FINAL PROGRAM

CVCT WASHINGTON, DC US

14th Global Cardio Vascular Clinical Trialists Forum

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

2017

NOVEMBER THURSDAY 30

DECEMBER SATURDAY 2

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GENERAL MESSAGE

14th Global Cardio Vascular Clinical Trialists Forum CVCT WASHINGTON, DC US

Welcome to the 14th annual Global CardioVascular Clinical Trialists (CVCT) Forum. After a year full of change we are once again proud to be hosted by the French Embassy in Washington, DC.

The CVCT Forum continues to be the "not to miss" gathering in the field of cardiovascular clinical trials. These meetings are unique, bringing together a carefully selected faculty of opinion leaders, clinical trialists, investigators, regulators, industry R&D experts, major CV journals editors, CV media reporters, payers, patient representatives, and practitioners. Over the years CVCT has attracted an audience from over 30 different countries, with participants coming from Western and Eastern Europe, the USA, Canada, South America, Asia and the Middle East.

Through our partnership with the NIH/NHLBI, this year CVCT is pleased to host a special workshop, "New NIH & NHLBI Policies and Funding Opportunities for Clinical Trialists". The NIH is developing new specific Funding Opportunity Announcement (FOA) for the different types of clinical trials it supports. The workshop will review the different types of FOAs available to clinical investigators and their specific requirements, with special focus on specific opportunities for new or early stage investigators.

As we look towards the future, we are providing new and exciting opportunities for Young Investigators to advance their career. This year, young investigators will have the opportunity to meet and greet Mike Lauer (NIH Deputy Director for Extramural Research) during a Q&A session over lunch. In addition, many will be meeting with mentors during our Career Escalator. An important step in the evolution of any young investigator career.

After a remarkable year for CVCT we are looking forward to continuing our reach of CVCT Worldwide. To achieve our goals, we need your contribution and experience at these meetings as we exchange ideas, aiming to help improve CV clinical trial science and treatment prospects for the world's many patients suffering from heart disease.

We would like to thank all those who have worked throughout this year to contribute to the success of the CVCT Forum.

Please don't hold back in the discussions over the coming days. We want to hear your voice!

Pr Faiez Zannad

Dr Bertram Pitt

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  Peter Libby (Boston, USA) and Jean-Claude Tardif (Montreal, CAD)

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SCIENTIFIC PROGRAM

Summary

PROGRAM AT-A-GLANCE

DAY 1 – **THURSDAY, NOVEMBER 30TH**

	8:00 - 10:00
TOQUEVILLE	New NIH & NHLBI Policies and Funding Opportunities for Clinical Trialists

	9:30am 12:30pm	12:30 1:00pm	1:00 2:00pm	2:00 3:00pm	3:00pm 3:30pm	3:30 7:30pm
AUDITORIUM	ATHEROSCLEROSIS TRIALS (I)	Keynote Lecture: «Can we abolish Coronary Artery Disease?» Eugene Braunwald	Lunch break	ATHEROSCLEROSIS TRIALS (II)	Coffee break	TRANSCATHETER HEART VALVE
BALLROOM	NOACs COMPASS			RENAL ENDPOINTS IN CKD, HEART FAILURE AND DIABETES TRIALS (I)		RENAL ENDPOINTS IN CKD, HEART FAILURE AND DIABETES TRIALS (II)
TOQUEVILLE			How the NIH can help Trialists of the Future Q&A Session			

DAY 2 – **FRIDAY, DECEMBER 1ST**

	8:00 10:30am	10:30 11:00am	11:00am 1:00pm	1:00 2:00pm	2:00 3:00pm	3:00 3:30pm	3:30 7:30pm
AUDITORIUM	CARDIOVASCULAR AND RENAL OUTCOME TRIALS IN DIABETES (I)	Coffee break	CARDIOVASCULAR AND RENAL OUTCOME TRIALS IN DIABETES (II)	Lunch break	CARDIOVASCULAR AND RENAL OUTCOME TRIALS IN DIABETES (III)	Coffee break	BIOMARKERS
BALLROOM	eTRIALS (I)		eTRIALS (II)		ATRIAL FIBRILLATION (I)		ATRIAL FIBRILLATION (II)
TOQUEVILLE		CVCT Career Escalator					

DAY 3 – **SATURDAY DECEMBER 2ND**

	8:00 10:30am	10:30 11:00am	11:00am 1:00pm	1:00 2:00pm	2:00 4:00pm	4:00 4:30pm	4:30 6:30pm
AUDITORIUM	HEART FAILURE (I)	Coffee break	HEART FAILURE (II)	Lunch break	WHY SOME CLINICAL TRIALS DO NOT WORK (I)	Coffee break	WHY SOME CLINICAL TRIALS DO NOT WORK (II)
BALLROOM	NEW TECHNOLOGIES (I)		NEW TECHNOLOGIES (II)		TIME IS MUSCLE. ACUTE INTERVENTION TRIALS (I)		TIME IS MUSCLE. ACUTE INTERVENTION TRIALS (II)
TOQUEVILLE		CVCT Career Escalator					

THURSDAY, NOVEMBER 30TH

TOCQUEVILLE

8:00 – 10:00 am

New NIH & NHLBI Policies and Funding Opportunities for Clinical Trialists

NIH is the largest public funder of clinical trials in the United States with NHLBI being the primary Institute responsible for heart, lung, blood, and sleep-related research funding. Over the last couple of years, NIH has embarked in a comprehensive reform process with the overall goal of improving the quality and efficiency of the clinical trials it supports. NHLBI has been at the forefront of this effort, by developing new specific Funding Opportunity Announcement (FOA) for the different types of clinical trials it supports, from early phases to large multisite trials. The workshop will review the different types of FOAs available to clinical investigators and their specific requirements, with special focus on specific opportunities for new or early stage investigators.

AUDITORIUM

9:30 am – 3:00 pm

ONGOING AND FUTURE ATHEROSCLEROSIS TRIALS
International Society of Cardiovascular Pharmacotherapy (ISCP) – CVCT Joint Session

Chairpersons: Wolfgang Koenig (Munich, GER); Jean-Claude Tardif (Montreal, CAN)

Residual risk still represents an important issue in patients with manifest cardiovascular disease despite standard of care treatment. Thus, over five years post-ACS still 20% of patients have experienced a recurrent event.

Several additional strategies have been reported this year or are presently being tested in large clinical trials like aggressive lowering of LDL cholesterol by PCSK9 inhibition or an RNA silencing mechanism, lowering of Lp(a) and finally triglycerides (TG) have seen a revival and their lowering is presently being tested in several trials applying different interventions like high-dose omega-3 and 6 or a SPARM (selective PPARα modulator). But novel strategies are at the horizon.

The recently published FOURIER Study has shown a 20% decrease of a combined endpoint consisting of cardiovascular death, MI and stroke in stable patients with manifest atherosclerosis and an index event that had occurred three years before randomization. These results fit very nicely in the cholesterol trialists estimation. However, despite having reached on treatment LDL-C levels of 30 mg/dl there was a significant number of patients with recurrent events, which is in line with 36% of patients showing progression in the previously published GLAGOV IVUS Trial also with evolocumab. Thus, there is room for other pathomechanisms and anti-inflammatory treatment on top of standard of care might represent a further option. During ESC this year results of the CANTOS trial in which 10,000 post MI patients were treated with an interleukin-1β antagonist have been presented, showing a positive outcome with a similar effect size on major cardiovascular endpoints as seen during potent LDL-C lowering with a PCSK9 inhibitor. Thus, this implicates proof of the "inflammation hypothesis" and a paradigm change in the treatment of patients with manifest atherosclerosis. This may enable a personalized approach to treatment identifying those with "residual cholesterol risk" versus those with "residual inflammatory risk".

