

ABADIE Eric

Directeur du Département de l'Enregistrement et des Etudes Cliniques Directeur de l'Evaluation Thérapeutique AFSSAPS 143-147, boulevard A. France 93285 SAINT-DENIScedex FRANCE

ADAMOPOULOS Chris

Centre d'investigation clinique Hopital Jeanne d'Arc 54201 Dommartin les toul FRANCE

ADAMS Kirkwood

Associate Professor Chapel Hill NC 27517 USA

AHMED Ali

Assistant Professor Division of Gerontology and Geriatric Medicine University of Alabama at Birmingham 1530 3 Avenue Sout CH 19 - Suite 219 BIRMINGHAM, Alabama 35294-2041 USA

ALLAFrançois

Service d'Epidémiologie et Evaluation Cliniques Centre d'épidémiologie clinique (INSERM/CHU) CHU de Nancy CO N° 34 54035 Nancy Cedex FRANCE

ALTMAN Douglas

ICRF Medical Statistics Group, Centre for Statistics in Medicine Institute of Health Sciences OXFORDOX3 7LF UNITED KINGDOM

BERNAUD Corine

Directeur Thérapeutique Cardiologie Métabolisme & Thrombose ASTRAZENECA 1, Place Renault 92844 RUEIL-MALMAISON cedex FRANCE

BORER Jeffrey S.

Chief, Division of Cardiovascular Pathophysiology Department of Medicine New York Presbyterian Hospital Weill Medical College of Cornell University 47 East 88th Street NEW-YORK, NY10128-1152 USA

CLELAND John

Academic Cardiology Unit University of Hull Castle Hill Hospital Castle Road HULLHU16 5JQ UNITED KINGDOM

COHN Jav

Cardiovascular Division, MMC 508 University of Minnesota 420 Delaware Street S.E. MINNEAPOLIS,MN 55455 USA

DESAI Mehul

Medical Officer in the Division of Cardiovascular and Renal Products FDA Bldg 2210903 New Hampshire Ave Silver Spring MD 20993 USA

EVANS Stephen

School of Hygiene and Tropical Department of Epidemiology and Population Health London School LONDON WC1E 7HT UK

FAYRenaud

Centre d'investigation clinique Hopital Jeanne d'Arc 54201 Dommartin les toul FRANCE

GATTIS STOUGH Wendy

Assistant Consulting Professor Expert Medical Communications & Consulting, LLC 108 Windfall Court CARY, NC 27511 USA

GELLER Nancy

Office of Biostatistics Research, National Heart, Lung and Blood Institute 2 Rockledge Centre, Room 8210, 6710 Rockledge Drive MCS 7938 BETHESDA MD 20892-7938 USA

GHADANFAR Mathieu

Global Brand Medical Director Aliskiren and Hypertension Cardiovascular Metabolism & Atherosclerosis NOVARTIS PHARMAAG Clinical Development & Medical Affairs Lichtstrasse 35 WSJ-202.2.33 CH-4002 BASEL SWITZERLAND

GORDON David

Division of Heart and Vascular Dieseases 6701 Rockledge Drive, Room 9152 BETHESDA, Maryland 20892-7940 USA

GUEZ David

SERVIER MEDICAL 22, rue Garnier 92201 NEUILLY-SUR-SEINE cedex FRANCE

HUNG James

Food and Drug Administration 5600 Fishers Lane ROCKVILLE, Maryland 20857 USA

HUVELLEEtienne

Centre d'investigation clinique Hopital Jeanne d'Arc 54201 DOMMARTIN LES TOUL

JULIAN Desmond

Dept of Cardiology University of Newcastle upon Tyne, Flat 1 7 Netherhall Gardens LONDONNW3 5RN UNITED KINGDOM

LEMAIRE François

Réanimation Médicale Hôpital Henri Mondor - Université Paris XII 94010 CRETEIL FRANCE

LIPICKYRaymond

DirectorLIPICKY, LLC 15201 Apricot Lane GAITHERSBURG, MD 20878 USA

LONGROIS Dan

Chirurgie Cardio-Vasculaire et Transplantations CHU de NANCY 54505 VANDOEUVRE-LES-NANCY FRANCE

LUBSEN Koos

SOCAR RESEARCH SA Chemin de Chantemerle 18 CH - 1260 NYON 2 SWITZERLAND

MADSEN Steinmar

Medical Director - Department of Pharmacotherapy Norwegian Medicines Agency Sven Oftedalsvei 8, 0950 Oslo OSLO NORWAY

MAILLERE Patricia

Directeur Général IRIS 6, place des Pléiades 92415 COURBEVOIE FRANCE

MOUNDEJI-BOUDIAF Lamia

Medical Director PDLBioPharma 118, rue de RIVOLI 75001 PARIS FRANCE

PERELMAN Michael

VP-Global Project Management SCHERING PLOUGH 2000 Galloping Hill Road KENILWORTH, NJ 07033 USA

PITT Bertram

Dept of Internal Medicine Taubman Center 24 Rilgeway Medical Center Drive ANN ARBOR, MI 48019-0366 USA

POCOCK Stuart

Medical Statistics Unit London School of Hygiene and Tropical Medicine Keppel Street LONDON, WC1E 7HT UNITED KINGDOM

POULEUR Hubert

Executive Director PFIZER INC 235 East 42nd Street 205/8/13 NEW YORK, NY10017 USA

ROLAND Edmond

Hôpital Européen Georges Pompidou 20, rue Leblanc 75908 PARIS cedex 15 FRANCE

ROSSIGNOLPatrick

Vascular medicine and hypertension department, Hôpital Européen Georges Pompidou 20, rue Leblanc 75908 Paris cedex 15 FRANCE

SACKETT David

Director, Trout Centre RR1 Markdale ONTARIO CANADANOC 1H0 CANADA

SHURIN Susan

NIH NHLBI Room 5A48 31 Center Drive MSC 2486 BETHESDA, MD 20892-2490 USA

SLEIGHT Peter

Cardiac dept John Radcliffe Hospital Headington OXFORD OX3 9DU UNITED KINGDOM

SOPKO George

NIH/NHLBI 6701 Rockledge Drive Suite 6044C BETHESDA, MD 20892-7940 USA

STEG Philippe Gabriel

Service de Cardiologie HOPITALBICHATCLAUDE BERNARD 46, rue Henri Huchard 75877 PARIS cedex 18 FRANCE

SUGARMAN Jeremy

Berman Bioethics Institute,
Department of Medicine
JOHNS HOPKINS UNIVERSITY,
Hampton House 351
624 N. Broadway
BALTIMORE, MD 21205
USA

WARREN John

MEDICINES AND HEALTHCARE PRODUCTS REGULATORYAGENCY(MHRA) Room 11.213 Market Towers - 1, Nine Elms Lane LONDON SW8 5NQ UNITED KINGDOM

WEDELHans

Nordic School of Public Health Apelsingatan 115 S-426 54 V. FROLUNDA SWEDEN

WITTES Janet

Statistics Collaborative 1710 Rhode Island Ave, NW WASHINGTON, DC 20008 USA

ZANNAD Faiez

CIC INSERM-CHU and Department of cardiology Hôpital Jeanne d'Arc 54200 DOMMARTIN LES TOUL FRANCE

Eric ABADIE

Dr E. ABADIE is a physician. He has qualified in internal medicine, cardiology and endocrinology-diabetology in Paris university in 1981.

After having been resident and consultant in several Parisian hospitals, he joined the pharmaceutical industry, being international project manager at Roussel Uclaf, Director of development at Wellcome, and Director of Medical Affairs at SNIP. In this latter position, he represented the pharmaceutical industry in the main official committees at the Ministry of Health such as the Marketing Authorization, Transparency, Pharmacovigilance Committees.

In 1994, he joined the French Medicine Agency as Director of Therapeutic Evaluation Department. In 1995, he was appointed French member of the Efficacy Working Party, satellite of the CPMP. In this position he has been Rapporteur (and author) of several CPMPclinical guidelines in the field of diabetology, cardiology, osteoporosis, and central nervous system. In 1997, he became CPMPmember. In the ICH process he has been the EU topic leader for the Common Technical Document. Since 2001, he is vice chairman of the CHMP, chairman of the Pharmacogenetics Working Party, and ICH Steering Committee member.

He is the author of approximately 100 publications in clinical and medical science, member of the Editorial board of Cardiology (2005), and Associate Professor at the Tor Vergata University, Roma and in the Department of Epidemiology and Public Health, Liege University. He holds also a Master of Business Administration at the Centre de Perfectionnement des Affaires in Paris (1992).

Ali AHMED

Business Address: Division of Gerontology and Geriatric Medicine,

University of Alabama at Birmingham

(UAB), 1530 3rd Avenue South, CH-19, Suite 219, Birmingham, Alabama 35294-2041

Phone: 1-205-934-9632; Fax: 1-205-975-7099; E-Mail: aahmed@uab.edu

ACADEMIC APPOINTMENTS

09/06 - Present Director, Geriatric Heart Failure Research Unit, Center for Heart Failure Research,

UAB

01/04 - Present Scientist, Center for Heart Failure Research, UAB

08/00 - Present Assistant Professor, Department of Epidemiology, School of Public Health, UAB

02/00 - Present Assistant Professor, Department of Medicine, School of Medicine, UAB,

HOSPITALAND OTHER PROFESSIONAL POSITIONS AND APPOINTMENTS

10/02 - Present Founding Director, Geriatric Heart Failure Clinic, UAB, Birmingham, AL 02/01 - Present Founding Director, Geriatric Heart Failure Clinic, VAMC, Birmingham, AL

EDUCATION

1997 - 1999 School of Public Health, UAB, Master of Public Health (Epidemiology)

1976 - 1982 Sher-e-Bangla Medical College, University of Dhaka, MBBS (M. D. Equivalent)

AWARDS/HONORS

2006 Elected a Fellow of the European Society of Cardiology 2004 Elected a Fellow of the American Heart Association 2003 Elected a Fellow of the American College of Cardiology

BOARD AND OTHER CERTIFICATIONS

1979-98 Diplomate, Internal Medicine and Geriatrics, ABIM (Number: 176470)

LICENSURE:

1996 State of Alabama Medical Licensure Commission # 20242

COUNCILS AND COMMITTEES

2006 - 2007
 2005 - 2008
 2004 - 2007
 2002 - 2004
 Member, Scientific Advisory Boards of the International Academy of Cardiology
 Chair-Elect, Membership Committee, Gerontological Society of America
 Member, Scientific Sessions Program Committee, AHAQuality of Care IWG
 Chair, Membership Committee, CM Section, Gerontological Society of America

RESEARCH AND GRANTS: (PASTAND CURRENT)

2006 - 2010 Ahmed A(PI). Heart failure, chronic kidney disease, and renin-angiotensin system

inhibition (1 R01 HL085561-01).

