently authored the chapter on Acute Heart Failure Syndromes in the ninth edition of Braunwald's Heart Disease.

In 2004, Dr. Gheorghiade founded the Acute Heart Failure Syndromes International Group, comprised of physicians, scientists, clinicians, and regulatory and governmental agencies from North America and Europe to advance the knowledge and care of patients with acute heart failure syndromes through clinical research.

This group has met annually, producing several consensus documents published in Circulation, Journal of the American College of Cardiology, and European Heart Journal.

In 2011, Dr. Gheorghiade assembled The Academic Research Team in Heart Failure (ART –HF) a group of expert clinicians and researchers with complimentary expertise to guide the development of heart failure therapeutics spanning the spectrum ranging from pre-clinical, phase I-III, and post marketing studies; to regulatory and guideline process and remains actively involved in animal and human research for the development of novel compounds for acute heart failure syndromes.

He dedicates significant time and energy to the mentorship of medical students, residents and junior faculty as attested by their primary authorship of more than 100 peer-reviewed publications in recent years. Improving outcomes of hospitalized patients with heart failure through research and education remains his top priorities.

David GORDON, NHLBI, Bethesda, USA

Dr. Gordon 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. 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.

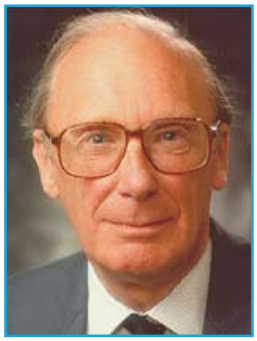
Robert HEMMINGS, MHRA, London, GBR

Rob is a professionally qualified medical statistician. He has been with the MHRA for 12 years and heads the group of medical statisticians. Much of Rob's time is spent educating medical colleagues in the importance and artistry of clinical trial statistics; their use in proof and in obfuscation. Rob holds the following positions within the European drug regulatory system:

- CHMP member: CHMP is the body responsible for preparing the opinions of the European Medicines Agency on questions concerning medicinal products for human use.
- Chair of the CHMP's Scientific Advice Working Party with responsibility for preparing advice to the pharmaceutical industry on the appropriate tests and trials to conduct in the development of a medicine for marketing authorisation.
- Rob is also a member of CHMP's Biostatistics Working Party with responsibility for giving advice on matters relating to clinical trial methodology across the EU regulatory network. Rob regularly speaks at national and international scientific meetings on a broad range of topics relating to medical statistics and drug licensing.

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.

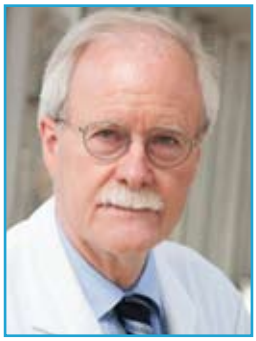


Desmond JULIAN, London, GBR

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. In 1962, he went to Sydney, Australia to set up one of the first coronary units. 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 Editor of the European Heart Journal from its inception in 1979 to 1988. 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.

Armin KOCH, Hannover, 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. Prof. Koch is a member of the Scientific Advice Working Party (SAWP) and the Biostatistics working party (BSWP) at the European Medicines Agency (EMA).



Wolfgang KOENIG, Ulm, GER

Wolfgang Koenig, MD, PhD, FRCP, FESC, FACC, FAHA is a Professor of Medicine and Cardiology at the University of Ulm Medical School, Ulm, Germany. He is Board certified in internal medicine, cardiology, and in intensive care medicine with special interest in invasive and interventional cardiology. At present he serves as a Consultant in Cardiology, and is the Director of the Preventive Cardiology Program and the Clinical Trial Unit (CTU) at the Department of Internal Medicine II - Cardiology of the University of Ulm Medical Center. Dr. Koenig`s research interests involve the molecular basis of atherothrombogenesis including genomics, metabolomics, and other technologies. Further interests include type 2 diabetes, the metabolic syndrome, the clinical pharmacology of cardiovascular active compounds, and the clinical epidemiology of cardiovascular disorders, focusing on the identification and evaluation of new biomarkers for cardiometabolic diseases. Dr. Koenig has published more than 500 research papers and reviews. He has an H-Index of 60. He is a member of the Editorial Board of Clinical Chemistry and Associate Editor of Atherosclerosis. Presently he serves on the Steering Committee of various large international randomized clinical trials testing innovative targets in cardiovascular medicine.