PCSK9 Trials

- **PCSK9: From discovery to clinical evidence**
  Marianne Abi-Fadel (Beirut, LBN)
- **FOURIER: enough evidence to justify widespread use? Did it fulfill its expectations?**
  Marc Sabatine (Boston, USA)

Trials of agents targeting inflammation

- **CANTOS: Anti-inflammatory treatment in the context of extreme low LDL levels. Is there still room for improvement?**
  Paul Ridker (Boston, USA)
- **Lessons from COLCOT and other ongoing and future anti-inflammatory trials**
  Jean-Claude Tardif (Montreal, CAN)

Further insights regarding into triglycerides as a target for intervention

- **Ongoing clinical trials: STRENGTH and PROMINENT**
  Aruna Pradhan (Boston, USA)
- **Targeting triglycerides: Is angiopoietin-like 4 (ANGPLT 4) a new target? Insights from genomic studies**
  Heribert Schunkert (Munich, GER)
- **Would angiopoietin-like 3 (ANGPLT 3) be the better target?**
  Sotirios Tsimikas (Ionis Pharmaceutical, USA)

Gaining precision with cardiovascular clinical trials using genomics
Marie-Pierre Dubé (Montreal, CAN)

Percutaneous coronary intervention in stable angina (ORBITA Trial)
Darrel Francis (London, GBR)

Industry Viewpoint
Don Black (Dalcore, CAN); Jay Edelberg (Sanofi, USA); Narimon Honarpour (Amgen, USA); David Kallend (The Medicine Company, USA); Tom Thuren (Novartis, CHE)

Regulatory Viewpoint
Pieter de Graeff (EMA, NED); James Smith (FDA, USA)

Payers Viewpoint: How much PCSK9 inhibition can the health care system afford?
Jakub P. Hlávka (Rand Corporation, USA)

Patient Viewpoint
Annemieke Lenselink (The Hague, NED); Marilyn Mann (Washington, USA)

The Forum. Moderated discussion with the audience
Regulatory and reimbursement Challenges
Chairpersons: Wolfgang Koenig (Munich, GER); Jean-Claude Tardif (Montreal, CAN)

Panelists: Marianne Abi-Fadel (Beirut, LEB); Don Black (Dalcore, CAN); Eugene Braunwald (Boston, USA); Pieter de Graeff (EMA, NED); Marie-Pierre Dubé (Montreal, CAN); Jay Edelberg (Sanofi, USA); Darrel Francis (London, GBR); Jakub P. Hlávka (Rand Corporation, USA); Narimon Honarpour (Amgen, USA); Larry Husten (CardioBrief, USA); David Kallend (The Medicine Company, USA); Wolfgang Koenig (Munich, GER); Annemieke Lenselink (The Hague, NED); Marilyn Mann (Washington, USA); Aruna Pradhan (Boston, USA); Paul Ridker (Boston, USA); Marc Sabatine (Boston, USA); Heribert Schunkert (Munich, GER); James Smith (FDA, USA); Jean-Claude Tardif (Montreal, CAN); Tom Thuren (Novartis, CHE); Sotirios Tsimikas (Ionis Pharmaceutical, USA)

AUDITORIUM

12:30 – 1:00 pm
Key note Lecture
“Can We Abolish Coronary Artery Disease?”
Eugene Braunwald (Boston, USA)

BALLROOM

9:30 am – 12:30 pm
EXPANDING THE INDICATIONS OF NOACs. DISSECTION OF THE COMPASS TRIAL IN PATIENTS WITH CORONARY AND/OR PERIPHERAL ARTERY DISEASE

Chairpersons: Deepak Bhatt (Boston, USA); Tabassome Simon (Paris, FRA)

- Peripheral artery disease (PAD) is considered to be a clinical manifestation of systemic atherosclerosis. Most patients presenting with peripheral artery disease are at high risk for myocardial infarction, ischemic stroke, and cardiovascular death. Concomitant clinical evidence of coronary disease magnifies this risk.
- Antiplatelet therapy and statins, are the cornerstone of care for the prevention of atherosclerotic events. However, the level of evidence in favor of aspirin in PAD is modest and is mainly based on a meta-analysis involving approximately 5000 patients. In two large clinical trials, in patients with asymptomatic atherosclerosis (which was defined as an abnormal ABI value) aspirin was not superior to placebo in preventing cardiovascular events.
- In the CAPRIE trial, in a broadly defined stable population of patients with atherosclerotic disease, including coronary artery disease, peripheral artery disease, and cerebrovascular disease, clopidogrel was superior to aspirin. Benefit was driven mainly by the subgroup of patients with PAD. These results from CAPRIE established clopidogrel as the first therapy for peripheral artery disease to be approved by the Food and Drug Administration.
- The CHARISMA trial, enrolling similar high-risk population of patients with atherosclerosis found no significant benefit for clopidogrel over aspirin in the risk of cardiovascular events in the overall population. However, there was a non-significant trend in the subgroup of patients with PAD. Dual antiplatelet therapy was associated with an increased risk of bleeding. On the basis of this evidence, clopidogrel monotherapy has been the preferred therapy to manage the atherothrombotic risk in patients with peripheral artery disease.
- In patients with symptomatic PAD enrolled in the EUCLID trial, ticagrelor was not superior to clopidogrel for the reduction of cardiovascular events, and each drug was associated with similar rates of major bleeding.
- The COMPASS trial randomized 27,402 patients with coronary artery disease or peripheral artery disease (PAD) to receive the oral anticoagulant rivaroxaban at 2.5 mg twice daily plus aspirin at 100 mg/day, or rivaroxaban 5 mg twice daily without aspirin, or aspirin 100 mg/day without rivaroxaban. The trial was stopped prematurely more than a year ahead of its planned March 2018 completion because, in an interim analysis, the primary end point of MI, stroke, or cardiovascular death «has reached its pre-specified criteria for superiority.»

COMPASS, Design, highlights of major results
Deepak Bhatt (Boston, USA)

Target patient population. To what patient do the COMPASS results apply?
Faiez Zannad (Nancy, FRA)

Stopping prematurely

- **Logistical considerations: Informing investigators, managing data backlog, IRB considerations, transitioning patients to open label**
  Jackie Bosch (Hamilton, CAN)
- **Methodological and interpretation considerations. How should it impact the interpretation, generalization of the results?**
  Stuart Pocock (London, GBR)

Mechanistic plausibility and potential for a class effect?
Deepak Bhatt (Boston, USA)

Patients with coronary artery disease and heart failure. Perspectives for COMMANDER-HF trial
Faiez Zannad (Nancy, FRA)

Industry Viewpoint
Nancy Cook Bruns (Bayer, GER); Peter DiBattiste (Janssen, USA); Martin Unverdorben (Daiichi Sankyo, USA)

Regulatory Viewpoint
Joseph Emmerich (EMA, FRA); Kaori Shinagawa (PMDA, JPN); Ellis Unger (FDA, USA)

The Forum. Moderated discussion with the audience
Revisiting the Aspirin dogma in secondary prevention?
Chairpersons: Deepak Bhatt (Boston, USA); Tabassome Simon (Paris, FRA)

Panelists: Deepak Bhatt (Boston, USA); Jackie Bosch (Hamilton, CAN); Nancy Cook Bruns (Bayer, GER); Peter DiBattiste (Janssen, USA); Joseph Emmerich (EMA, FRA); Stuart Pocock (London, GBR); Kaori Shinagawa (PMDA, JPN); Tabassome Simon (Paris, FRA); Ellis Unger (FDA, USA); Martin Unverdorben (Daiichi Sankyo, USA); Faiez Zannad (Nancy, FRA)

BALLROOM

2:00 – 7:30 pm
RENAL ENDPOINTS IN CKD, HEART FAILURE AND DIABETES TRIALS.
ASN/Kidney Heath Initiative (KHI) & INI CRCT - CVCT Joint Session

Chairpersons: Prabir Roy-Chaudhury (Tucson, USA); Patrick Rossignol (Nancy, FRA)

- Cardiovascular death is either the leading or one of the main causes of death in patients with chronic kidney disease (CKD).
- CKD is one of the main features associated with poor outcomes in cardiovascular disease patients, especially those with heart failure and/or diabetes.
- The most suitable choice of components of the composite endpoint for a cardiovascular outcome trial conducted specifically in the CKD population is obviously key for success and depends on the specific therapy being tested.
- Renal endpoints are pathophysiologically relevant in a CKD population even if the primary intervention target is cardiovascular disease, and a composite endpoint reflecting both cardiovascular and renal outcomes may be desirable, especially if the intervention is expected to affect both systems.
- However, a challenging problem is which endpoints to combine and how to interpret the results of the composite endpoint.
- Moreover the meaning of a worsening renal function may be different depending on the considered setting (acutely decompensated heart failure vs. chronic, renin angiotensin aldosterone system inhibition (RAASi) use and uptitration, biphasic temporal effect of SGLT2 inhibition on kidney function).
- One may also wonder if changes in estimated glomerular filtration rate and/or microalbuminuria should be considered as relevant biotargets and surrogates of outcomes whilst assessing the cardiovascular benefit of a new compound and if any, which outcome (cardiovascular or renal) should be prioritized for testing if the compound exhibits cardiorenal effects.
- Finally, should we pay attention to a worsening in renal function under RAASi as long as potassium concentrations are maintained in the normal range with a potassium binder?