2003 - 2007 Ahmed A(PI): Heart Failure and Beta-Blocker Use in Older Adults

(1 K23 AG019211-01A1-4).

EDITORIALBOARD MEMBERSHIPS

2005 - Member, Editorial Board, Journals of Gerontology, Medical Sciences
 2005 - Member, Editorial Board, American Journal of Geriatric Cardiology
 2005 - Member, Editorial Board, Archives of Gerontology and Geriatrics

François ALLA MD, PhD

Public Health Practitioner, Epidemiologist, Associate Professor at the University Hospital of Nancy

Ecole de santé publique, Faculté de médecine de Nancy, Université Henri Poincaré, Nancy 1 Avenue de la Forêt de Haye, 54505 Vandoeuvre-les-Nancy. Tél. : 03 83 59 25 88, Fax. : 03 83 59 26 90

EDUCATION

- 2002: PhD in Epidemiology (Doctorat de l'Université de Nancy I)
 subiect: "Prognostic Studies. Application to Severe Heart Failure"
- 1999: Specialty in Public Health (DES de santé publique et médecine sociale)
- 1999: Medical Doctor Degree (Doctorat en médecine)

POSITIONS

- current position: Associate Professor of Public Health at School of Public Health, Nancy Faculty of medicine Practitioner in epidemiology and evaluation department, Nancy University Hospital (maitre de conférence des universités - praticien hospitalier)

- 2000/2002 Assistant Professor (assistant hospitalo-universitaire)

- 1994/2000 Resident (interne des hôpitaux)

OTHERS

Editor-in-Chief of Santé Publique, peer-reviewed journal of the French Society of Public Health (Société Française de Santé Publique); Vice-President of the French Society of Public Health.

Major publications in cardiovascular field

Duval X, Alla F, Doco-Lecompte T, Le Moing V, Delahaye F, Mainardi JL, Plesiat P, Célard M, Hoen B, Leport C. Diabetes Mellitus and Infective Endocarditis: the Insulin factor in patient morbidity and mortality. European Heart J 2006 (in press)

Zannad F, Mebazaa A, Juillière Y, Cohen-Solal A, Guize L, Alla F, Rougé P, Blin P, Barlet MH, Paolozzi L, Vincent C, Desnos M, Samii K, for the EFICAlnvestigators. Clinical profile, contemporary management and one-year mortality in patients with severe acute heart failure syndromes: The EFICAstudy. Eur J Heart Fail 2006 (in press)

Duval X, Alla F, Hoen B, Danielou F, Larrieu S, Delahaye F, Leport C, Briancon S. Estimated risk of endocarditis in adults with predisposing cardiac conditions undergoing dental procedures with or without antibiotic prophylaxis. Clin Infect Dis 2006;42(12):e102-7 Alla F, Kearney-Schwartz A, Radauceanu A, Das Dores S, Dousset B, Zannad F. Early changes in serum markers of cardiac extracellular matrix turnover in patients with uncomplicated hypertension and type II diabetes. Eur J Heart Fail 2006;8(2):147-53. Quilliot D, Alla F, Bohme P, Bruntz JF, Hammadi M, Dousset B, Ziegler O, Zannad F. Myocardial collagen turnover in normotensive obese patients: relation to insulin resistance. Int J Obes (Lond) 2005;29(11):1321-8.

Duval X, Selton-Suty C, Alla F, Salvador-Mazenq M, Bernard Y, Weber M, Lacassin F, Nazeyrolas P, Chidiac C, Hoen B, Leport C, AEPEI. Endocarditis in patients with a permanent pacemaker: a 1-year epidemiological survey on infective endocarditis due to valvular and/or pacemaker infection. Clinical Infectious Diseases 2004;39:(1):68-74.

Brembilla-Perrot B, Suty-Selton C, Alla F, Beurrier D, Houriez P, Claudon O, Terrier de la Chaise A, Louis P, Sadoul N, Andronache M, Miltjoen H, Juilliere Y. Facteurs de risque de mortalité cardiaque en cas de syncope et d'antécédents d'infarctus du myocarde. Arch Mal Coeur Vaiss 2003;96(12):1181-6.

Hoen B, Alla F, Selton-Suty C, Beguinot I, Bouvet A, Briancon S, Casalta JP, Danchin N, Delahaye F, Etienne J, Le Moing V, Leport C, Mainardi JL, Ruimy R, Vandenesch F; Association pour l'Etude et la Prevention de l'Endocardite Infectieuse (AEPEI) Study Group. Changing profile of infective endocarditis: results of a 1-year survey in France. JAMA2002;288:75-81

Alla F, Briançon S, Guillemin F, Juillière Y, Zannad F, EPICALinvestigators. Self-Rating of Quality of Life Provides Additional Prognostic Information in Heart Failure. Insights into the EPICALstudy. Eur J Heart Fail 2002;4:337-43.

Echemann M, Alla F, Briançon S, Juillière Y, Virion JM, Mertès PM, Villemot JP, Zannad F, for the EPICALInvestigators. Antithrombotic therapy is associated with better survival in patients with severe heart failure and left ventricular systolic dysfunction (EPICALstudy). Eur J Heart Fail 2002;4:647-54.

Zannad F, Dousset B, Alla F. Treatment of Congestive Heart Failure. Interfering the Aldosterone-Cardiac Extracellular Matrix Relationship. Hypertension 2001;38:1227-1232.

Zannad F, Alla F, Dousset B, Perez Aand Pitt B. Limitation of the Excessive Extracellular Matrix Turnover may Contribute to the Survival Benefit of Spironolactone Therapy in Patients With Congestive Heart Failure. Insights from the RALES Trial. Circulation 2000;102: 2700-2706.

Alla F, Briancon S, Juilliere Y, Mertes PM, Villemot JP, Zannad F. Differential clinical prognostic classifications in dilated and ischemic advanced heart failure: the EPICALstudy. Am Heart J 2000;139(5):895-904.

Angioi M, Danchin N, Alla F, Gangloff C, Sunthorn H, Rodriguez R, Preiss JP, Grentzinger A, Houplon P, Juilliere Y, Cherrier F. Long-term outcome in patients treated by intracoronary stenting with ticlopidine and aspirin, and deleterious prognostic role of unstable angina pectoris. Am J Cardiol 2000;85(9):1065-70.

Zannad F, Briançon S, Juillière Y, Mertès PM, Villemot JP, Alla F, Virion JM, and the EPICALInvestigators. Incidence, clinical and etiologic features, and outcomes of advanced chronic heart failure: the EPICALstudy. J Am Coll Cardiol 1999;33:734-42.

Doug ALTMAN

graduated in statistics in 1970. After 6 years in epidemiological research at St Thomas Hospital Medical School he spent 11 years working for the Medical Research Council in a wide variety of clinical areas. He has been director of the Medical Statistics Group of Cancer Research UK (previously ICRF) since 1988 and founded the Centre for Statistics in Medicine in Oxford in 1995.

Doug is author of Practical Statistics for Medical Research (1991) and co-editor of Statistics with Confidence (1989 and 2000) and Systematic Reviews in Health Care (1995 and 2001). He has published over 300 articles in per reviewed journals, including many aimed at clarifying statistical methods and ideas for medical researchers. He is statistical advisor to the Cochrane Collaboration and the BMJ.

His interests include the use and abuse of statistics in medical research, studies of prognosis, regression modelling, randomised trials, meta-analysis, and studies of medical measurement.

He has a long-standing interest in the reporting of medical research, and is an executive member of several groups working on reporting guidelines, including CONSORTfor randomised trials, QUOROM for systematic reviews, STROBE for epidemiological studies, and REMARK for tumour marker prognostic studies.

Corine BERNAUD

MD is presently Cardiovascular, Metabolism & Thrombosis Medical Director, in AstraZeneca France. Corine Bernaud joined the pharmaceutical industry sixteen years ago after four years of medical practice as a general practitioner and sports medicine specialist. She joined Pfizer France in 1990 then Sankyo Pharma France in 2004. She has contributed to the design, monitoring and steering of several clinical trials in cardiology and a number of publications in peer reviewed journals.

Jeffrey S. BORER M.D.

Jeffrey S. Borer, M.D. is the Gladys and Roland Harriman Professor of Cardiovascular Medicine at Weill Medical College of Cornell University, where he also is Professor of Radiology and of Cardiothoracic Surgery and, administratively, chairs the Division of Cardiovascular Pathophysiology and The Howard Gilman Institute for Valvular Heart Diseases.

He received his undergraduate education at Harvard, his medical degree from Cornell, and his postgraduate training at the Massachusetts General Hospital and in the Cardiology Branch of the National Heart, Lung and Blood Institute, where he subsequently established the Nuclear Cardiology service and served as its first Chief. He was a Senior Fulbright Hays Scholar and Glorney-Raisbeck Fellow in 1974-75 at Guy's Hospital, University of London, in London, England. In 1979, he returned to Cornell. Dr. Borer is Editor-in-Chief of Cardiology, one of the world's oldest peer-reviewed cardiovascular journals, and of Advances in Cardiology, and serves on the Editorial Boards of 10 major peer-reviewed journals. Since 1977 he has served continually as an Advisor/Consultant to the Cardio-Renal Division of the U.S.F.D.A., chairing the Cardio-Renal Advisory Committee for 3 separate terms, the last ending in 2004, and currently is a recurring Guest Member of the Cardiovascular Devices Advisory Committee and other FDAAdvisory Committees. From 1984 to 2004, he served continually as an Advisor to NASA(and, in 1999, received the Public Service Medal of NASA). He was President of the New York Cardiological Society in 1990-91, President of the New York State Chapter of the American College of Cardiology from 1997 to 1999, member of the Board of Governors of the American College of Cardiology from 1997-2000, member of Board of Governors of the Society of Cardiac Angiography and Interventions from 1995 to 2000, and member of the Board of Trustees of the Certification Board of Nuclear Cardiology from 1996 to 2002. Currently, he is President of the Heart Valve Society of America. He has authored 4 books and authored or co-authored more than 350 journal articles, reviews and chapters. His major research achievements have included (1) establishment of the benefits of the drug, nitroglycerin, during acute myocardial infarction (1971-75); (2) development of real-time radionuclide cineangiography and its application during exercise (1976-1979); (3) development of non-invasive prognostic indices in patients with coronary artery and valvular diseases (1979-present); (4) exploration of the cellular and molecular bases of heart failure in regurgitant valvular diseases and other volume overload states (1984-present), for which he has received numerous

professional awards/recognitions, including the Hans Peter Krayenbeuhl Memorial Award for Distinguished

Contribution in Research in Cardiac Function of the International Academy of Cardiology (2002).