Stuart KUPFER, Takeda, USA

Stuart Kupfer serves as Global Therapeutic Area Head of Cardiovascular Medicine at Takeda Pharmaceuticals International and is based in Deerfield, IL, USA. His areas of research include heart failure, hypertension, thrombosis, diabetes, 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.

Michael LAUER, NHLBI, Bethesda, USA

Michael Lauer, M.D., 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 spent 14 years at Cleveland Clinic as Professor of Medicine, Epidemiology, and Biostatistics. 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 has received numerous awards including the NIH Equal Employment Opportunity Award of the Year and the Arthur S. Flemming Award for Exceptional Federal Service.

Alice MASCETTE, NHLBI, Bethesda, USA

Alice M. Mascette, M.D., is a board-certified cardiologist with more than 20 years of clinical experience spanning interventional and outpatient cardiology and medical education.

She joined the National Heart, Lung, and Blood Institute (NHLBI) in 2003.

While there, Dr. Mascette has served as Senior Clinical Science Adviser and as Chief of the Heart Failure & Arrhythmias Branch in the Division of Cardiovascular Sciences and as the Director of the Clinical and Molecular Medicine Program in the former Division of Heart and Vascular Disease. She has served as Project Officer for the Occluded Artery Trial, the Heart Failure Clinical Research Network, and the CABANA trial, and has overseen the initiation and/or management of two other large clinical trials networks, including the Resuscitation Outcomes Consortium.

She has recently been named the Acting Deputy Director of the newly formed NIH Office of Emergency Care Research. She is a fellow in the American College of Cardiology, American College of Physicians, and the American Heart Association.

She participates in clinical training at Walter Reed Army Medical Center and holds an adjunct appointment at the U.S. Uniformed Services University of the Health Sciences in Bethesda, MD.

John MC MURRAY, Glasgow, GBR

John McMurray, FESC, is Professor of Medical Cardiology and convener for clinical research in the Institute of Cardiovascular & Medical Sciences at the University of Glasgow.

He is also Lead Consultant Cardiologist at the Western Infirmary, Glasgow.
Professor McMurray served as the inaugural Eugene Braunwald Scholar in Cardiovascular Disease at the Brigham and Women's Hospital, Boston and visiting Professor of Medicine, Harvard University, Boston, Massachusetts USA 2010/2011.

He is immediate Past-President of the Heart Failure Association of the European Society of Cardiology (HFA of the ESC).
His primary research interests are in heart failure, coronary heart disease, diabetes and atrial fibrillation, with a focus on clinical trials, epidemiology, and health services research. He also has an interest in socioeconomic determinants of health and outcomes.

Professor McMurray is, or was, the principal investigator, member of the executive committee or steering committee member in a number of large trials in heart failure and other cardiovascular diseases.

He has also run or participated in a number of end-point and safety committees.

He has published approximately 400 original papers, reviews, and book chapters and is the primary author or editor of thirteen books. He was the lead author of the WHO and first SIGN guidelines on the management of heart failure, a member of the 2008 ESC heart failure guideline Task-Force, and Chair of the 2012 Task-Force.

Professor McMurray sits on the editorial board of several leading cardiovascular journals, including New England Journal of Medicine, European Heart Journal and European Journal of Heart Failure.