Understanding and overcoming the challenges to involving patients with kidney disease in cardiovascular trials: KHI Project Overview
Julie Ishida (San Francisco, USA)

- **Involving patients with kidney disease in cardiovascular and diabetes trials: Lessons Learned and Future Directions**
  Charles Herzog (Minneapolis, USA)
- **The Issue with competing risk and composite endpoints**
  Janet Wittes (Washington, USA)
- **Changes in GFR: How to assess? Reversible vs. irreversible, short – term vs. long-term, and when are these good news, neutral news, or bad news?**
  Michael Felker (Durham, USA); Claudio Ronco (Vicenza, ITA)
- **Are surrogate endpoints inevitable?**
  George Bakris (Chicago, USA)

Definitions of 'Worsening Renal Function' in cardiorenal trials. How to balance sensitivity and specificity?
Patrick Rossignol (Nancy, FRA)

Should renal function ever be a primary efficacy endpoint or only a safety endpoint in heart failure?

- **Cardiologist Viewpoint**
  Faiez Zannad (Nancy, FRA)
- **Nephrologist Viewpoint**
  Prabir Roy-Chaudhury (Tucson, USA)

Renal endpoints in the setting of CV prevention trials

- **Hypertension**
  George Bakris (Chicago, USA)
- **Diabetes Kidney Disease**
  - **FIGARO – FIDELIO**
    Bertram Pitt (Ann Arbor, USA)
  - **CREDENCE**
    Vlado Perkovic (Sydney, AUS)
- **Regulatory Viewpoint**
  Angeles Alonso Garcia (EMA, GBR); Aliza Thompson (FDA, USA)
- **Industry and CRO Perspective**
  Barbara Gillespie (Covance, USA); Jula Inrig (IQVIA, USA); Richard Nkulikiyinka (Bayer, GER); Alain Romero (Relypsa, USA);
- **Patients' Perspective**
  Cynthia Chauhan (Wichita, USA)

THE FORUM
Moderated discussion with the audience
Chairpersons: Prabir Roy-Chaudhury (Tucson, USA); Patrick Rossignol (Nancy, FRA)

Panelists: Angeles Alonso Garcia (EMA, GBR); George Bakris (Chicago, USA); Erica Caveney (IQVIA, USA); Cynthia Chauhan (Wichita, USA); Michael Felker (Durham, USA); Barbara Gillespie (Covance, USA); Charles Herzog (Minneapolis, USA); Jula Inrig (IQVIA, USA); Julie Ishida (San Francisco, USA); Richard Nkulikiyinka (Bayer, GER); Vlado Perkovic (Sydney, AUS); Bertram Pitt (Ann Arbor, USA); Alain Romero (Relypsa, USA); Claudio Ronco (Vicenza, ITA); Patrick Rossignol (Nancy, FRA); Prabir Roy-Chaudhury (Tucson, USA); Aliza Thompson (FDA, USA); Janet Wittes (Washington, USA); Faiez Zannad (Nancy, FRA)

AUDITORIUM

3:30 – 7:30 pm
TRANSCATHETER HEART VALVE THERAPIES TRIALS

Chairpersons: Robert Bonow (Chicago, USA); Ileana Pina (New York, USA)

- Could THV device approval follow a pathway analogous to that of surgical heart valves by incorporating OPC? Would this be more appropriate only for approval of new-generation THVs in high and extreme-risk patient populations?
- Should approval of THV devices for low- and intermediate-risk patients or for new indications be based on data from randomized, clinical trials?
- How contemporary registries may be useful as a platform for regulatory reform of cardiovascular devices, for generating data to serve as a comparator arm for future trials and to establish objective performance criteria? To perform comprehensive, reliable, and timely post-marketing safety surveillance
- Surgical heart valves can be approved on the basis of objective performance criteria (OPC). In contrast, stricter criteria for transcatheter heart valve (THV) approval, including randomized, clinical trials. FDA has recently approved new-generation THVs based on single-arm studies.

Trial design and endpoint definitions for transcatheter valve trials
Pieter Kappetein (Rotterdam, NED)

When and how to apply to transcatheter valve trials?
Jeffrey Borer (New York, USA)

Industry Perspective
Martyn Thomas (Edwards, USA)

Statistical considerations beyond objective performance criteria in transcatheter valve trials?
Mike Boulware (Medtronic, USA)

Insights from Transcatheter Valve Replacement (TAVR) Registries
Ileana Pina (New York, USA)

Registries as a platform for regulatory approval. Are we there yet? What actions are needed to get there?
Roxana Mehran (New York, USA)

Mitral valve replacement trials and repair
Jeffrey Popma (Boston, USA)

Upstream TAVI in the less sick: when to replace the valve?
Thierry Folliguet (Nancy, FRA)

TAVI and Sutureless aortic valve in intermediate risks patients: pros and cons. The PERSIST Trial
Thierry Folliguet (Nancy, FRA)

NHLBI Perspective
Marissa Miller (NHLBI, USA)

Industry Perspective
Patrick Verta (Edwards, USA)

Regulatory Perspective
Alan Fraser (Cardiff, GBR); Bernard Vasseur (FDA, USA)

Payers Viewpoint: How far upstream will TAVI be reimbursable? Based on which evidence?
Tamara Syrek Jensen (CMS, USA); Harindra Wijeysundera (Canadian Agency for Drugs and Technologies in Health, CAN)

Thrombosis trials in TAVR patients

- **Thrombus apposition and valve mobility/durability in TAVR. The rationale for OAC.**
  Rajendra Makkar (Los Angeles, USA)
- **Industry Perspective**
  Martin Unverdorben (Daiichi Sankyo, USA)
- **Regulatory Perspective: Which study designs may be accepted to obtain approval of an antithrombotic regimen?**
  Karen Hicks (FDA, USA)

Patient Viewpoint
Stefan Teunis (Oldenzaal, NED)

The Forum: Moderated discussion with the audience
How to tackle the ever-evolving technologies? How to optimize anti-bleeding strategies?
Chairpersons: Robert Bonow (Chicago, USA); Ileana Pina (New York, USA)

Panelists: Robert Bonow (Chicago, USA); Jeffrey Borer (New York, USA); Mike Boulware (Medtronic, USA); Thierry Folliguet (Nancy, FRA); Alan Fraser (Cardiff, GBR); Karen Hicks (FDA, USA); Pieter Kappetein (Rotterdam, NED); Rajendra Makkar (Los Angeles, USA); Roxana Mehran (New York, USA); Marissa Miller (NHLBI, USA); Ileana Pina (New York, USA); Jeffrey Popma (Boston, USA); Dan Schaber (Medtronic); Tamara Syrek Jensen (CMS, USA); Stefan Teunis (Oldenzaal, NED); Martyn Thomas (Edwards, USA); Martin Unverdorben (Daiichi Sankyo, USA); Bernard Vasseur (FDA, USA); Patrick Verta (Edwards, USA); Harindra Wijeysundera (Canadian Agency for Drugs and Technologies in Health, CAN)

FRIDAY, DECEMBER 1ST

BALLROOM

8:00 am – 1:00 pm

eTRIALS: OPPORTUNITIES AND CHALLENGES

Chairpersons: Robert Califf (Durham, USA); Bram Zuckerman (FDA, USA)

- This session aims at discussing the current state of the use of digital technology and mobile health in clinical trials in cardiovascular medicine, what data is available for utilizing digital technology as a supportive tool or an intervention in clinical trials, and how can digital technology be used to streamline clinical trial conduct (reduce visits, enrollment/recruitment, subject retention, safety data collection, "site-less" remote clinical trials).
- Potential outcomes (ex. PRO, HR/BP, and activity trackers) can be used with digital health. Can these be used for new drug registration trials and/or post-marketing trials?
- Experts in large IT data platforms will present case studies and discuss what can be gained in CV clinical trial conduct and what are the barriers/challenges to utilizing digital technology in global CV clinical trials?