John G.F. CLELAND

Medical Education: University of Glasgow 1972-1977

Qualifications: Bachelor of Medicine & Surgery (with commendation) 1977

Doctor of Medicine 1991

Fellow of the Royal College of Physicians Fellow of the European Society of Cardiology Fellow of the American College of Cardiology

Previous Senior Appointments:

1989-1994. Senior Lecturer in Cardiology,

Royal Postgraduate Medical School,

Hammersmith Hospital.

1994-1998 Senior British Heart Foundation Research Fellow, Medical Research Council Clinical

Research Initiative in Heart Failure, University of Glasgow.

Research Focus:

Clinical aspects of advanced heart disease ranging from epidemiology, through pathophysiology to clinical trials designed to improve patients' symptoms and well-being and to prolong their survival.

Since 1999 an international reference centre for the management of heart failure has been established in Kingston upon Hull placing it in the top 10-20 clinical research centres for advanced heart disease in the world. It is the largest clinical programme for heart failure in Britain. The programme allows the development of new techniques for earlier and more accurate diagnosis, better risk assessment and for delivering the highest quality modern therapy. The programme also examines the costs of delivering quality care to determine how limited resources can deliver the most benefit for patients now and in the future.

Special Appointments:

Consultant: - World Health Organisation

- National Institute of Clinical Excellence UK

Senior Consulting Editor (Past Editor-in-Chief): European Journal of Heart Failure

Editorial Board: - Journal of American College of Cardiology

- Seminars in Cardiology

Associate Editor of the Cardiovascular Clinical Trials Forum
 Associate Editor of the Cochrane Cardiovascular Review Board

The Circulation Frontier

Committee: - Data Standards Committee, American College of Cardiology

Chairman: - Study Group On Diagnosis Of Heart Failure, European Society of Cardiology

Chairman (2006-7) - British Society for Heart Failure

Past-Secretary: - British Cardiac Society

Past-Chairman: - Heart Failure Association of the European Society of Cardiology

Jay N. Cohn MD is Professor of Medicine, Cardiovascular Division, Department of Medicine, and Director of the Rasmussen Center for Cardiovascular Disease Prevention, at the University of Minnesota Medical School, Minnesota, Minnesota.

Dr. Cohn received his M.D. from Cornell University Medical School in 1956 and completed his internship and residency at Beth Israel Hospital in Boston. He served as a fellow in cardiovascular research and as a clinical investigator at the Veterans Affairs (VA) Hospital and Georgetown University from 1960 to 1965. He was Chief of Hypertension and Clinical Hemodynamics at the VAHospital from 1965 to 1974 and Professor of Medicine at Georgetown University. Dr. Cohn was Head of the Cardiovascular Division at the University of Minnesota from 1974 to 1996.

Dr. Cohn is internationally recognized for his contributions to our understanding of cardiovascular disease and for his leadership in designing and carrying out clinical trials to document efficacy of new interventions for heart failure. He has pioneered in assessment of cardiovascular function in patients with hypertension, shock, acute myocardial infarction and heart failure. He was the first to advocate vasodilator therapy for heart failure, including nitroprusside, nitrates with hydralazine and converting enzyme inhibitors. He organized and chaired the first long-term trials in heart failure, the Veterans Affairs Cooperative Study Program on vasodilator therapy of heart failure (V-HeFT). Dr. Cohn was one of the first to advocate bedside hemodynamic monitoring in acutely ill individuals and was the first to identify the syndrome of right ventricular infarction. He was among the first to identify neurohormonal activation as a key contributor to the progression of heart failure and to set the stage for neurohormonal inhibiting therapy. His animal and clinical studies have established the importance of structural remodeling of the left ventricle as the basis for the progression of heart failure and for the therapeutic response to drugs that prolong life and reduce long-term morbidity. In recent years he has focused on efforts at early identification of cardiovascular disease in order to initiate therapy before organ system disease develops. His innovative efforts at early detection have included screening to diagnose stiffening of the small arteries, utilizing a methodology he developed at the University of Minnesota which is now FDA-approved and marketed worldwide.

Dr. Cohn is the founder of the Heart Failure Society of America and served as the first president of this society, which is now the premier organization in the world of health professionals dedicated to the diagnosis and treatment of heart failure. He also founded and served as editor-in-chief of the first journal dedicated to heart failure, the Journal of Cardiac Failure, which is now one of the most frequently cited cardiovascular journals. He is the author of more than 600 scientific publications and has written extensively on circulatory physiology, hypertension, congestive heart failure and its treatment, nervous system control mechanisms in heart failure, and vascular compliance. He holds a number of patents, including those related to pulsewave analysis for the measurement of arterial elasticity and use of hydralazine and isosorbide dinitrate for the treatment of heart failure. He serves on the editorial boards of many of the major journals in the field. He is co-editor of the cardiology text, Cardiovascular Medicine, and editor of the textbook, Drug Treatment of Heart Failure.

Dr. Cohn is a Master of the American College of Physicians, a fellow of the American College of Cardiology and the American Association for the Advancement of Science and is a member of the Association of American Physicians and the American Society for Clinical Investigation as well as many other professional societies. He is a Past President of the Heart Failure Society of America, the International Society of Hypertension, and the American Society of Hypertension and has served as an officer of the American Heart Association and the American Federation for Clinical Research. He served as chairman of the Cardiorenal Advisory Committee of the Food and Drug Administration and has served on a number of government boards and committees.

Dr. Cohn has been the recipient of a number of awards including the Arthur S. Flemming Award, the James B. Herrick Award of the American Heart Association (AHA), the Distinguished Service Award (AHA), the AHA Scientific Councils' Distinguished Achievement Award, the Distinguished Scientist Award of the American College of Cardiology, the Novartis Award of the Council for High Blood Pressure Research, the Lifetime Achievement Award of the Heart Failure Society of America, the William S. Harvey Award, the Sir Thomas Lauder Brunton Award and the Arrigo Recordati International Prize for Scientific Research: Lifetime Achievement in Heart Failure, the Henry Ford Heart & Vascular Institute's Lifetime Research Achievement Award, induction into the Academic Health Center's Academy for Excellence in Health Research at the University of Minnesota and the Clinical Scholar Award for 2006 of the University of Minnesota Medical Center. He has presented numerous honorary lectures around the world and has served as visiting professor at many universities here and abroad.

Stephen J. W. EVANS

CURRENTPOST Professor of Pharmacoepidemiology, Dept of Epidemiology & Population Health, The London School of Hygiene and Tropical Medicine.

PREVIOUS RELEVANTPOSTS

Aug 2000-April 2002 Specialist in Epidemiology, Medicines Control Agency Feb 1999-Jul 2000 Principal Consultant Statistician, Quintiles, East Sussex Nov 1995-Jan 1999 Head of Epidemiology Unit, Medicines Control Agency

The London Hospital Medical College (University of London) 1973-1995. Professor of Medical Statistics, (previously Reader, Senior Lecturer, Lecturer) Department of Epidemiology and Medical Statistics, Head of Computer Department & Honorary Lecturer in Computer Science (1973-78). Responsible for teaching & research, particularly consulting on statistics.

UNIVERSITYEDUCATION

1961 64 & 65-66 Keele University, Staffordshire

B.A. Hons 2.1 1966 (Physics, Chemistry joint Honours, Mathematics subsidiary)
Swarthmore College, Pennsylvania, USA1964 65 (Exchange Scholarship)

1978 London School of Hygiene & Tropical Medicine MSc Medical Statistics

MEMBERSHIPOF PROFESSIONALINSTITUTIONS AND SOCIETIES

1993 Fellow, Royal Statistical Society (FSS) 1977 Chartered Statistician (C.Stat)

Chair (94-96) RSS Medical Section. RSS Honours Committee (1995-99)

1991-2003 Honorary Member of the Faculty of Public Health Medicine of the Royal College of

Physicians (Hon MFPHM)

Honorary Member, Royal College of Radiologists (Hon MRCR)
 Fellow of the Royal College of Physicians of Edinburgh (FRCPEdin)
 Inaugural President, British Society of Pharmacoepidemiology

2003-6 Chair, Academic Council International Society of Pharmacoepidemiology

EDITORIALBOARDS (current only)

Associate Editor: Pharmacoepidemiology and Drug Safety. Section Editor ("Statistics in the Medical Literature") for Statistics in Medicine. Statistical advisor to British Medical Journal & member of `Hanging' Committee. Int J of Pharmaceutical Medicine; Statistical Methods in Medical Research; Gut; J. of Drug Evaluation; British Journal of Clinical Pharmacology

SOME RECENTPUBLICATIONS

- -Evans, SJW. Pharmacovigilance: a science or fielding emergencies? Statist. Med. 2000; 19:3199-209.
- -Evans SJW, Waller PC, Davis S. Use of proportional reporting ratios (PRRs) for signal generation from spontaneous adverse drug reaction reports. Pharmacoepidemiology & Drug Safety 2001; 10: 483-6.
- -Aylin P, Alves B, Best N, Cook A, Elliott P, Evans SJW, Lawrence AE, Murray GD, Pollock J, Spiegelhalter D. Comparison of UK paediatric cardiac surgical performance by analysis of routinely collected data 1984-96: was Bristol an outlier? Lancet 2001; 358: 181-7
- -Evans S. Statistical Methods of Signal Detection in Pharmacovigilance Eds Mann R & Andrews E. Chichester, Wiley 2002.
- -Waller PC, Evans SJ. Amodel for the future conduct of pharmacovigilance.Pharmacoepidemiol Drug Saf. 2003;12:17-29.
- -Loannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D; CONSORTGroup. Better reporting of harms in randomized trials: an extension of the CONSORTstatement. Ann Intern Med. 2004;141:781-8.
- Martinez C, Rietbrock S, Wise L, Ashby D, Chick J, Moseley J, Evans S, Gunnell D. Antidepressant treatment and the risk of fatal and non-fatal self harm in first episode depression: nested case-control study. BMJ. 2005;330:389.
- -Evans SJW & Day S. Medicines and Healthcare products Regulatory Agency (MHRA) In: Armitage P, Colton T(eds) Encyclopedia of biostatistics. 2nd edn. Chichester: John Wiley, 2005.
- -Al-Marzouki S, Roberts I, Marshall T, Evans S. The effect of scientific misconduct on the results of clinical trials: ADelphi survey. Contemp Clin Trials. 2005;26:331-7.
- -CIOMS VI. Management of Safety Information from Clinical Trials. CIOMS, Geneva, 2005. (Especially Chapter VI, Statistical Analysis of safety Data from Clinical Trials).
- -Waller PC, Evans SJ, Beard K. Drug safety and regulation. BMJ. 2005;331:4-5.
- -Al-Marzouki S, Evans S, Marshall T, & Roberts I. Are these data real? Statistical methods for the detection of data fabrication in clinical trials. BMJ 2005;331: 267-270.
- -Rothman KJ, Evans S. Extra scrutiny for industry funded trials. BMJ. 2005;331:1350-1.
- -Kim J, Evans S, Smeeth L, & Pocock S. Hormone replacement therapy and acute myocardial infarction: a large observational study exploring the influence of age. Int J Epidemiology 2006; 35(3):731-738
- -Waller PC, Evans SJW, Beard K. Drug safety and the media. Br. J. Clin. Pharmac. 2006 2006;61:123-6.
- -Coleman JJ, Ferner RE, Evans SJW. Monitoring for Adverse Drug Reactions. Br. J. Clin. Pharmac 2006; 61(4):371-378
- -Piaggio, G.; Elbourne, D.R.; Altman, D.G.; Pocock, S.J.; Evans, S.J. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORTstatement. JAMA, 2006; 295(10):1152-60.