Roxana MEHRAN, New York, USA

Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI, is Professor of Medicine and Director of Interventional Cardiovascular Research and Clinical Trials at the Zena and Michael A. Weiner Cardiovascular Institute at Mount Sinai School of Medicine. Dr. Mehran completed her training in internal medicine at the University of Connecticut, where she was also a Chief Medical Resident, before continuing with Fellowships in Cardiovascular Disease and Interventional Cardiology at Mount Sinai Medical Center. Dr. Mehran is internationally recognized for her work as a clinical trial specialist with complex data analyses and outcomes research within the field of interventional cardiology and for her experience and expertise in working with regulatory agencies to conduct clinical trials. Her research interests expand from mechanisms of restenosis to treatment and prevention of acute kidney injury in cardiac patients, as well as advancing treatments for acute coronary syndromes and acute myocardial infarction. In addition to founding a highly regarded academic research organization (ARO) within the Cardiovascular Research Foundation, she is also a widely published author and frequent invited speaker at national and international scientific conferences such as American Heart Association, American College of Cardiology, European Society of Cardiology, and EuroPCR. She has served as Course Co-Director of the annual Transcatheter Cardiovascular Therapeutics (TCT) for the last 13 years. Dr. Mehran serves on editorial board of multiple peer reviewed journals, including Journal of the American College of Cardiology, Circulation, and Circulation Research. She currently serves on the board of trustees of SCAI, as a member of the Program Committee for the American Heart Association Scientific Sessions, as a member of the board of directors for Harboring Hearts, and as Program Chair for Society of Cardiac Angiography and Interventions (SCAI- WIN (Women in Innovations)) Initiative, and is also the Chief Scientific Officer of the Clinical Trials Center at the Cardiovascular Research Foundation (NYC).

Jerry MENIKOFF, OHRP, Rockville, USA

Jerry Menikoff, M.D., J.D., is the Director of the U.S. Office for Human Research Protections. This office leads the Department of Health and Human Services' efforts to ensure the responsible conduct of research involving human subjects. Prior to this, he was in charge of the human subjects protections program at the National Institutes of Health.

Prior to joining the NIH, Dr. Menikoff was Associate Professor of Law, Ethics & Medicine at the University of Kansas. He has been a faculty fellow at the MacLean Center for Clinical Medical Ethics at the University of Chicago, and at the Center for Ethics and the Professions at Harvard University. He also has been on the faculty of the University of Chicago School of Law and other law schools. He is the author of the textbook Law and Bioethics: An Introduction (Georgetown University Press 2001) and of What the Doctor Didn't Say: The Hidden Truth about Medical Research (Oxford University Press 2006). He is a co-author of The Ethics and Regulation of Research with Human Subjects (LexisNexis 2005).

Christopher O'CONNOR, Durham, USA

Dr. O'Connor is the Director of the Heart Center and Division Chief of Cardiology and Clinical Pharmacology at Duke University. He is a Professor of Medicine and Associate Professor in Psychiatry and Behavior Sciences. He is a Fellow of the ACC, the AHA, and the ESC. He has served on over 90 CEC and DSMC committees in 25 years and served as Chair or Co-Chair on many of these committees. He has an extensive record of successful mentorship of trainees and has published over 400 manuscripts. He has served as PI or Co-PI on over 20 national and international clinical trials with an extensive record of NIH/NHLBI and industry grants. His research interests include: acute heart failure; co-morbidities in heart failure; clinical trials; biomarkers; and novel pharmacological and non-pharmacological approaches for the treatment of heart failure. Dr. O'Connor completed his undergraduate and medical school training at University of Maryland and his Internal Medicine residency and Cardiology Fellowships at Duke University.

Mira PAVLOVIC, HAS, Paris, FRA

Mira Pavlovic-Ganascia, MD, practicing physician and Deputy Director for Health Technology Assessment at the Hauté Autorité de Santé (HAS), France, in charge of national and European activities related to health technology assessment (HTA), in particular those related to the EUnetHTA. HAS is the EUnetHTA JA1WP5
Co-lead and EUnetHTA JA2WP7 lead partner.
Previously heavily involved in regulatory science; Head of Scientific Advice Unit at the French Medicines Agency (AFSSAPS), Vice-Chair of Scientific Advice Working Party (SAWP), a member of Efficacy Working Party (EWP), and Biosimilar Medicinal Products Working Party (BMWP) at the EMA.