Key note Lecture
"Integrating Data Science with Evidence Generation"
Robert Califf (Durham, USA)
(Former commissioner, FDA, People Centered Research Foundation, Verily, Durham, USA)

Opportunities and challenges with medical informatics use for clinical trials?
Adrian Hernandez (Durham, USA)

IBM Watson Health
Irene Dankwa-Mullan (IBM, USA)

Health eHeart Study and Health eHeart Alliance
Carol Maguire (San Francisco, USA)

Approach to Virtual Trials (eConsent to ePROs)
Anthony Costello (Medidata, USA)

The National Patient Centered Clinical Research Network (PCORnet)
Adrian Hernandez (Durham, USA)

Sweden heart registry for randomized registry trials
Stefan James (Uppsala, SWE)

Issues in the acquisition, analysis, and sharing of data in the field of cardiovascular science
Elliot Antman (Boston, USA)

How to move from hospital visit and patient reported outcomes to real-life objective measurements
Pierre-Yves Frouin (Bioserenity, FRA)

Utility of geofencing to capture missing hospitalizations in clinical trials
Abhinav Sharma (Stanford, USA and Nancy, FRA)

Methodology/Statistical Viewpoint
Nancy Geller (NHLBI, USA)

Investigator Viewpoint
Mintu Turakhia (Stanford, USA)

Industry Viewpoint
Nancy Dreyer (IQVIA, USA) Helina Kassahun (Amgen, USA); Kenneth Stein (Boston Scientific, USA)

Patient's Perspective for Clinical E-Trials
Debbe McCall (Murrieta, USA)

Regulatory Viewpoint
Bakul Patel (FDA, USA); Gail Pearson (NHLBI, USA); Krishna Prasad (EMA, GBR); Bram Zuckerman (FDA, USA)

Media Viewpoint
Ron Winslow (Freelance Journalist, USA)

The Forum. Moderated discussion with the audience
Chairpersons: Robert Califf (Durham, USA); Bram Zuckerman (FDA, USA)

Panelists: Elliot Antman (Boston, USA); Robert Califf (Durham, USA); Anthony Costello (Medidata, USA); Debbe McCall (Murrieta, USA); Irene Dankwa-Mullan (IBM, USA); Nancy Dreyer (IQVIA, USA); Pierre-Yves Frouin (Bioserenity, FRA); Nancy Geller (NHLBI, USA); Adrian Hernandez (Durham, USA); Stefan James (Uppsala, SWE); Helina Kassahun (Amgen, USA); Carol Maguire (San Francisco, USA); Bakul Patel (FDA, USA); Gail Pearson (NHLBI, USA); Krishna Prasad (EMA, GBR) Dan Schaber (Medtronic, USA); Kenneth Stein (Boston Scientific, USA); Mintu Turakhia (Stanford, USA); Ron Winslow (Freelance Journalist, USA); Bram Zuckerman (FDA, USA)

AUDITORIUM

8:00 am – 3:00 pm
EVOLVING APPROACH TO THE CONDUCT OF CARDIOVASCULAR AND RENAL OUTCOME TRIALS IN DIABETES. HOW DO RECENT TRIALS INFORM FUTURE DRUG DEVELOPMENT?

Chairpersons: Bruce Neal (Sydney, AUS); Felipe Martinez (Cordoba, ARG)

- Regulatory agencies state that reduction of glycated haemoglobin (HbA1C) is an appropriate primary endpoint in diabetes drug development, as it reflects glucose control, and is known to be correlated with a reduced risk of micro vascular complications.
- Until recently, data have not supported a beneficial effect of improving glycemia in diabetes on CV outcomes. Beneficial effects on macro-vascular complications can only be evaluated properly in large scale and long-term controlled clinical trials, which are not considered mandatory for marketing authorisation approval.
- In case it is considered necessary to perform a more in-depth assessment of the cardiovascular safety profile of a new drug intended for the treatment of diabetes, EMA recommends two approaches: a meta-analytic approach of outcome data generated in the phase II/III studies, or a dedicated cardiovascular outcome study.
- The FDA guidance recommends a dedicated preapproval CV trial powered to establish safety by establishing an upper bound of the two-sided 95% confidence interval below 1.8 with the requirement for a subsequent trial to establish non-inferiority to rule out an upper bound confidence interval exceeding 1.3 for a new drug intended for the treatment of diabetes.
- Would a more tailored approach, requiring a CVOT depending on the mechanism of action of a specific drug and based on nonclinical and early phase clinical data be more appropriate?
- The EMA's and FDA's preferred safety endpoint, is a composite of cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke. Heart failure events occur with a similar frequency as myocardial infarction and with a greater frequency than stroke in patients with type 2 diabetes mellitus at high cardiovascular risk. Regulatory agencies should recommend including heart failure events as endpoints in diabetes clinical trials, whether evaluating efficacy or safety. Should only heart failure requiring hospitalization be the CHF endpoint? Should the focus on primary endpoint (3pt MACE vs CHF) be a function of the mechanism of action of the drug under development?
- Trials set in compliance with this guidance have occasionally been powered for efficacy, or efficacy has been tested as part of the statistical hierarchy after CV safety has been established. If efficacy (superiority over standard of care) has been established in a trial (as for empagliflozin, liraglutide, and semaglutide), does this have the same strength of evidence as a trial designed for superiority? Should criteria for establishing CV efficacy based on a single trial be explicitly described and, if so, what is an appropriate p value for superiority?
- Some molecules seem to impact atherosclerosis related endpoints, others improve MACE events with mechanisms other than atherosclerosis, and/or heart failure related endpoints.
- Trials using agents from the same pharmacological classes produced discrepant results (LEADER and SUSTAIN6 vs. ELIXA and EXSCEL; SAVOR vs. other DPPIV trials; EMPA-REG vs. CANVAS raising issues about class effect vs structural/pharmacokinetic differences between molecules of the same class.
- There are emerging data suggesting an association between severe hypoglycaemia and death, which should be taken into account in differentiating among new drugs intended for the treatment of diabetes.

Endpoint related issues

- **Non-inferiority cardiovascular safety endpoints in diabetes trials. Are efficacy endpoint trials preferable**
  Steven Nissen (Cleveland, USA)
- **Cardiologist Viewpoint**
  Naveed Sattar (Glasgow, USA)
- **Diabetologist Viewpoint**
  Steven Marso (Kansas City, USA)
- **Should MACE be the primary endpoint in CV diabetes efficacy/safety outcome trials irrespective of the drug's mechanism of action? "Atherosclerosis" endpoints and/or heart failure endpoints**
  Faiez Zannad (Nancy, FRA)
- **Severe hypoglycemia and all-cause mortality in CVOTs: What have we learned?**
  Michael Farkouh (Toronto, CAN)

Patient population related issues

- **Challenges of primary prevention (CV risk) and limitations of secondary prevention (history of CV events) target populations?**
  Bruce Neal (Sydney, AUS)
- **Addressing patients with CKD**
  Vlado Perkovic (Sydney, AUS)
- **Going beyond diabetes. Non-diabetes trials of new drugs initially intended for the treatment of diabetes**
  Milton Packer (Dallas, USA)

Methodological issues

- **The issue with non-inferiority design and interim analyses. Protecting subsequent trial conduct during/following an interim analysis**
  Darren McGuire (Dallas, USA)
- **Methodological refinements may help streamline future diabetes trials.**
  Cyrus Mehta (Boston, USA)