Mehul DESAI

M.D. is board certified in Internal Medicine and Clinical Pharmacology. His current position is as a Medical Officer in the Division of Cardiovascular and Renal Products at the U.S. Food and Drug Administration. He has been in that position for more than 4 years.

Renaud FAY

PharmD

Personnal information Born in 1951 in France

D ()	
Professional	eynerience

Professional experience		
Since 2004	data manager and biostatistician in the Clinical Investigation Center (ICI) INSERM-CHU of Nancy (France)	
1993-2003	data manager and biostatistian in a CRO (MRC, Methodology and Clinical Research, Reims, France)	
1985-1991	academic staff member in the University Hospital and Faculty of Medicine of Reims (France, Toxixology and Functional Explorations Laboratory)	
Formation 1985-1987 1982-1984 1976-1981	master of Pharmacology (University Hospital and Faculty of Medicine of Nancy, France) internship of Biology (University Hospital and Faculty of Medicine of Reims, France) University Hospital and Faculty of Medicine of Reims, France. Terminal degree: Pharmacy Doctor	

Nancy L. GELLER

is the Director of the Office of Biostatistics Research at the National Heart, Lung and Blood Institute of the National Institutes of Health, a position she has held since 1990. She directs a group of 10 statisticians who collaborate in the design, implementation, monitoring and analysis of multicenter clinical trials in heart, lung and blood diseases and sleep disorders. She has been or is involved in a number of cardiovascular trials, including Post-CABG, PEACE, AFFIRM, the Women's Health Initiative, FREEDOM and ACCORD. She has research interests in clinical trial methodology, especially in issues of clinical trial design, monitoring and multiplicity, i.e, multiple endpoints and multiple treatment comparisons. She served as President of the International Society for Clinical Biostatistics from 1999-2000. She has been an Associate Editor of Biometrics since 1989 and on the Editorial Board of the journal Clinical Trials since its inception in 2003. She is a Fellow of the American Statistical Association.

Some Cardiovascular Clinical Trial Articles by Dr. Geller

Conti, C.R., Geller, N.L. Knatterud, G., Forman, S., Pratt, C., Pepine, C.J. and Sopko, G. for the ACIP Investigators (1997). Definitions of angina status and prediction for cardiac events in patients with coronary artery disease enrolled in the asymptomatic cardiac ischemia pilot (ACIP). American Journal of Cardiology 79:889-892.

The Post Coronary Artery Bypass Graft (POST-CABG) Trial Investigators (includes N. Geller as member of Writing Committee) (1997). The effect of aggressive LDLcholesterol lowering and low dose anticoagulation on obstructive changes in saphenous vein coronary bypass grafts. The New England Journal of Medicine 336:153-162.

The PEACE Investigators (includes N. Geller as member of Writing Committee). (2004). Effects of angiotensin converting enzyme inhibition in patients with stable coronary artery disease: the Prevention of Events with Angiotensin Converting Enzyme Inhibition (PEACE) Trial. New England Journal of Medicine 351:2058-2068. Curtis, A.B., Gersh, B.J., Corley, S.D., DiMarco, J.P., Domanski, M.J., Geller, N., Greene, H.L., Kellen, J.C., Mickel, M., Nelson, J.D., Rosenberg, Y., Schron, E., Shemanski, L., Waldo, A.L., Wyse, D.G.for the AFFIRM Investigators. (2005). Clinical factors that influence response to treatment strategies in atrial fibrillation: the AFFIRM study. American Heart Journal 149:645-649.

Geller, N.L. and Friedman, L. (2005). Cooperative heart disease trials. Encyclopedia of Biostatistics, Peter Armitage and Theodore Colton, Eds. John Wiley & sons, New York and Chichester, Vol II, 1169-1180.

Mathieu M. GHADANFAR MD, FAHA, FESC

Dr Ghadanfar is currently VP, Global Brand Medical Director for Aliskiren and Hypertension at the Cardiovascular, Metabolic, and Atherosclerosis Group in clinical development and medical affairs at Novartis World Headquarters in Basel, Switzerland.

Dr Ghadanfar received his Medical Degree and a Degree in Clinical Pharmacology and Methodology of Clinical Trials from the University of Paris -VI in Paris, France. He completed postgraduate education as a Cardiology and Vascular Medicine specialist and received a diploma in echocardiography, also at the University of Paris -VI in Paris, France. He has 10 years of university-hospital practice in intensive coronary care and cardiac arrhythmias at Hôpital Pitié-Salpetrière and Hôpital Broussais, both in Paris, and at Hôpital Saint Germain, in St Germain en Laye, France.

In 1990, Dr Ghadanfar joined Pfizer Clinical Research and Development Operations in Paris, France. He later moved to Pfizer European Research and Development in Sandwich, United Kingdom, in 1996. In July 1997 he moved to United States to Pfizer Global Pharmaceuticals Group-World headquarters in New York in 1997 as a Senior Medical Director and Worldwide Team Leader at the Cardiovascular Group in Medical Affairs until August 2006.

Dr Ghadanfar is Fellow of the European Society of Cardiology (ESC), Fellow of the American Heart Association (AHA). He is member of the European Society of Hypertension (ESH), the American Society of Hypertension (ASH) and the European Heart and Rhythm Association (EHRA).

David Jeremy GORDON

Job Title: Special Assistant for Clinical Studies, DCVD, NHLBI, NIH

Education:

1971 Ph.D., Department of Chemistry, University of Chicago (Thesis: Optical Activity as a Structural Probe in Biological Membranes and Other Particulate Systems -- Information and Artifact.)

1973 M.D., University of Chicago Pritzker Medical School

M.P.H., Department of Epidemiology, University of North Carolina, Chapel Hill (Thesis: Dietary Determinants of Plasma Cholesterol Change in the Recruitment Phase of the Lipid Research Clinics Coronary Primary Prevention Trial.)

Major Projects:

Lipid Research Clinics (LRC) Coronary Primary Prevention Trial (CPPT)

Cholesterol Reduction in Seniors Program (CRISP) Pilot Study

NHLBI Conference on Cost and Health Implications of Cholesterol Lowering

Workshop on Analysis of Cholesterol-Lowering Trials

Antihypertensive and Lipid Lowering to prevent Heart Attack Trial (ALLHAT)

Women's Angiographic Vitamin and Estrogen (WAVE) Trial

Bypass Angioplasty Revascularization Investigations II Diabetes (BARI 2D) Trial

Cell Therapy Network

Advisory Panels:

National Cholesterol Education Program Adult Treatment Panel I-II (ex officio)

National Cholesterol Education Program Adult Treatment Panel III

Research Interests/Publications:

Dr. Gordon has authored or co-authored more than 70 publications in the field of cardiovascular epidemiology and clinical trials. Topics include:

The LRC-CPPT, ALLHAT-LLT, and other cholesterol lowering trials. Lead author of LRC collaborative study design and 2nd results paper.

Role of circulating HDLand triglycerides in coronary artery disease.

Seasonal variation in cholesterol.

Exercise ECG testing as a correlate of cardiovascular risk factors and predictor of cardiovascular events.

Meta-analysis of cholesterol trials.

Impact of diet, exercise, and weight on circulating lipids.

Cholesterol in the elderly.

As a graduate student, Dr. Gordon was the primary author of four peer-reviewed publications on optical activity as a structural probe of particulate systems. As an NHLBI post-doctoral fellow, Dr. Gordon was the primary author of four peer-reviewed publications on the isolation and characterization of cytoplasmic actins.

David GUEZ

is director of Medical Innovation and R&D Coordination (Strategic planning, information systems, project and portefolio management) at the Institut de Recherches Internationales Servier. He was trained as a medical doctor in Paris (France) and as a specialist in cardiology and internal medicine (mainly geriatry) between 1977 and 1985.

He joined Servier in 1985 and was responsible for drug development in cardiovascular and neurological diseases; from 2002-2006 he served as Director of Therapeutic Research in charge of the 8 therapeutic divisions in Servier responsible for conception and management of strategy and development plan in cardiovascular, neuropsychiatry, oncology, rheumatology, endocrinology and metabolic diseases from phase I to registration for all medicines and for their life-plan.

He also participates in several R&D processes as a member of the R&D Board.

James HUNG

Dr. H.M. James Hung is presently Director of Division of Biometrics I, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research, US FDA. The division provides services for Division of Cardiovascular and Renal Products, Division of Neurology Products and Division of Psychiatry Products. He has been working for FDAfor more than 18 years. During his tenure with FDA, he reviewed many large mortality/morbidity clinical trials in cardiovascular and renal disease areas. He published articles in Biometrics, Statistics in Medicine, Controlled Clinical Trials, Biometrical Journal, Journal of Biopharmaceutical Statistics, etc. His research covers many areas of clinical biostatistics, such as factorial design clinical trials, utility of p-value distribution, adaptive design/analysis in clinical trials, and non-inferiority trials.