Marc PFEFFER, Boston, USA

Dr. Marc A. Pfeffer, a graduate of Rockford College in Rockford, Illinois, received both his doctorate in physiology and biophysics and his medical degree from the University of Oklahoma in Oklahoma City.
He completed his internship, residency and clinical fellowship at the Peter Bent Brigham Hospital, Harvard Medical School in Boston.
Dr. Pfeffer is currently the Dzau Professor of Medicine at Harvard Medical School and physician in the Cardiology Division at Brigham and Women's Hospital.
Dr. Pfeffer also serves as medical director of Partners Research and Education Program (PREP).
Dr. Pfeffer has distinguished himself as a translational investigator. Along with his late wife, Dr. Janice Pfeffer, and Eugene Braunwald, M.D., their studies in an experimental model of myocardial infarction first introduced the concept of an insidious deleterious structural remodeling of the impaired ventricle.
They demonstrated in both animals and man that angiotensin converting enzyme (ACE) inhibitors could attenuate these adverse structural and functional changes providing the rationale for the use of these agents in patients experiencing a myocardial infarction.
Pfeffer led the first definitive clinical trial demonstrating that this use could prolong survival and prevent the development of heart failure, which has improved the prognosis of untold numbers of survivors of myocardial infarction.
From his major initial discovery, Dr. Pfeffer's career trajectory has been to lead a number of other key practicechanging, randomized controlled clinical trials. Indeed,a common theme for his substantial contributions has been in the utilization of the randomized controlled trial to enhance the academic mission.
Dr. Pfeffer has had a principal role in several practicechanging clinical trials such as SAVE, CARE, HEART, VALIANT, CHARM and PEACE. He is currently a leading investigator in ARISE, TOPCAT and TREAT.
He is generally considered as a team builder and takes pride in academic advancement of trainees and junior faculty collaborating on the trials, and embedding important mechanistic substudies within the major randomized trials to enhance our understanding of the pathophysiology of the disease processes.
Pfeffer's trials have set high standards for relationships with the sponsors whether industry or NHLBI. He is known for his fairness in data sharing and assisting others in developing meaningful scholarly works from study databases. His studies have improved medical practice and patient prognosis.

Ileana Piña, New york, USA

Ileana L. Piña, MD, MPH, FACC, FAHA, FACP
Professor of Medicine & Professor of Epidemiology/Biostatistics
Case Western Reserve University
Graduated Quality Scholar
Louis Stokes Administration of Veteran's Affairs

Dr. Piña, a cardiologist and heart failure/transplant expert received her MD at the University of Miami in 1976. She continued her education and received her Masters of Public Health in 2009 after completing a 3 year Fellowship in Quality at the Cleveland VA. She has served as Director of the Exercise Laboratory at the University of Miami, of Heart Failure and Cardiac Rehabilitation at Hahnemann University, of Cardiomyopathy at Temple University and Heart Failure/Transplantation at University Hospitals Health System at Case Medical Center. Dr. Piña is the Principal Investigator of as well as has participated in many studies focused on improving heart failure and rehabilitation.

She serves as an advisor/consultant to the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health and the Division of Epidemiology which allows her to assist in evaluation and review cardiovascular medical devices, epidemiologic research studies while working with the FDA staff.

Dr. Piña is internationally recognized for her research in rehabilitation and recovery of heart failure patients. She has over 70 publications and is a world-renown speaker on this subject. She has been a recurrent presenter/speaker in the World Congress of Cardiology in Spain, Argentina, Berlin, and Beijing. She is also a National Spokesperson for Go Red for Women and the Heart Truth of Ohio in which she is dedicated to finding out why and coming up with solutions for women who suffer from Heart Disease, which will enable them to live healthier, longer, lives.

In 1995, Dr. Piña established and initiated The National Heart Failure Training Program (N-Heft™) at Case Western Reserve University with Hector Ventura of Ochsner Medical Center in New Orleans, Louisiana which is a program that seeks to educate physicians and other healthcare professionals in best practices for treating heart failure.

Dr. Piña is a recipient of many Outstanding Service Awards and Best Doctors recognition Awards 2010. She sits on numerous committees and chairs countless scientific sessions and meetings and is currently a member for the AHA (American Heart Association) Writing Group Women's Cardiovascular Diseases Prevention Guidelines. She also representes the AHA at the Electronic Health Inititaive (eHI) and AHRQ Task Force on Workplace.