Industry Viewpoint
Elisabeth Björk (AstraZeneca, SWE); Jyothis George (Boehringer Ingelheim, GER); Stephen Gough (NovoNordisk, DEN); Kirk Ways (Janssen, USA)

Regulatory Viewpoint
Robert Temple (FDA, USA)

NIH Viewpoint
Yves Rosenberg (NHLBI, USA)

Payers' Viewpoint: How to value a diabetes drug with CV mortality benefit?
Lorenzo Mantovani (CESP, ITA)

Patient Viewpoint
Patrick Gee (Chesterfield, USA)

The Forum. Moderated discussion with the audience
Refining the current regulatory guidance.
Chairpersons: Bruce Neal (Sydney, AUS); Felipe Martinez (Cordoba, ARG)

Panelists: Elisabeth Björk (AstraZeneca, SWE); Erica Caveney (IQVIA, USA); Michael Farkouh (Toronto, CAN); Patrick Gee (Chesterfield, USA); Jyothis George (Boehringer Ingelheim, GER); Stephen Gough (NovoNordisk, DEN); Larry Husten (CardioBrief, USA); Darren McGuire (Dallas, USA); Lorenzo Mantovani (CESP, ITA); Felipe Martinez (Cordoba, ARG); Cyrus Mehta (Boston, USA); Bruce Neal (Sydney, AUS); Steven Marso (Kansas City, USA); Steven Nissen (Cleveland, USA); Milton Packer (Dallas, USA); Vlado Perkovic (Sydney, AUS); Stuart Pocock (London, GBR); Susan Quella (Rochester, USA); Yves Rosenberg (NHLBI, USA); Naveed Sattar (Glasgow, GBR); Robert Temple (FDA, USA); Kirk Ways (Janssen, USA); Faiez Zannad (Nancy, FRA)

AUDITORIUM

3:30 – 7:30 pm
THE FUTURE OF CARDIOVASCULAR BIOMARKERS: FROM RISK STRATIFICATION TO PRECISION MEDICINE
A Critical Mechanisms of Disease (CMOD) – CVCT Joint Session

Chairpersons: Nick Mills (Edinburgh, GBR); Jean-Claude Tardif (Montreal, CAN)

- High sensitivity troponins are useful for diagnosis and prognosis in patients with suspected acute coronary syndrome. Though a large volume of evidence to support their utility in such settings has been generated, there is a lack of consensus on the optimal way in which to apply these assays in clinical practice. Novel, rapid algorithms may hold the key to improved patient care using these biomarkers, but much remains to be discussed.
- Recent publications have focused the attention of many clinicians on the potential role for biomarkers of cardiac injury in refining the approach to cardiovascular (CV) risk stratification in the general population. Whether this will ultimately change practice remains to be seen.
- Biomarkers may serve to discriminate various substrates for coronary syndromes and heart failure that could direct individuals to different management strategies. As such, they may stratify patients mechanistically and therapeutically and might help achieve the goal of a more precision management and personalized approach.
- Whether these concepts have gained power and how much are these pertinent to precision and personalized medicine, and how to incorporate in future CV trials is a matter of intense debate.
- Lessons learnt from the mixed success of biomarker – guided clinical trials need to be shared with the aim of refining methodology and moving the area forward

Key note Lecture
"Circulating and Imaging Biomarkers of Atherosclerosis and Prospects of Precision Management and Personalized Approach of Cardiovascular Disease"
Peter Libby (Boston, USA)

Is CV risk modified by therapies and can that be monitored using CV biomarkers?
Nick Mills (Edinburgh, GBR)

The role of biomarkers in detecting risk of cardiac toxicity in cancer trials.
Jean-Claude Tardif (Montreal, CAN)

Can high sensitive troponins improve cardiovascular risk stratification in the general population?

- **In EU:** Johannes Neumann (Hamburg, GER)
- **In US:** Christie Ballantyne (Houston, USA)

Risk stratification of suspected ACS patients: Optimal algorithm?
Agim Beshiri (Abbott, USA)

Health Economics and Outcomes impact of risk stratification with novel CV biomarkers
Amy Durtschi (Abbott, USA)

Imaging to guide HF therapy
Faiez Zannad (Nancy, FRA)

Biomarker guided therapy trials failed so far. Methodological lessons
Kirkwood Adams (Chapel Hill, USA)

Advancing Precision Medicine:
Current and future proteogenomic strategies for biomarker discovery and development
Ida Grundberg (Olink, USA)

Industry Viewpoint
Gillian Murtagh (Abbott, USA); André Ziegler (Roche, CHE)

Media Viewpoint
Ron Winslow (Freelance Journalist, USA)

The Forum. Moderated discussion with the audience
Are we ready for precision CV medicine?
Chairpersons: Nick Mills (Edinburgh, GBR), Jean Claude Tardif (Montreal, CAN)

Panelists: Kirkwood Adams (Chapel Hill, USA); Christie Ballantyne (Houston, USA); Agim Beshiri (Abbott, USA); Ida Grundberg (Olink, USA); Peter Libby (Boston, USA); Amy Durtschi (Abbott, USA); Nick Mills (Edinburgh, GBR); Gillian Murtagh (Abbott, USA); Johannes Neumann (Hamburg, GER); Jean-Claude Provost (GE Healthcare, GBR); Jean-Claude Tardif (Montreal, CAN); Ron Winslow (Freelance Journalist, USA); Faiez Zannad (Nancy, FRA); André Ziegler (Roche, CHE)

BALLROOM

2:00 – 7:30 pm

ATRIAL FIBRILLATION TRIALS
HRS – CVCT Joint Session

Chairpersons: George Van Hare (Saint Louis, USA); Healther Ross (Tempe, USA)

- **Ablation trials**
  - Current guidelines recommend pulmonary-vein isolation by means of catheter ablation as treatment for drug-refractory paroxysmal atrial fibrillation. Radiofrequency ablation is the most common method, and cryoballoon ablation is the second most frequently used technology.
  - It was recently reported that cryoballoon ablation was noninferior to radiofrequency ablation with respect to efficacy for the treatment of patients with drug-refractory paroxysmal atrial fibrillation, and there was no significant difference between the two methods with regard to overall safety. (FIRE AND ICE).
  - It is not known whether successful ablation of AF, regardless of technique, will result in reduced mortality. This is under investigation in the Catheter Ablation versus Anti-arrhythmic Drug Therapy for Atrial Fibrillation (CABANA) and Catheter Ablation versus Standard Conventional Treatment in Patients With LV Dysfunction and AF (CASTLE-AF)
  - However, specifically in persistent atrial fibrillation in patients with heart failure catheter ablation, whether ablation is superior to amiodarone was examined in a randomized study which showed that catheter ablation of atrial fibrillation is superior to amiodarone in achieving freedom from AF at long-term follow-up and reducing unplanned hospitalization and mortality in patients with heart failure and persistent AF.
- **NOAC trials**
  - Trials reporting anticoagulant benefits in AF were done in people with either symptomatic AF or paroxysmal AF long enough to be recorded on multiple ECGs.
  - Diagnosis of short term AF is of uncertain significance. It seems that only longer-lasting AF associates with stroke.
  - How valuable short-duration AF as a surrogate marker is questionable and needs further substantiation.
  - Guidelines recommendations regarding anticoagulant therapy after percutaneous coronary intervention (PCI) among patients with atrial fibrillation (AF) rely on retrospective, nonrandomized observational data. Currently, patients are treated with triple-therapy (dual antiplatelet therapy [DAPT] + oral anticoagulation therapy), but neither the duration of DAPT nor the level of anticoagulation has been studied in a randomized fashion. Recent studies also suggest dual pathway therapy with clopidogrel plus oral anticoagulation therapy may be superior, and other studies suggest that novel oral anticoagulants such as rivaroxaban may further improve patient outcomes.
  - The PIONEER AF-PCI study is the first randomized comparison of VKA vs novel oral anticoagulant therapy in patients with AF receiving antiplatelet therapy after PCI to assess the relative risks of bleeding complications.

- **Left atrial appendage closure trials**
  After the initial trials and within the context of controversial evidence of efficacy of the FDA approved Watchman percutaneous left atrial appendage closure (LAAC), further data are derived from registries. CMS covers FDA approved LAAC for non-valvular atrial fibrillation through Coverage with Evidence Development (CED) in patients enrolled in certain well designed registries and in FDA approved trials. Patients unsuitable for oral anticoagulation are further evaluated within the ASAP-TOO trial.