Etienne HUVELLE

PHYSICIAN (MD) - ELECTRICALENGINEER SPECIALIZED IN ELECTRONICS AND PHYSICS (MSEE)

EDUCATION

- SECONDARYEDUCATION: HUMANITES LATIN-SCIENCES obtained the grade of High Distinction and the Government special prize (18 june 1979)
- Awarded diploma of MEDICALDOCTOR, 19 July 1986, with High Distinction (University of Liège, Belgium)
- Awarded MASTER IN SCIENCE OF ELECTRICALENGINEERING (specialized in Electronics and Physics with the Theme Medical Engineering Signal Processing), 3 July 1992, with Highest Distinction (University of Liège)

Thesis realized in the department of Prof. F.X. LITT(Applied Mathematics Department): image reconstruction from convolution-backprojection and from linograms: comparison of the two algorithms (public presentation in June 1992).

ACTIVITIES AND FUNCTIONS

- August 1992 August 2006: Sr Clinical Research Engineer for the International Research and Clinical Department of Guidant Europe and Sulzer Intermedics Europe
- Currently Research Physician at CIC INSERM-CHU, Nancy, France

PATENTS - PUBLICATIONS

Patents: -US Patent #7,041,061: Kramer A, Huvelle E.

Method and Apparatus for Quantification of Cardiac Wall Motion Asynchrony. May 9, 2006.

-US Patent # 6.522.914: Huvelle E. Cuesta P.

Method and Apparatuses for Monitoring Hemodynamic Activities Using an Intracardiac Impedance-Derived Parameter. Feb 18, 2003.

Manuscripts:

Zannad F, Huvelle E, Dickstein K, van Veldhuisen DJ, Stellbrink C, Køber L, Cazeau S, Ritter P, Maggioni AP, Ferrari R, Lechat P; Left bundle branch block as a risk factor for progression to heart failure. Accepted in Eur J Heart Fail (2006)

Auricchio A, Stellbrink C, Butter C, Sack S, Vogt J, Misier AR, Bocker D, Block M, Kirkels JH, Kramer A, Huvelle E; Pacing Therapies in Congestive Heart Failure II Study Group; Guidant Heart Failure Research Group. Clinical efficacy of cardiac resynchronization therapy using left ventricular pacing in heart failure patients stratified by severity of ventricular conduction delay. J Am Coll Cardiol. 2003; 42 (12): 2109-16.

Fenelon G, Stambler BS, Huvelle E, Brugada P, Stevenson WG; European VENTAK MINI Investigator Group. Left ventricular dysfunction is associated with prolonged average ventricular fibrillation cycle length in patients with implantable cardioverter defibrillators. J Interv Card Electrophysiol. 2002; 7 (3): 249-54.

Breithardt OA, Stellbrink C, Kramer AP, Sinha AM, Franke A, Salo R, Schiffgens B, Huvelle E, Auricchio A; PATH-CHF Study Group. Pacing Therapies for Congestive Heart Failure. Echocardiographic quantification of left ventricular asynchrony predicts an acute hemodynamic benefit of cardiac resynchronization therapy. J Am Coll Cardiol. 2002; 40 (3): 536-45.

Butter C, Auricchio A, Stellbrink C, Fleck E, Ding J, Yu Y, Huvelle E, Spinelli J; Pacing Therapy for Chronic Heart Failure II Study Group. Effect of resynchronization therapy stimulation site on the systolic function of heart failure patients. Circulation. 2001; 104 (25): 3026-9.

Butter C, Auricchio A, Stellbrink C, Schlegl M, Fleck E, Horsch W, Huvelle E, Ding J, Kramer A. Should stimulation site be tailored in the individual heart failure patient? Am J Cardiol. 2000; 86 (9 Suppl 1): K144-K151.

Breithardt OA, Stellbrink C, Franke A, Auricchio A, Huvelle E, Sack S, Bakker P, Hanrath P. Echocardiographic evidence of hemodynamic and clinical improvement in patients paced for heart failure. Am J Cardiol. 2000; 86 (9 Suppl 1): K133-K137.

Fenelon G, Huvelle E, Brugada P. Initial clinical experience with a new small sized third-generation implantable cardioverter defibrillator: results of a multicenter study. PACE 1997; 20 (12 Pt I): 2967-2974.

Klein H, Huvelle E, Nisam S. Initial clinical experience with a new down-sized implantable cardioverter defibrillator. Am J Cardiol 1996; 78 (Suppl 5A): 9-14.

Desmond JULIAN

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. 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 CONSENSUS, ISIS-2 and 4S. He was awarded the Gold Medal of the European Society of Cardiology in 1998 and the International Service Award of the American College of Cardiology in 2005.

François LEMAIRE

MD

François Lemaire, born in 1941, is Professor of medical intensive care at Paris XII University, school of medicine of Créteil. He is a member of the medical staff of the medical ICU of Henri Mondor Hosp (Assistance Publique-Hôpitaux de Paris), of which he was chief from 1986 to 2001. His field of expertise has long been the ARDS and optimization of mechanical ventilation. Dr Lemaire is currently the secretary of he "Coordination des promoteurs institutionnels français" (Coalition of French Academic Sponsors") and the Président of the "Délégation à la recherche clinique en Isle de France".

His main interest is currently the regulation of clinical research, after the implementation of the European Union Directive 2001/20/CE. Dr Lemaire was a founding member of the European Society of Intensive care Medicine, a former editor of its journal, Intensive Care Medicine (1989-1995), is presently an associate

editor to the American Journal of Respiratory and Critical Care Medicine. He leads currently a ESICM (European Society of Intensive Care Medicine) Task Force on the regulation of clinical research at the

Raymond John LIPICKY

European level.

MD is the Director of LIPICKY, LLC (a consulting company) having retired (March 2002) after 21 years of service) from the U.S Food and Drug Administration (FDA) where he held the position of Director, Division of Cardio-Renal Drug Products, Office of Drug Evaluation I, Center for Drug Evaluation and Research. Previously, he was on the faculty of University of Cincinnati, College of Medicine (for 14 years) where he held the positions of Professor of Pharmacology and Professor of Medicine and Director, Division of Clinical Pharmacology at the time he joined FDA. He is a graduate of the University of Cincinnati College of Medicine, trained in Internal Medicine and Cardiology. He also has an had an appointment as Visiting Scientist at the Marine Biological Laboratory (Woods Hole, MA) where, for about 30 years, he had a summer laboratory pursuing an interest in drug effects on electrically-excitable membranes.

Dan LONGROIS

MD, PhD

Dan Longrois is born in 1959 in Romania and is a French citizen. He obtained his Medical Doctor degree in 1987 from the Faculté de Médecine Paris VI, University Pierre et Marie Curie, in Paris. He obtained the French Board of Anesthesia and Intensive Care in 1991 in Paris. From 1991 to 1993, he served as a Research Fellow in the Cardiovascular Division at the Brigham and Women's Hospital, Harvard Medical School in Boston, MA, USA. In 1996, he obtained his Ph.D. in cardiovascular pharmacology at the University Pierre and Marie Curie, in Paris.

He is now Professor of Anesthesia and Intensive Care at the Medical Faculty of the Henri Poincaré University of Nancy, France. He is Head of the two Anesthesia and Intensive Care Departments of the academic hospital of Nancy, and a member of a research group "Unité INSERM U 684" at the Medical Faculty of Nancy. He conducts his research, in the area of the regulation of the inflammatory response in cardiovascular diseases.

Pr Longrois is a member of the Scientific Committee of the French Society of Anesthesia and Intensive Care, a member of the Medical and Scientific Committee of the French "Agence de la Biomédecine. He currently presides the French College of Perfusion. He had served as a member on the Editorial board of the French Journal of Anesthesia and Intensive Care "Annales Françaises d'Anesthésie-Réanimation". He has contributed more than 100 scientific publications and authored several book chapters on cardiovascular pharmacology and physiopathology related to anesthesia and intensive care.

Pr Longrois has contributed to the design, conduct and steering of several clinical trials in anesthesia, intensive care and cardiology. He has served as member of Endpoint Committees and Data and Safety Monitoring Boards for several trials in the fields of anesthesia, intensive care and cardiology.

Jacobus LUBSEN

Jacobus Lubsen's (1942) main interests are the translation of clinical problems into appropriate clinical trial design and/or their decision analytic modelling. He studied engineering in Delft, medicine in Rotterdam and epidemiology at the Harvard School of Public Health in Boston. After completing a cum laude thesis on acute chest pain syndromes in general practice, he started in 1978 the Clinical Epidemiology group at the Department of Cardiology (Thoraxcentre) of the Erasmus University Rotterdam. In 1985 he was appointed professor of medicine at Erasmus and in 1987 Chairman of the Centre for Clinical Decision Analysis. From 1990 - 2006 he was scientific director of SOCAR Research SA, a Swiss-based cardiovascular clinical research organisation. At SOCAR, he was 'responsible biostatistician' of the ACTION study, the first-ever clinical outcome trial in patients with stable symptomatic coronary disease. As a part-time faculty member at the Erasmus University, he contributes regularly to teaching in clinical trials and decision analysis, and lectures frequently at international meetings. He is a past member of the Dutch Health Council.

Steinar MADSEN

Steinar Madsen, MD, FACP(Hon) (b. 1956 in Oslo, Norway) is medical director, Department of Pharmacotherapy at the Norwegian Medicines Agency (NoMA) in Oslo, Norway. Dr. Madsen graduated from the University of Oslo in 1981. After internship and military service, he was research fellow in neuroanatomy and neurochemistry at the University of Oslo 1984-88. From 1988 to 1995 he trained in internal medicine and cardiology at Baerum Hospital and the National Hospital in Oslo. From 1995 to 2000 he was lecturer and consultant at the National Hospital and Baerum Hospital. In 2000 he moved to the NoMA. Dr. Madsen's primary responsibilities are pharmacotherapy, adverse events and safe use of medicines. He is a member of the Herbal Medicines Products Committee under the European Medicines Agency. Dr. Madsen has been president of the Norwegian Society of Internal Medicine and is Honorary Fellow of the American College of Physicians. Dr. Madsen is working part time as cardiologist in specialist practice. He has published about 100 papers, mainly in the fields of neurochemistry, clinical cardiology, pharmacology, adverse drug reactions and the history of medicine.

Patricia MAILLERE

Pharm. D.

Current Position: Director Worldwide Regulatory Affairs - I.R.I.S-Les Laboratoires Servier

Responsibilities:

Worldwide development support (regulatory strategy, authorisations for clinical studies, scientific advices ...)