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 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. His particular methodologic interests include: standards for the statistical reporting of trials and epidemiological studies, the statistical ethical and organisational principles for data monitoring including early stopping guidelines, the presentation of time-to-event (survival) data, the pros and cons of equivalence trials, and problems of multiplicity in trial reporting eg subgroup analyses, multiple outcomes and covariate adjustment.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 Cardiovascular Research Foundation in New York and the New England Research Institutes in Boston. He is a frequent lecturer on a variety of clinical trial 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.

Rita REDBERG, San Francisco, USA

Rita F. Redberg, MD, MSc, has been a cardiologist and Professor of Medicine at the University of California, San Francisco since 1990. Dr. Redberg is currently the Chief Editor of Archives of Internal Medicine and has spearheaded the journal's new focus on health care reform and "less is more", which highlights areas of health care with no known benefit and definite risks. Her research interests are in the area of health policy and technology assessment focusing on how evidence relates to FDA approval, insurance coverage and medical guidelines and practice, particularly in the area of medical devices. Dr. Redberg is a member of the Medicare Payment Advisory Commission, which advises Congress on Medicare payment issues. She also served on the Medicare Evidence, Development and Coverage Advisory Committee from 2003-2006 and was reappointed in 2012 as Chair of MEDCAC. Dr Redberg is a member of the California Technology Assessment Forum, the Medical Policy Technology and Advisory Committee, and the Food and Drug Administration Cardiovascular Devices Expert Panel, and is a consultant for the Center for Medical Technology Policy. She gave Congressional testimony four times in 2011 in hearings related to the issue of balancing safety and innovation in medical device approvals Dr. Redberg worked in the office of Senator Hatch and with the Senate Judiciary Committee on FDA-related matters during her tenure as a Robert Wood Johnson Health Policy Fellow, 2003-2006.

Dr. Redberg was a member of the Institute of Medicine's Learning Health Care Committee, which produced the report Best Care at Lower Cost in September 2012. She chaired the AHA/ACC Writing Group on Primary Prevention Performance Measures and is a member of the American College of Cardiology's (ACC) Clinical Quality Committee and serves on the Quality in Technology Work Group. She does comparative effectiveness research, and serves on the American College of Cardiology's Comparative Effectiveness Work Group, represents the ACC on the Institute of Clinical and Economic Review Advisory Board and serves on other ACC Committees, including several on appropriate use of cardiac imaging. She was honored by receiving the Women's Day Red Dress Award in 2011 for her leadership in the area of heart disease in women. Dr. Redberg graduated from Cornell University and the University of Pennsylvania Medical School and has a Master of Science in Health Policy and Administration from the London School of Economics.

Yves ROSENBERG, NHLBI, Bethesda, 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, 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 from the University of Lyon, France. 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 17 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. The major studies he currently is involved include: ACCORDION (Action to Control Cardiovascular Risk in Diabetes Follow-On Study); FREEDOM (Future Revascularization Evaluation in Patients with Diabetes mellitus Optimal Management of Multivessel Disease).
Dr. Rosenberg is also the lead NIH Project Scientist for a randomized trial of genotype-guided warfarin therapy (COAG), the first large scale (1,200 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

Ph. D. student, INSERM Unit 460, Dr Michel, Paris (11/2000-31/10/2002)
fellowship in vascular biology, Center for Molecular and Vascular Biology, Katholieke Universiteit Leuven (Belgium) : Pr Lijnen, Pr Collen (11/2002-31/10/2003)
Chief-Assistant, then Assistant Professor (05/2006-04-2007) : Vascular Medicine and Hypertension department, Pr Fiessinger, Hôpital Européen Georges Pompidou (Assistance Publique-Hôpitaux de Paris), Paris, and Faculté de Médecine René Descartes-Paris V ; associate researcher, INSERM 765 (formerly U 428), Pr Emmerich. (11/2003-04/2006)
Assistant-Professor (Therapeutics), delegate physician of the Nancy University Hospital & INSERM Clinical Investigation Centre (Coordinating physician : Pr Zannad) ; associate researcher, INSERM 961, Dr Lacolley. (05/2007)
Professor of therapeutics (2010)
steering committee member of the Hepzero trial (2011)
PI of the ALCHEMIST trial (2012)

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Dan SCHABER, Medtronic, USA

Dan Schaber PharmD is Vice-President Heart Failure Clinical Research, Medtronic Inc.