- **Research on the causes and mechanisms of AF points to the role of fibrosis. Trials of anti-fibrotic agents?**

Trials of anti-thrombotic therapy in AF Ablation (AXAFA - AFNET 5 trial)
Paulus Kirchhof (Birmingham, GBR)

NOACs in patients with atrial fibrillation who undergo percutaneous coronary intervention.
Harry Crijns (Maastricht, NED)

Targeted anticoagulation for short-term device detected AF. Is it ripe for a prospective NOAC trial?
Renato Lopes (Durham, USA)

The value of trial derived novel biomarker-based bleeding risk score for patients with AF.
Ziad Hijazi (Uppsala, SWE)

Left Atrial Appendage Closure. Registry non-randomized evidence and how it aligns with randomized trial evidence
Lucas Boersma (Nieuwegein, NED)

Targeting the right patient population. Are trials addressing personalized AFib prevention/ treatment strategies?
Nassir Marrouche (Salt Lake City, USA)

Vascular closure device to shorten time to ambulation after AF ablation. The AMBULATE Trial
Mintu Turakhia (Stanford, USA)

Industry Perspective
Peter Dibattiste (Janssen, USA); Kenneth Stein (Boston Scientific, USA); Martin Unverdorben (Daiichi Sankyo, USA)

Regulatory Perspective
Andrew Farb (FDA, USA); Pieter de Graeff (EMA, NED)

Benefit/risk and cost effectiveness considerations of anti-thrombotic strategies in AF

- **Payers Perspective**
  Joseph Chin (CMS, USA)

- **Patient Viewpoint**
  Natascha Van der Post (Nijmegen, NED)

The Forum. Moderated discussion with the audience

How to progress from evidence generation to change in practice.
Chairpersons: George Van Hare (Saint Louis, USA); Heather Ross (Tempe, USA)

Panelists: Lucas Boersma (Nieuwegein, NED); Joseph Chin (CMS, USA); Harry Crijns (Maastricht, NED); Pieter de Graeff (EMA, NED); Peter Dibattiste (Janssen, USA); Andrew Farb (FDA, USA); Ziad Hijazi (Uppsala, SWE); Paulus Kirchhof (Birmingham, GBR); Renato Lopes (Durham, USA); Nassir Marrouche (Salt Lake City, USA); Heather Ross (Tempe, USA); Kenneth Stein (Boston Scientific, USA); Mintu Turakhia (Stanford, USA); Martin Unverdorben (Daiichi Sankyo, USA); Natascha Van der Post (Nijmegen, NED); George Van Hare (Saint Louis, USA)

AUDITORIUM

8:00 – 1:00 pm
POSITIVE SIGNALS FROM RECENT NEUTRAL HEART FAILURE TRIALS: TIME FOR AN AUTOPSY
HFSA – CVCT Joint Session

Chairpersons: Christopher O'Connor (Washington, USA); Mona Fiuzat (Durham, USA)

- So-called "neutral" or "negative" trials contribute to the body of evidence with a drug, device, or procedure. Such trials often provide relevant knowledge to the field and often inform planning of subsequent randomized trials.
- When a trial fails to show statistically significant evidence of benefit of an experimental intervention, the cardiovascular community should ask whether the intervention worked, but the trial was flawed in some way, or the trial was valid but the intervention was ineffective.
- The appropriate next steps after completion of an inconclusive trial are influenced by 1) whether a strong mechanistic or biologic rationale supports use of the treatment and 2) the overall assessment of potential reasons why the trial did not meet its primary objective.
- It is crucial, but often difficult, to determine if a clinical outcomes trial did not show a treatment effect because of errors in trial design or execution or if the treatment was truly ineffective.

  "Autopsy is performed by anatomists with the principal aim of an autopsy is to determine the cause of death, the state of health of the person before he or she died, and whether any medical diagnosis and treatment before death was appropriate."
- The objective of this session is to have trial specialists examine failed trials with the aim of determining causes of failure, the robustness of the trials before they failed, and whether any appropriate early examination or corrective action could have prevented negative/neutral results.
- The aim is ultimately to draw lessons that may inform the design and the conduct of future trials. Future trials may be designed addressing lessons learned from informative but inconclusive trials, applying different patient populations, alternate treatment regimens, or different outcomes. Alternatively, trials should be viewed in the broader context of how the results can inform the field.

Introduction
Christopher O'Connor (Washington, USA)

One main reason I believe my trial didn't meet its primary endpoint:

- **RELAX-AHF-2:** John Teerlink (San Francisco, USA)
- **TRUE AHF:** Milton Packer (Dallas, USA)
- **TOPCAT:** Bertram Pitt (Ann Arbor, USA)
- **GUIDE IT:** Michael Felker (Durham, USA)
- **BLAST:** Peter Pang (Chicago, USA)
- **Vericiguat in HFpef:** Javed Butler (New York, USA)
- **HF ACTION:** Dave Whellan (Durham, USA)
- **BEST:** Mike Bristow (Aurora, USA)
- **SERVE-HF:** Faiez Zannad (Nancy, FRA)

Advanced analytics in clinical trials:
Tariq Ahmad (New Haven, USA)

Statistical Viewpoint
Nancy Geller (NHLBI, USA); Cyrus Mehta (Boston, USA)

Investigator Viewpoint
Karl Swedberg (Goteborg, SWE)

Industry Viewpoint
Jim Carr (Stealth Biotherapeutics, USA); Claudio Gimpelewicz (Novartis, CHE); Lothar Roessig (Bayer, GER); James Strait (Merck, USA)

NHLBI Viewpoint
George Sopko (NHLBI, USA)

CRO Viewpoint
Monica Shah (IQVIA, USA); Allen Kindman (IQVIA, USA)

Patient Viewpoint
Natascha Van der Post (Nijmegen, NED)

The Forum. Moderated discussion with the audience
What lessons have we learned? How is success secured in ongoing trials?
Chairpersons: Christopher O'Connor (Washington, USA); Mona Fiuzat (Durham, USA)

Panelists: Mike Bristow (Aurora, USA); Javed Butler (New York, USA); Jim Carr (Stealth Biotherapeutics, USA); Michael Felker (Durham, USA); Mona Fiuzat (Durham, USA); Nancy Geller (NHLBI, USA); Claudio Gimpelewicz (Novartis, CHE); Allen Kindman (IQVIA, USA); Cyrus Mehta (Boston, USA); Christopher O'Connor (Washington, USA); Milton Packer (Dallas, USA); Peter Pang (Chicago, USA); Bertram Pitt (Ann Arbor, USA); Lothar Roessig (Bayer, GER); Monica Shah (IQVIA, USA); James Strait (Merck, USA); George Sopko (NHLBI, USA); Karl Swedberg (Goteborg, SWE); John Teerlink (San Francisco, USA); Natascha Van der Post (Nijmegen, NED); Dave Whellan (Durham, USA); Faiez Zannad (Nancy, FRA)

BALLROOM

8:00 am – 1:00 pm

EVALUATION OF NEW TECHNOLOGIES IN CARDIOVASCULAR CARE. BRIDGING EVIDENCE-BASED WITH VALUE-BASED HEALTH CARE

MedTech Europe & Advamed – CVCT Joint Session

Chairpersons: Jeffrey Borer (New York, USA); Nadim Yared (CVRx, USA)

- Regulators and payers sometimes differ in their perspectives on medical advances and the weight they place on components of the evidence base. These contrasting priorities can lead to divergence between regulatory and payer decisions and delays or barriers in patients' access to new therapies.
- Those involved in coverage decisions have not routinely been integrated in the drug development process pre-approval, specifically with respect to clinical trial design. Inclusion of payer representatives sooner in the development process would provide opportunities to detect discordance among stakeholders in terms of data priorities, facilitate cooperation to align objectives, agree on the evidence required for approval and reimbursement, improve transparency and accountability of payer decision making, and ideally minimize delays in patient access to new therapies.
- Research on the benefits and performance of devices differs between 'therapeutic' devices (e.g. pacemakers, nerve stimulators, prostheses) and 'non-therapeutic' devices (e.g. diagnostic, monitoring, screening or prognostic tests).
- "Value-based healthcare", focuses on outcomes that are relevant to patients, including, but not limited to, clinical outcomes
- Therefore a linked or network of evidence approach may be better suited to device evaluations than a 'hierarchy of evidence' approach.
- Health ministers in EU recently mandated that the OECD develop an instrument to collect information (Paris) to be able to compare the performance of health systems, as well as the performance of clinicians and technology.
- MedTech companies and organizations in Europe and the USA currently has programs in place to drive "value-based healthcare".
- Device evaluations are enhanced when device developers, manufacturers, trialists, regulators, payers, health professionals and patients collaborate to agree on the "Burden of proof" and describe at an early stage the potential mechanisms/pathways through which achieve "value-based healthcare", ultimately

improving timely patient access to new treatments that reduce the burden of disease or prolong life.