Worldwide registration procedures and product maintenance

Pharmaceutical Affairs in France (including Transparence activities and promotion control)

Scientific Information Management

Clinical Quality Assurance

Past positions:

1984-1994 Regulatory Affairs Department - Head USA/Canada / Japan - 2 NEC approved

1995-2000 RandD Coordination Director

2000-now Worlwide Regulatory Affairs Director: 4 MRP, 2 centralised procedures, 2 arbitrations

Societies:

AFAR founding member

International Pharmaceutical Excipient Council (IPEC): ex-board member and group leader

DIAspeaker or session chair in various occasions

EFPIA: member of the Scientific, Technical and Regulatory Policy Committee

(STR PC) group

Lamia MOUNEDJI-BOUDIAF

MD

Medical Director, PDLBioPharma France

Specialist in Medical Oncology (Paris 1995)

Postgraduate diploma in Basic Sciences (Paris 1996)

10 years experience in the Pharmaceutical industry (1996 -2006):

- Clinical research (Phase I, II and III international trials, FDAand EMEAfilings) and post marketing experience in oncology (Shering Plough and Sanofi-Aventis).
- Current area of interest at PDLBioPharma: Clinical trials in:

Cardiovascular Diseases with a focus on Acute Decompensated Heart Failure

Oncology

Inflammatory Bowel Diseases

Michael PERELMAN MA, MB, BChir, FRCP

VP, Global Project Management - Senior Project Team Leader, Schering Plough Research institute

I trained in medicine in the UK and worked as a Cardiology specialist for 10 years before joining the pharmaceutical industry in 1985. My technical area of expertise was cardiac electrophysiology with an emphasis on arrhythmia management.

Within the pharmaceutical industry I have been involved in a wide range of activities focussed on strategic development of novel products for a range of therapeutic areas. This has involved the direct management of clinical research as well as direct management of the regulatory process, both on a global basis. Most recently, my role has expanded into a matrix management role for some of the highest priority programs within Schering-Plough as well as having a portfolio responsibility for products within the cardiovascular and metabolic areas. My key focus is the development of a novel anti-platelet agent that utilizes an alternate pathway to that affected by available therapies.

Stuart John POCOCK

Degrees

BA(Upper, 2nd Honours, Mathematics) 1967 - Cambridge University
MSc with Distinction (Statistics) 1968 - Imperial College, London University
PhD (Medical Statistics) 1972 - London School of Hygiene & Tropical Medicine

Posts held

1989 -	Professor of Medical Statistics, London School of Hygiene & Tropical Medicine.
1987-89	Professor of Medical Statistics, Royal Free Hospital School of Medicine
1984-87	Reader in Medical Statistics, Royal Free Hospital School of Medicine
1978-84	Senior Lecturer in Medical Statistics, Royal Free Hospital School of Medicine
1974-78	Statistician (lecturer scale) University of Edinburgh Medical School
1972-74	Visiting Assistant Professor, State University of New York at Buffalo
1969-72	Statistician (lecturer scale), London School of Hygiene & Tropical Medicine

Bertram PITT

M.D.

		А٦		

1945-49	Forrest Hills High School, Forest Hills, NY
1949-53	Cornell University, New York, New York, B.A
1953-59	University of Basel, Switzerland, M.D.

POSTDOCTORAL TRAINING

POSTDOCTORALTRAINING		
1959-60	Intern, Beth Israel Hospital, New York, NY	
1960-62	Assistant Resident, Beth Israel Hospital, Boston, MA	
1961-62	Teaching Fellow in Medicine, Harvard University, Boston, MA	
1962-63	Chief Resident, Medicine, Beth Israel Hospital, Boston, MA	
1962-63	Assistant in Medicine, Harvard University Teaching Fellow in Medicine, Tufts University, Boston, MA	
1966-67	National Heart Institute Special Fellow, Department of Medicine, Division of Cardiology,	
	Johns Hopkins University, Baltimore, MD	

ACADEMIC APPOINTMENTS

ACADEMIC APPOINTMENTS		
1967-68	Instructor in Medicine, Johns Hopkins University	
1968-72	Assistant Professor Medicine, Johns Hopkins University	
1972-77	Associate Professor of Medicine, Johns Hopkins University	
1977-97rofessor of Internal Medicine, Director, Division of Cardiology, University of Michigan School of Medicine		
1991-99	Professor of Internal Medicine, Associate Chairman for Academic and Industrial	
	Programs, Department of Internal Medicine, University of Michigan School of Medicine	
1999-	Professor if Internal Medicine, University of Michigan School of Medicine	

CERTIFICATION AND LICENSURE

Medical Licensure	1960 Connecticut
	1960 New York
	1963 Massachusetts
	1967 Maryland

1978 Michigan

Board Certification 1973 American Board of Internal Medicine

1973 American Board of Cardiology

HONORS AND AWARDS

110110	TO THE THE THE
1976-6	6Bronze Award, American Heart Association - Maryland Affiliate
1977	Haille Selassie Lecturer, British Heart Foundation
1978	Outstanding Cardiology Staff - University of Michigan
2000	Johns Hopkins University Society of Scholars
2001	Forest Dewey Dodrill Award for Excellence-American Heart Association
2002	Paul Dekruif Lifetime Achievement Award - University of Michigan

MEMBERSHIPAND OFFICES IN PROFESSIONALSOCIETIES

American Physiological Society - Circulation Group; American Federation for Clinical Research; American

Heart Association

Council on Circulation: 1982-83 Chairman

Council on Radiology:

1987 Fellow, Council on Clinical Cardiology, American Society for Clinical Investigation - Emeritus

2003 Membership, International Society for Heart Research

1994 Fellow, American College of Cardiology, Trustee

1993 American Society of Nuclear Cardiology, Founding Member

1990-93 President, Michigan Chapter of American College of Cardiology

1988-92 Cardiovascular Norms Committee, Member, American College of Cardiology Michigan Heart

Association of University Cardiologists American College of Physicians

1988-91 Cardiovascular Norms Committee, American College of Cardiology

1985-90 American Journal of Noninvasive Cardiology Consultant, Society for Cardiac Angiography

1985-87 Chairman, Young Investigator's Award Committee, American College of Cardiology

1985 Vice Chairman of the Cardiovascular Council, Central Society for Clinical Research

1982 Association of American Physicians ; Society of Nuclear Medicine ; Fellow, American College of Chest Physicians

Hubert POULEUR

M.D., Ph.D., is Executive Director in Pfizer Global Research and Development .

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 addition to his teaching activities, he was involved in basic pharmacologic research and in clinical research, and was a recipient of multiple grants including a grant from the National Heart, Lung and Blood Institute from 1986 to 1992, as one of the P.I.'s of the SOLVD project. In 1993, Dr. Pouleur joined Pfizer Central Research in Groton and moved to the NYHeadquarters in 2001. From 1993 to 2000, his drug development experience encompassed more than a dozen of new clinical entities, leading to the approval of 6 new drugs.

Dr. Pouleur is a past member of the Council of the European Society for Clinical Investigation, a Fellow of the American College of Cardiology, a Fellow of the American Heart Association, a Fellow of the Council of Circulation of the AHAand a Fellow of the European Society of Cardiology. He is author or co-author of more than 180 articles published in peer reviewed journals.

Edmond ROLAND MD. FAHA

Dr Roland is graduated from the University of Paris, France and board certified in cardiology. After several years of clinical appointment academic institutions, he joined the pharmaceutical industry and spent several years in the US. As Head of worldwide cardiovascular clinical research, he gained extensive experience in global drug development and international regulatory processes. Since 2001, he has resumed clinical activities. Currently, Dr Roland is an attending cardiologist at the teaching hospital "Hopital Européen Georges Pompidou" in Paris. He is also a Clinical Expert for the French Agency for Safety of Health Products (AFSSAPS). In addition, he is a member of the EMEAEfficacy Working Party sub-group on cardiovascular issues. The mission of this subgroup is to develop EMEAguidance documents for clinical trials on cardiovascular products.

Patrick ROSSIGNOL

1. Education (degrees, dates, universities)

Master degree (DEA) in Biology and Pathology of the epithelia, 1998, University of Paris VI "Pierre et Marie Curie"

Medical Doctorate, specialty nephrology, 2000, University of Paris V "Necker-Enfants Malades" Complementary fellowship in Vascular medicine: 2004, University of Paris V "Necker-Enfants Malades"

Ph. D. "Biology and pharmacology of hemostasis": 2005, University of Paris VII "Denis Diderot"

2. Professional/research experience

professional medical experience

- * Internship: 1994-1996 and 1998-2000, Paris Hospitals
- * Medical Military Service: 1996-1997, Val de Grace Hospital, Paris
- * 11/2003-04/2006: Chief-Assistant, then Assistant Professor (05/2006-): 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.

research carreer

* Clinical research: 1999-2000, concerning renovascular hypertension; 2002- current: associate investigator of AMETHYST(Aneurysm, METalloproteinases, and HYpertension STudy), promoted by INSERM.

*Basic research in cell biology:

- 1997-1998: INSERM Unit 356, Pr Paillard, Paris
- 11/2000-31/10/2002: INSERM Unit 460, Dr Michel, Paris
- 1/11/2002-31/10/2003: fellowship in vascular biology, Center for Molecular and Vascular Biology, Katholieke Universiteit Leuven (Belgium): Pr Lijnen, Pr Collen.
- 11/2003: associate researcher, INSERM 765 (formerly U 428), Pr Emmerich.