In this role, Dan is responsible for providing overall leadership and direction on a worldwide basis for new product approval, new indication approval and post market approval clinical research in heart failure.

Dan has more than 25 years experience in the pharmaceutical and medical device industry. Dan joined Medtronic in 1987 from the University of Minnesota and Minneapolis Children's Medical Center where he was an Assistant Professor of Clinical Pharmacy.

Since coming to Medtronic he has held management positions in the clinical research, product development, regulatory and marketing organizations of Cardiac Rhythm Management.

From 1995 thru 1998 Dan was on an expatriate assignment in Switzerland where he served as the Business Director for the Tachyarrhythmia and EP Systems businesses.

In 1998 he returned to the U.S. where he has held senior leadership positions in Cardiac Rhythm Marketing, Bradyarrythmia Therapy, Program Leadership for the implantable hemodynamic monitor and Clinical Research Strategy.

Dan has a Doctor of Pharmacy degree from the University of Minnesota and was Pediatric Clinical Pharmacy Fellow at Minneapolis Children's Medical Center.

Kaori SHINAGAWA, PMDA, JAP

Dr. Kaori Shinagawa 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.

Kenneth STEIN, Boston Scientific, USA
Senior Vice President & Chief Medical Officer Cardiac Rhythm Management

Ken Stein, MD, FACC, FHRS, is currently Chief Medical Officer and Senior Vice President for Boston Scientific's Cardiac Rhythm Management (CRM) division of the Cardiology, Rhythm and Vascular (CRV) Group.
Dr. Stein held the position of Associate Director of Clinical Cardiac Electrophysiology at Weill Cornell Medical Center and Associate Professor of Medicine at Cornell University prior to joining Boston Scientific in September of 2009.
Dr. Stein currently oversees the development and execution of clinical strategy for the Company's CRM division.
Ken is a Phi Beta Kappa graduate of Harvard College (magna cum laude in Economics), and he earned his MD from New York University School of Medicine. He completed his medical internship and residency at The New York-Presbyterian Hospital/Weill Cornell Medical Center, where he also completed his cardiology and electrophysiology training. He has published widely in the areas of cardiac electrophysiology with special interest in cardiac resynchronization therapy and risk stratification for sudden cardiac arrest.

Scott WASSERMAN, Amgen, USA

Dr. Wasserman is an Executive Medical Director in Global Development at Amgen where he is responsible for the clinical development of novel cardiovascular therapeutics in the Cardiovascular Therapeutic Area. During more than seven years at Amgen, he has taken new therapies, including small and large molecules, from phase 1 through phase 3 clinical development. He set strategy and led numerous critical programs in heart failure, anemia, osteoporosis, fracture healing, and lipid metabolism. Most recently, Dr. Wasserman's efforts focus on the design and execution of global clinical trials in heart failure, hypercholesterolemia, and the emerging cardiovascular pipeline.
Prior to joining Amgen, he was on faculty at Stanford University in the Division of Cardiovascular Medicine where he was the principal investigator on NIH-funded research that examined endothelial gene expression and served as an attending cardiologist at the Palo Alto Veterans Administration Hospital. Dr. Wasserman received his M.D., Magna Cum Laude from Harvard Medical School and his B.S., Magna Cum Laude from Haverford College. He completed his postgraduate training in Internal Medicine and Cardiovascular Medicine at Stanford University and is board certified in both disciplines.