Panel on Evaluation Systems for New Technology: Overview & comparison of evaluation systems. Discussion on whether certain evaluation systems are better suited for certain types of devices/ disease states/ healthcare system. Identification of one evaluation system that is preferred over others.

- **Evidence based evaluations of Medical Technology and Biomarkers: what does it actually mean and what do we want?**
  - **The EU Perspective**
    Carl Moons (Utrecht, NED)
- **Medicare Evaluation: What is the process & what evidence is required for coverage today?**
  Joseph Chin (CMS, USA)
- **Willingness-to-pay: Europe's Most Economically Advantageous Tender pilot (MEAT)**
  Yves Verboven (MedTech Europe, BEL)

Panel on Streamlining Clinical Trial Data Collection with Evaluation System Requirements: Overview & comparison of relevant types of clinical data, with a focus on how each serves (or does not serve) one of the respective evaluation systems. Discussion on why and how evaluation systems must evolve to take such critical data into account.

- **Patient-Reported Outcomes: How should they be valued?**
  Michael Nassif (Kansas City, USA)
- **Real-world data collection: What is the value of this for device therapy?**
  Dalal Nirav (Abbott, USA)

Industry Viewpoint
Philip Adamson (St Jude, USA); Robin Bostic (Abbott, USA); Julia Stubben (CVRx, CHE); Nadim Yared (CVRx, USA)

Regulatory Viewpoint
John Whyte (FDA, USA); Bram Zuckerman (FDA, USA)

Payers' Perspective
Joseph Chin (CMS, USA); Leeza Osipenko (NICE, GBR)

The Forum. Moderated discussion with the audience. The Role of Payers in Cardiovascular Clinical Research: Addressing the Misalignment between Approval and Reimbursement.
Chairpersons: Jeffrey Borer (New York, USA); Nadim Yared (CVRx, USA)

Panelists: Philip Adamson (St Jude, USA); Jeffrey Borer (New York, USA); Robin Bostic (Abbott, USA); Joseph Chin (CMS, USA); Carl Moons (Utrecht, NED); Michael Nassif (Kansas City, USA); Dalal Nirav (Abbott, USA); Leeza Osipenko (NICE, GBR); Julia Stubben (CVRx, CHE); Yves Verboven (MedTech Europe, BEL); John Whyte (FDA, USA); Nadim Yared (CVRx, USA); Bram Zuckerman (FDA, USA)

AUDITORIUM

2:00 – 6:30 pm
WHY SOME CLINICAL TRIALS DO NOT WORK OR HAVE AN IMPACT. ARE THERE WAYS TO DO A BETTER JOB?
An International Society of Cardiovascular Pharmacology (ISCP) – CVCT Joint Session

Chairpersons: Angeles Alonso Garcia (London, GBR); Milton Packer (Dallas, USA)

- The structure of a large international clinical trial is complex. It typically involves a sponsor, a leadership committee, numerous geographically-dispersed investigators, and a group responsible for operational functions.
- A pharmaceutical executive or academic leader must decide whether to propose a very large expensive clinical trial to upper management. The data supporting the drug is marginal. He/ she advocate strongly for investment, emphasizing data that are hopeful but minimizing risks.
- The leadership committee defines the trial hypotheses and the methods by which the hypotheses can be tested in an unbiased manner. Members focus on the big picture, but do they really know how the trial is being executed?
- Most sponsors lack internal resources to execute the trial and thus seek help from an outside vendor, a CRO. Their procurement office provides the contract to the lowest bidder.

- The CRO is itself a business enterprise, which has a responsibility to carry out the trial in a manner financially advantageous to its owners or shareholders. They identify investigators who can recruit quickly and inexpensively.
- The investigators are paid to recruit patients. Some are very creative in enrolling patients very quickly. When the trial is over, they will receive little academic credit, but will rapidly move on to the next trial.
- The operations group is charged with ensuring that patients are recruited into the trial on schedule and that the data quality can be made to appear to be reasonable.
- The data are collected, but the analysis unit understands that certain results will yield predictable benefits. If this is a phase II trial, a trial yielding positive results is likely to be followed by additional substantial investment in more studies.
- If this is a phase III trial, the results are rarely satisfying; i.e., the trial's primary hypothesis has proven to be valid, and the supporting data are of very high quality. Much more often than not, both the leadership committee and the sponsor are disappointed by the results. There may be some positive signals, but one can find them only after a very diligent and creative search.
- The results of the trial are presented, and internet scavengers emerge from their hiding places to feast. If the trial is markedly positive, these vultures seek perceived flaws or hold the trial's conduct to unrealistic standards. If not, they demand replication (even if it is unethical or not feasible). If the results are disappointing, they rejoice in their claims that they predicted the trial's failure.
- The results of the trial are published. How should a new study be interpreted? Many physicians do not even make an attempt to read and understand the primary publication; often they wait for the chatter on the internet or official guidelines to tell them what to do. Physicians have insufficient knowledge, time or motivation to perform a proper evaluation.

An overview of the problem seen from the US
Milton Packer (Dallas, USA)

How do sponsors make a decision to support a trial?
David Kallend (The Medicine Company, USA); Kenneth Stein (Boston Scientific, USA)

Can academic leaders oversell an idea?
Paul Armstrong (Edmonton, CAN); Karl Swedberg (Goteborg, SWE)

Who should be minding the store?
Janet Wittes (Statistics Collaborative, USA)

Why do I sometimes have trouble sleeping at night?
Scott Solomon (Boston, USA)

Are academic investigator becoming extinct?
Bertram Pitt (Ann Arbor, USA)

Which types of investigative sites do regulators worry about?
Norman Stockbridge (FDA, USA)

Are practitioners paying any attention to the results of trials?
Antoni Martínez-Rubio (Barcelona, ESP)

What do journal editors think of professional cynics?
Robert M. Golub (JAMA Cardiology, USA); Joseph Hill (Circulation, USA); John Jarcho (NEJM, USA); Stuart Spencer (The Lancet, GBR)

Are payers happy when a trial shows a benefit of an expensive drug?
Leeza Osipenko (NICE, GBR)

Media Viewpoint
Ron Winslow (Freelance Journalist, USA)

THE FORUM
Moderated discussion with the audience
Chairpersons: Angeles Alonso Garcia (London, GBR); Milton Packer (Dallas, USA)

Panelists: Angeles Alonso Garcia (London, GBR); Paul Armstrong (Edmonton, CAN); Robert M. Golub (JAMA Cardiology, USA); Joseph Hill (Circulation, USA); Larry Husten (CardioBrief, USA); John Jarcho (NEJM, USA); David Kallend (The Medicine Company, USA); Antoni Martínez-Rubio (Barcelona, ESP); Leeza Osipenko (NICE, GBR); Milton Packer (Dallas, USA); Bertram Pitt (Ann Arbor, USA); Scott Solomon (Boston, USA); Stuart Spencer (The Lancet, GBR); Kenneth Stein (Boston Scientific, USA); Norman Stockbridge (FDA, USA); Karl Swedberg (Goteborg, SWE); Ron Winslow (Freelance Journalist, USA); Janet Wittes (Statistics Collaborative, USA)