3. Recent publications

- 1. Rossignol P, Luttun A, Martin-Ventura JL, Lupu F, Carmeliet P, Collen D, Anglès-Cano E, Lijnen H-R. Plasminogen activation: a mediator of vascular smooth muscle cell apoptosis in atherosclerotic plaques. J. Thromb Haemost 2006, 4: 664-670.
- 2. Rossignol P, Cambillau M, Mouradian D, Plouin PF, Chatellier G, Jacob MP. Variations with time of plasma concentrations of matrix metalloproteinases 2 and 9 and tissue inhibitors of matrix metalloproteinases 1 and 2. Thromb Res. 2006, March 10, Epub
- 3. Caligiuri G, Rossignol P, Julia P, Groyer E, Mouradian D, Urbain D, Misra N, Ollivier V, Sapoval M, Boutouyrie P, Kaveri S.V, Nicoletti A, Lafont A. Reduced immunoregulatory CD31+ Tcells in patients with atherosclerotic abdominal aortic aneurysm. Arterioscler Thromb Vasc Biol 2006, 26: 618-23.
- 4. Rossignol P, Bouton MC, Bryckaert M, Jacob M-P, Bezeaud A, Jandrot-Perrus M, Guillin MC, Michel JB, Meilhac O. Apar doxical pro-apoptotic effect of thrombin on vascular smooth muscle cells. Exp Cell Res. 2004;299:279-85.
- 5.Rossignol P, Ho-Tin-Noé B, Vranckx R, Bouton MC, Meilhac O, Lijnen H.R, Guillin MC, Michel JB, Anglès-Cano E. Protease nexin-1 inhibits plasminogen activation-induced apoptosis of adherent cells J. Biol Chem 2004;279:10346-56

David L. SACKETT

OC, MD, FRSC, FRCP(Ottawa, London, Edinborough)

After training in internal medicine, nephrology and epidemiology Dave Sackett's first career (age 32) was as the founding Chair of Clinical Epidemiology & Biostatistics at McMaster. In his second career he began to design, execute, interpret, monitor, write and teach about randomized clinical trials, an activity that continues to the present, some 200 trials later. His third career was dedicated to developing and disseminating "critical appraisal" strategies for busy clinicians, and ended when he decided he was out of date clinically and returned (at age 49) to a two-year "retreading" residency in General Internal Medicine. His fourth career (and the only one he didn't enjoy) was as Physician-in-Chief at Chedoke-McMaster Hospitals. His fifth career was as Head of the Division of General Internal Medicine for Hamilton and Attending Physician at the Henderson General Hospital. When a chair was created for him at Oxford, he took up his sixth career as foundation Director of the NHS R&D Centre for Evidence-Based Medicine, Consultant on the Medical Service at the John Radcliffe Hospital, and Foundation Co-Editor of Evidence-Based Medicine. At present he is Director of the Trout Research & Education Centre at Irish Lake in Canada, where he reads, researches, writes and teaches about clinical-practice research.

Susan B. SHURIN MD

Susan B. Shurin, MD, assumed the position of Deputy Director, National Heart, Lung, and Blood Institute at the National Institutes of Health, in February, 2006. As part of the senior leadership team of the Institute, she works with NHLBI Director, Dr. Elizabeth Nabel, to establish and implement research policy in the areas of cardiovascular diseases, lung diseases, blood disorders, obesity, and sleep disorders.

Dr. Shurin is a graduate of Harvard College and Johns Hopkins University School of Medicine. She trained in pediatrics at Johns Hopkins Hospital and Boston City Hospital, and in Pediatric Hematology-Oncology at Children's Hospital Medical Center in Boston.

Dr. Shurin was Chief of the division of pediatric hematology/oncology at Rainbow Babies and Children's Hospital in Cleveland, Ohio, serving as medical director of the inpatient and ambulatory pediatric units at University Hospitals of Cleveland. She directed the pediatric hematology/oncology training program, and clinical programs in sickle cell disease, hemophilia, oncology, and pediatric marrow transplant. As Professor of Pediatrics and Oncology at the Case School of Medicine, she was heavily involved in graduate and undergraduate medical education. She conducted laboratory research on neutrophil physiology, and clinical research in the areas of iron metabolism and chelation therapy, sickle cell disease, hemophilia and childhood cancer. She is a member of multiple professional organizations, including the American Society of Hematology/Oncology, American Society of Hematology, American Academy of Pediatrics, and the American Board of Pediatrics. Dr. Shurin completed a fellowship in the Executive Leadership in Academic Medicine program at Drexel University.

Dr. Shurin served as Vice President and Secretary of the Corporation of Case Western Reserve University, where she was a member of the President's cabinet, the primary liaison with the Board of Trustees. In that capacity, she implemented a board governance reform, participated in creating a campus master plan and strategic plan.

Peter SLEIGHT

Education: Gonville and Caius College, Cambridge, St. Bartholomew's Hospital Medical College, London

Now Hon Consultant Physician Oxford Radcliffe NHS Trust

Emeritus Prof. of Cardiovascular medicine Univ. of Oxford

Emeritus Fellow Exeter Coll. Oxford

Previously:

1961-1963 University of California, (Cardiovascular Research Inst.) (Dr. J.H. Comroe, Jr.) Bissinger Fellow.

Wellcome Foundation Travel Fellowship

1964-1966 MRC Senior Clinical Research Officer, Hon. Consultant Depts. Physiology and the

Regius Professor of Medicine -Cardiology (Sir George Pickering) Oxford

1966-1973 Consultant Physician, United Oxford Hospitals

1972-1973 Visiting Professor, Univ. Sydney, Warren McDonald Senior Fellow of the Australian

Heart Foundation

1987 Visiting Professor, Flinders University, Adelaide, S.Australia

1992 Visiting Professor, University of Pavia, Italy

1972 - 1994 Field Marshal Alexander Professor of Cardiovascular Medicine, University of Oxford

1988 - 94 Civilian Consultant in Medicine to the Royal Air Force

Honorary Membership of Other Societies:

Australia and New Zealand Cardiac Society, Polish Society of Hypertension;

Polish Cardiac Society, European Society of Hypertension

Degrees: 1950 - BA, part II (Pathology) Class II (i) 1953 - MB, BChir

1964 - MD, (Cantab) 1965 - DM (Oxon) - by incorporation 1975 - Hon. MD Federal Univ. Pernambuco, Recife, Brazil 2000 - MD (honoris causa). Medical University of Gdansk

Awards: 1963 - Young Investigators Award, American College of Cardiology

1980 - Gold Medal BMAScientific Film Competition, for History of Hypertension

1988 - Evian Award for Medicine and Science

1990 - Int. Soc. of Hypertension - MSD Award for distinguished research 2000 - Galen Medal for Therapeutics 2000, Society of Apothecaries

2000 - Aspirin Foundation Senior Award (with C. Baigent, E. Collins & R. Peto)

2002 - Honorary Membership European Society Hypertension

2003 - Mackenzie Medal, British Cardiac Society

2004 - Louis Bishop Lecturer American College of Cardiology

2005 - Alberto Zanchetti Lifetime Achievement Award, European Society of Hypertension

2005 - Lifetime Research Award, Russian Federation of Cardiology

Other Appointments: 1983 - 91 Editor, Cardiovascular Research.

1993 - 2003 Editor J. Cardiovascular Risk.

Past Editorial Boards, Circulation, Hypertension. British Heart Journal, Clin & Exper.Physiol & Pharmacol., J.Ambulatory Monitoring. 1980 - 2000, Consultant Advisor, Civil Aviation Authority, Fellow of the American College of Cardiology

1989 - 94 Cardiovasc. Review Group, Dept. of Health Member several Data Monitoring Boards for large clinical trials

Chair: Medical Staff Council, United Oxford Hospitals. 1968 - 1972

I.S.I.S. Trials Group 1980 - (4 very large randomised controlled trials of the treatment of heart attack - in up to 60,000 patients and 1000 + hospitals in 31 countries, in the ISIS-4 trial) BHF/MRC Heart Protection Study. SEARCH Trial. ONTARGET& TRANSCEND Trials

Action on Smoking and Health (ASH) 1982 - 1993

Chairman, Specialist Advisory Committee in Cardiology, JCHMT1987 - 1991

Education Committee, British Heart Foundation 1989 -94

Chairman, International Agency on Tobacco and Health 1991 - 1993, Vice-President 1993-

World Hypertension League , President 1995-2000. 1993- 95 President, British Hypertension Society

Councillor: Physiol. Soc. London. Europ. Soc. Cardiology., Int.Soc. Hyper., Assoc. Physicians of Great Britain and Ireland.

British Cardiac Society 1983 - 1991. European Society of Hypertension 1989

Books: Scientific Foundations of Cardiol. Eds. P.Sleight & J.V.Jones 1983 / Hypertension Eds. E.D.Freis & P.Sleight 1982 /

Thrombolysis Eds. P.Sleight & D.A.Chamberlain 1990 /

Human Arterial Baroreceptors. D.Eckberg & P.Sleight, O.U.P. 1992

Journals: Papers on Blood Pressure Monitoring & Control; Autonomic Control of the Circulation;

I.S.I.S. trials on the Treatment of Myocardial Infarction; Risk Factor Management in Prevention of Coronary Heart

Disease. HOPE prevention trial of ramipril/Vit.E., ONTARGETstudy co-chair

George SOPKO

Dr. Sopko is a senior staff member and cardiology expert in the Division of Heart and Vascular Diseases (DHVD), the National Heart, Lung, and Blood Institute (NHLBI), at the National Institutes of Health (NIH), Bethesda, Maryland.

Dr. Sopko began his medical career in Czech Republic and received his first M.D. from Masaryk University (formerly Purkyne University), Brno, Czech Republic in 1967. He served in the Czech Air Force from 1967-68 as Flight and Oral Surgeon and was honorably discharged as Second Lieutenant. In 1969, he moved to the United States and worked as manual laborer and orderly for two years while learning English. He received his second M.D. from Case Western Reserve University in 1973. He then completed his internship and residency in internal medicine at Georgetown University Medical Service at the D.C. General Hospital in Washington, and fulfilled fellowship requirements in cardiology at the University of Vermont Medical Center in 1978.

In 1978, he joined the University of Minnesota as an NIH Postdoctoral Individual National Research Service Award Fellow at the Laboratory of Physiologic Hygiene, School of Public Health, in cardiovascular disease prevention and epidemiology. In 1981, Dr. Sopko received an M.P.H. from the University of Minnesota, School of Public Health, and also joined the cardiology faculty as Assistant Professor of Medicine. During his tenure there in the Division of Cardiology, Dr. Sopko became interested in exercise physiology, energy expenditure, and cardiovascular risk factor modification. He participated as a clinic cardiologist in several NIH-funded Programs (the Multiple Risk Factor Intervention Trial--MRFITand the Lipid Research Clinics program-LRC) and conducted randomized studies on the effects of exercise and diet modification, and cardiovascular drugs on exercise capacity and cardiovascular risk factors.

In 1983, Dr. Sopko moved to St. Louis, Missouri, to develop and direct the Cardiovascular Risk Reduction Center in the Division of Cardiology, Department of Medicine, at the St. Louis University Medical Center. While there, he developed a city-wide health prevention program for major corporations in the St. Louis Metropolitan Area (e.g., McDonald-Douglas, Mallinckrodt, and Southwestern Bell). He also became the Medical Director of the Executive Cardiovascular Improvement Program, Cardiovascular Fitness and Rehabilitation Center, St. Louis University. He also collaborated with St. Louis County and City public school systems to develop a new health curriculum that focused on diet, exercise, and smoking prevention and, with the Missouri State Department of Health, to develop and implement a state-wide intervention on smoking, nutrition, and hypertension.