Janet WITTES, Washington, USA

Janet Wittes, Ph.D., is President of Statistics Collaborative, Inc. which she founded in 1990. Previously, she was Chief, Biostatistics Research Branch, National Heart, Lung, and Blood Institute (NHLBI) and on the faculty of the Department of Mathematical Science, Hunter College of the City University of New York. She was formerly Editor in Chief of Controlled Clinical Trials. In 2006, she was awarded the Janet L. Norwood Award for Outstanding Achievement by a Woman in the Statistical Sciences.

Her research has focused on the design and analysis of randomized clinical trials, capture recapture methods in epidemiology, sample size recalculation problems in clinical studies, and incorporation of subjective outcomes in clinical trials. She is a coauthor of the monograph, “Statistical Monitoring of Clinical Trials – A Unified Approach” by Proschan, Lan, and Wittes.

She is a Fellow of the American Statistical Association, the Society for Clinical Trials (SCT), the American Association for the Advancement of Science, and an elected member of the International Statistical Institute. She received her A.B. in Mathematics from Radcliffe College (1964) and her Ph.D. in Statistics from Harvard University (1965, 1970).

Andrew ZALEWSKI, Novartis, USA

Andrew Zalewski, M.D. is Vice-President and the Head of Clinical Science Unit for Cardiovascular Disease overseeing heart failure, thrombosis and atherosclerosis portfolio in Novartis Pharmaceuticals Corp. He is also Professor of Medicine (Cardiology) at Thomas Jefferson University in Philadelphia, USA.

Dr. Zalewski joined Novartis in 2008. Between 2002 and 2008, he led clinical development of several products in cardiometabolic area in GlaxoSmithKline, including design and conduct of several mechanistic studies (biomarkers, multimodality imaging) and cardiovascular outcomes trials.

He continues to publish and lectures on topics of atherosclerosis, acute coronary syndrome, and plaque vulnerability.
He is US board certified cardiologist.
Dr. Zalewski has been on the faculty of the Thomas Jefferson University in Philadelphia since 1985 where his clinical activities centered on interventional cardiology, coronary imaging and devices. He is past recipient of the W.W. Smith Endowed Chair in Cardiovascular Research. Between 1990 and 2002, he directed multidisciplinary Cardiovascular Research Center in the Division of Cardiology at Thomas Jefferson University in Philadelphia, USA.
His research, supported by the National Institutes of Health and American Heart Association, focused on atherosclerosis and vascular biology and resulted in numerous peer-reviewed publications.

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. In 1981 he served as a Research Fellow at the Clinical Pharmacology Medical Research Unit of Oxford University, UK and in 1986 he obtained his PhD in cardiovascular clinical pharmacology at the University of Lyon. 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 Past Chairman of the Board of the French Society of Hypertension, Fellow of the European Society of Cardiology (ESC), Chairman of the ESC Working group on pharmacology and drug therapy as well as Board member of the ESC Heart Failure Association. He 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. : Executive Steering committee member: CIBIS 11, RALES VALIANT, RECOVER, MOXCON, EPHESUS,, EVEREST, AURORA, EXAMINE, ASTRONAUT, AXIOM-ACS, SERVE-HF, HF-ACTION; NECTAR-HF, PEARL-HF, ALBATROSS, REMINDRE, FOSIDIAL (Chairman), EMPHASIS-HF (Chairman) Steering Committee membership: APSI, FIRST, CIBIS I, ASCEND-HF, CAPRICORN, , Critical Event Committee: CAPRICORN, RESPECT, SCOUT, EchoCRT Data and Safety Monitoring Board HEAAL, ASPIRE.

Nevine ZARIFFA, AstraZeneca, USA

Névine's current role is VP of Biometrics and Information Sciences at AstraZeneca and was previously at GlaxoSmithKline.

During her career, she amassed a wealth of experience in her specialist area of statistics and also driving strategic programmes. She has supported all phases of drug development, and has led global teams of quantitative experts in statistics, programming, data management, modeling, epidemiology and health economics.

Névine has also led - or played an integral part in - numerous strategic initiatives, working with company colleagues, medical associations, academics and other groups (both PhRMA and FDA-sponsored) to enhance the value of quantitative sciences beyond the traditional role of designing, analysing and interpreting clinical trials.

She is the author or co-author of 26 publications in peer-reviewed journals.

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