In 1987, Dr. Sopko moved to Bethesda, Maryland, and joined the NHLBI, where he remains to this day. He plans, develops, directs, coordinates, and conducts basic, applied, and clinical research in cardiovascular disease. He has responsibility for promoting efforts to enhance our understanding of the etiology and pathophysiology of heart disease; to improve methods of diagnosis, treatment and prevention of these diseases; to participate in developing policy and prioritization regarding pioneering research programs-both domestic and international—to meet national needs.

He has served as the Program Director or Deputy Program Director for many NIH-supported clinical trials or studies involving international cooperation.

Dr. Sopko has served on multiple NIH task forces and panels and co-chaired a number of workshop and working groups, and also served on many other task forces as the NIH or NHLBI representative.

Dr. Sopko has received a number of awards, most notably the Combat Casualty Care Research Program Award for Excellence, U.S. Army Medical Research and Materiel Command, Department of Defense for "Your Dedication and Perseverance in Spearheading the NHLBI's Pulse Resuscitation Initiative which Resulted in Extensive Trauma Collaboration with U.S. Army Medical Research and Materiel Command" in 2004. Other awards include: (1) the NIH Merit Award "for initiative, dedication, and leadership to enhance cardiovascular medicine and public health", in 2003; (2) the NIH Merit Group Award "for exemplary leadership and creativity in development of an initiative to improve resuscitation outcomes from out-of-hospital arrest", in 2003, and (3) the NIH Award of Merit "for the exceptional management of clinical trials within the Cardiac Diseases Branch and superior leadership in the development of strategies to address cardiovascular diseases", in 1999.

He has been a guest reviewer for several journals, including the Journal of the American Medical Association, Circulation, and the Journal of Cardiac Rehabilitation. He is a Diplomate of the American Board of Internal Medicine and Cardiovascular Diseases.

Gabriel STEG

Dr Steg has been a Professor of Cardiology in Université Paris VII - Denis Diderot, since 1994. He is a former member of the Institut Universitaire de France, a fellow of the European Society of Cardiology and American College of Cardiology. He is current chairman of the Public Relations committee of the European Society of Cardiology. He works as interventional cardiologist and is director of the Coronary Care Unit of Hôpital Bichat in Paris.

Dr Steg's research interests are in the field of coronary artery disease. He is involved in studies of mechanical and pharmacologic intervention in acute myocardial infarction, but has also recently turned his attention to secondary prevention, long-term risk assessment and management of atherothrombosis. He is a former president of the Thrombosis Working Group of the French Society of Cardiology and belongs to the nucleus of the Thrombosis Working Group of the European Society of Cardiology. Dr Steg participated in the steering or executive committees of trials such as CAPTIM, GUSTO-V, CHARISMA, OASIS-5 and 6, and was the principal investigator of investigator-driven and industry-sponsored trials and registries. He is co-chair of the GRACE and the REACH Registries publication committees. He was DSMB or CEC member or chair for several large trials. Dr Steg has authored more than 300 articles in peer-reviewed international journals, and is a member of the editorial board for European Heart Journal and for Theheart.org. He is a member of the Task Force updating the ESC guidelines on the Management of acute myocardial infarction in patients presenting with STsegment elevation, a member of the international ESC/ACC-AHA/WHF/WHO Task force for the definition of myocardial infarction and a member of the Guideline Committee for the VIII Guidelines on antithrombotic therapy of the ACCP.

Jeremy SUGARMAN MD, MPH, MA

is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, Deputy Director for Medicine of the Phoebe R. Berman Bioethics Institute, and Professor of Health Policy and Management at the Johns Hopkins University. Dr. Sugarman served as Senior Policy and Research Analyst for the White House Advisory Committee on Human Radiation Experiments and as a consultant to the National Bioethics Advisory Commission for its project on international research ethics. In both of these roles, Dr. Sugarman conducted empirical research to inform policy-making. Dr. Sugarman continues to conduct both theoretical and empirical research in medical ethics. His work concentrates on informed consent, research ethics, and the ethical issues associated with emerging technologies. He is the author of over 125 publications in peer-reviewed journals. In addition, he has edited or co-edited four books (Beyond Consent: Seeking Justice in Research; Ethics of Research with Human Subjects: Selected Policies and Resources; Ethics in Primary Care; and Methods in Medical Ethics). Dr. Sugarman is a contributing editor for IRB, and is on the editorial boards of Accountability in Research, the American Journal of Bioethics, Clinical Trials, and Theoretical Medicine and Bioethics. Dr. Sugarman serves on the Scientific and Research Advisory Board for the Canadian Blood Service. He is currently Chair for the Ethics Working Group of the HIV Prevention Trials Network, the Ethics Officer for the Resuscitation Outcomes Consortium, and Co-Chair of the Johns Hopkins' Embryonic Stem Cell Oversight Committee. Dr Sugarman is a Fellow of the American Association for the Advancement of Science, the American College of Physicians, and the Hastings Center.

John WARREN

John Warren is a clinical scientist who has worked for the UK Medicines Healthcare products Regulatory Agency as a clinical assessor since 1995. He is involved in the evaluation of new drug applications for both the UK and Europe and is a member of the European Scientific Advice Working Party.

Previously he trained in Clinical Pharmacology at the Royal Postgraduate Medical School and subsequently was appointed as a Senior Lecturer at the National Heart and Lung Institute, with Honorary Consultant status at the Brompton, Charing Cross and Chelsea & Westminster Hospitals.

Hans WEDEL

Professor

I have been professor in Epidemiology and Biostatistics at the Nordic School of Public Health, Gothenburg, Sweden since 1982. During six years I was the chairman of the "Committee for Research and Education" at Nordic School of Public Health. For six years I was a member of the prioritising group for Epidemiology and Social Medicine at the Swedish Medical Research Council. I have been president of the Swedish Epidemiological Society and the Swedish Society of Biostatistics. I was educated as a statistician at Gothenburg University. My special research areas are cardiovascular epidemiology and clinical trials in cardiovascular medicine.

I have kept my interest in both epidemiology and clinical trials during the years.

Until 1982 I was the responsible statistician for several large cohort studies in Gothenburg and worked close together with medical doctors and computer specialists.

During 1979-80 I was a visiting-scientist at Biostatistics Branch, NHLBI, Bethesda, Maryland. In 1993 I had a sabbatical year partly at University of Wisconsin, Madison and partly at Stanford University.

I have been on the Steering Committee or DSMB for several large clinical trials. I was the statistician on the Steering Committee for HAPPY, MIAMI, HOT, 4S, MERIT, CONSENSUS-2, OPTIMAAL, LIFE, DIGAMI I+II, and at present ASCOTand CORONA. I was a member of the DSMB for STOPI+II, ATLAS, FRISCII, LOWASA, IDEAL, ALERT, EXPRESS, CARE-HF and ESSENTIALand now for HEAAL, DIRECT, AURORA, SCASTand NOCTET.

My reference list consists of more than 200 scientific publications. During 2003-2005 I have been coauthor in more than 40 scientific peer reviewed papers. One of these has been published in New England Journal of Medicine, 5 in Lancet and 2 in JAMA.

Janet WITTES

Dr. Wittes received her BAin Mathematics from Radcliffe College, and her MA& PhD in Statistics from Harvard University. She was a member of the Department of Mathematical Sciences from 1976 through 1983. She then became Chief of the Biostatistics Research Branch, National Heart, Lung, and Blood Institute. In 1990 she formed Statistics Collaborative, Inc., a statistical consulting company. Her research has focused on the design and analysis of randomized clinical trials. She is a Fellow of the American Statistical Association, the American Association for the Advancement of Science, and the Society for Clinical Trials. She is a past President of The International Biometric Society - Eastern North American Region (1995) and The Society for Clinical Trials (2001). From 1990 through 1995 she served as the Editor-in-Chief of Controlled Clinical Trials. She is a member of many Data and Safety Monitoring Boards (DSMBs) for randomized clinical trials sponsored by both industry and government. Coauthored with Drs. Michael Proschan and Gordon Lan, her recently (2006) published book, entitled "Monitoring Clinical Trials: AUnified Approach" deals with methods for interim analysis of clinical trials.

Faiez ZANNAD MD. PhD. FESC

Faiez Zannad is born in 1951 in Tunisia and is a french citizen. He has obtained his Medical Doctor degree in 1979 from the Faculté de Médecine de Nancy. He also graduated there as a Cardiology specialist in 1979. During year 1981, he served as a Research Fellow at the Clinical Pharmacology Medical Research Unit of Oxford University, UK. In 1986, he obtained his Ph.D. in cardiovascular clinical pharmacology at the University of Lyon.

He is now Professor of Therapeutics at the Medical Faculty of the Henri Poincaré University of Nancy. He is 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 (Equipe d'Accueil) "Cardiac and arterial remodelling" at the Faculté de Médecine. He conducts his research, in the area of physiopathology, genetics and pharmacotherapeutics of hypertension and heart failure.

Dr Zannad is Fellow of the European Society of Cardiology (FESC), General Secretary of the Board of the French Society of Hypertension as well as a member of a large number of international societies in cardiology, hypertension, pharmacology and therapeutics. He is an active member of the ESC Heart Failure Working Group and a nucleus member of the ESC pharmacology and drug therapy Working Group. He had served as a member on the Editorial board of the Journal of Hypertension and the Journal of Cardiovascular Pharmacology. He is currently Co- Editor in chief of Fundamental and Clinical Pharmacology, the official journal of the European Pharmacology Society. With Professor Bertram Pitt (Ann Arbor, USA), he is chairman and organizer of the annual international meetings: The Cardiovascular Clinical Trialists Workshop and The Cardiovascular Clinical Trialists Forum as well as, with Mihai Gheorgiade of the Acute Heart Failure Syndromes Workshop. He has contributed more than 200 scientific publications and published several books on cardiovascular pharmacotherapy.

Dr Zannad has contributed to the design, conduct and steering of several large clinical trials in cardiology. He has a number of collaborations with international groups, including the Duke Clinical Research Initiative about NIH funded trials.

He has served as member of Critical Event Committees (CAPRICORN, RESPECT, SCOUT), Data and Safety Monitoring Board (HEAAL) and Steering Committees: APSI, FIRST, CIBIS I and II (Executive committee), RALES (Executive committee), CAPRICORN, FOSIDIAL(Chairman), VALIANT, RECOVER, MOXCON, EPHESUS (Executive committee), AURORA(Executive committee) EVEREST; HF-ACTION. He has participated in the protocol writing groups in the RALES, CAPRICORN, CIBIS II and EPHESUS Trials.