BALLROOM

2:00 – 6:30 pm

TIME IS MUSCLE. ACUTE INTERVENTION TRIALS IN CORONARY ARTERY DISEASE AND IN HEART FAILURE

Chairpersons: Roxana Mehran (New York, USA); Alexandre Mebazaa (Paris, FRA)

1. Advances and remaining gaps in the early management of acute coronary syndromes

- **How early is early? Chest pain characteristics and opportunities for very early management from contemporary databases**

  Speaker: Patrick Badertscher (Basel, CHE)
  Discussant: Justin Ezekowitz (Edmonton, CAN)
- **Pre hospital, pre PCI intervention. Review of the evidence: Did ATLANTIC and ACCOAST really fail?**
  Roxana Mehran (New York, USA)
- **How different is a STEMI from a NSTEMI in their infancy?**
  Roxana Mehran (New York, USA)
- **10-year trends in time to reperfusion of STEMI patients in France**
  Tabassome Simon (Paris, FRA)
- **Home based detection of cardiac ischemia**
  Olivier Chételat (Neuchâtel, CHE)
- **Industry Viewpoint**
  Sébastien Roux (Idorsia, CHE)
- **Regulatory Viewpoint**
  Ellis Unger (FDA, USA)

2. Advances and remaining gaps in the early management of heart failure

- **Early pre-admission diagnosis and management of HF congestion related dyspnea.**
  Nicolas Girerd (Nancy, FRA)
- **Early therapy in AHF. Rearview and ways forward. How to progress from proof of concept to outcome trials**
  Alexandre Mebazaa (Paris, FRA)
- **Diuretic – decongesting strategies trials**
  Eric J. Velazquez (Durham, USA)
- **Industry Viewpoint**
  Shalabh Singhal (BMS, USA)
- **Regulatory Viewpoint**
  Robert Temple (FDA, USA)

Patient education: Community intervention (campaign) vs targeted education of patients
Holli DeVon (Chicago, USA)

Patient Viewpoint
Annemieke Lenselink (The Hague, NED); Natascha Van der Post (Nijmegen, NED)

THE FORUM
Moderated discussion with the audience
Chairpersons: Roxana Mehran (New York, USA); Alexandre Mebazaa (Paris, FRA)

Panelists: Patrick Badertscher (Basel, CHE); Olivier Chételat (Neuchâtel, CHE); Holli DeVon (Chicago, USA); Justin Ezekowitz (Edmonton, CAN); Nicolas Girerd (Nancy, FRA); Annemieke Lenselink (The Hague, NED); Alexandre Mebazaa (Paris, FRA); Roxana Mehran (New York, USA); Sébastien Roux (Idorsia, CHE); Tabassome Simon (Paris, FRA); Shalabh Singhal (BMS, USA); Robert Temple (FDA, USA); Ellis Unger (FDA, USA); Natascha Van der Post (Nijmegen, NED); Eric J. Velazquez (Durham, USA)

CVCT YOUNG INVESTIGATOR GRANTS (CVCT YIGs)

The Global CVCT Forum supports young investigators through a grant scheme enabling them to access and participate in the CVCT Forum, an event dedicated to clinical trials in cardiovascular disease. At the CVCT they learn from and network with key opinion leaders, principal investigators and regulatory and R&D industry experts, to shape their future practice toward CV clinical trial related activities. Our scientific committee learns about candidates in the following ways:

- **Grant applications submitted via the CVCT website** - www.globalcvctforum.com
- **Nomination by CVCT faculty members - CVCT** Meetings are supported by unrestricted educational grants with no allocation for speakers fees. In recognition of the valued contribution of faculty members and with a view to attracting young investigators to the field of cardiovascular clinical trial science, CVCT invites faculty members to recommend one fellow who could be invited to attend the CVCT Forum.

We are pleased to welcome the following young investigators to CVCT Forum 2017:

Aaron Aday
Faraz Ahmad
Ahmed Al-Badri
Maria Ali
Miguel Alvarez
Mattia Arrigo
Shreyas Arun Chawathey
Sriya Avadhani
Allan Böhm
Leo Buckley
Chathuri Daluwatte
Natalia de Albuquerque Rocha
Simon-Pierre Demers
Edward Duran
Sandy El Bitar
Gabby Elbaz Greener
Alexander Fanaroff
Joao Ferreira
Patrick Fuchs
Aiste Galkine
Sonia Garg
Eiman Ghaffarpasand
Vera Gorbachova
Tanush Gupta
Dagmar Hernandez-Suarez
Katlyn Koepp
Marek Kozinski
Elizabeth Krebs
Luke Laffin
Nino Mihatov
David F. Miranda
Jonathan Newman
PhuongGiang Nguyen
Connor O'Brien
Luis Ortega-Paz
Kershaw Patel
Alexander Perino
Mitchell Psotka
Aniket Rali
Federico Ronco
Gaetano Ruocco
Frances Russell
Gianluigi Savarese
Abhinav Sharma
Oksana Sirenko
Konstantinos Stathogiannis
Jozine ter Maaten
Tobias Daniel Trippel
Muthiah Vaduganathan
Iryna Vyshnevska
Markus Wallner
Michael Wilkinson

CVCT LIBRARY AND CVCT PUBLICATIONS

We offer a complete record of previous CVCT Forum presentations, including the webcast programs of 2011 and 2012, freely available on our website: www.globalcvctforum.com

The CVCT Library includes webcasts of selected sessions and slide sets from most of the presentations and also the latest CVCT publications.

In addition we are pleased to welcome the young writer team to the CVCT Forum 2017:
The dedicated CVCT writing group produces manuscripts resulting from high-level scientific discussions at the CVCT Forum, working with key faculty and leadership from the sessions.

The writing group is led by Dr Fiuzat and Dr Mentz (Co-Directors of the editorial board and writing group), working alongside junior faculty or fellows who have been identified as members.

Marat Fudim, USA
Sounok Sen, USA
Tariq Ahmad, USA
Mitch Psotka, USA
Muthiah Vaduganathan
Abhinav Sharma, USA

CVCT publications reference list - Visit www.globalcvctforum.com to read the articles in full.

2017

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ORGANISED BY THE CLINICAL INVESTIGATION CENTER

Nancy Inserm 1433 Clinical Plurithematic Investigation Centre (CIC-P), headed by Pr Faiez Zannad, is supported by the **National Institution for Health Care and Medical Research** (Inserm), **Nancy University Hospital,** and the Université de Lorraine.

With its staff specifically dedicated to clinical research, it acts as an interface between basic research and completed medical research, and its purpose is to produce new scientific and medical knowledge in compliance with ethical and legal standards. The CIC objectives are:

• To provide logistical and technical support for the design and imple mentation of research projects

• To develop clinical research especially in cardiovascular diseases, aging and metabolism, within the community of university hospitals and research laboratories, and in particular within Inserm, as well as with general hospitals and health care facilities and private practice investigators

• To train physicians, pharmacists and paramedics in clinical research, the use of good clinical practices and quality control.

The CIC provides support throughout each entire project, from the preparatory stage to termination and follow-up.

www.chu-nancy.fr

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The **Heart Failure Society of America** (HFSA) provides a forum for all those interested in heart function, heart failure, and congestive heart failure (CHF) research and patient care. Membership is open to all health care professionals with an interest in cardiovascular medicine, including cardiologists, cardiac surgeons, internists, geriatricians, general and family practitioners, scientists, cardiac rehabilitation specialists, nurses, industry or allied personnel. .

http://www.hfsa.org/

The **Heart Rhythm Society** aims to improve the care of patients by advancing research, education and optimal health care policies and standards. The Heart Rhythm Society is a leading resource on cardiac pacing and electrophysiology. This specialty organization represents medical, allied health, and science professionals from more than 70 countries who specialize in cardiac rhythm disorders.

www.hrsonline.org

The **Kidney Health Initiative,** established in September 2012, is a public-private partnership founded by the American Society of Nephrology and the U.S. Food and Drug Administration (FDA). With over 80 member organizations, KHI administers multi-disciplinary projects in order to improve patient safety and foster the development of novel therapies for patients with kidney diseases. Through the leadership and support of the KHI Patient and Family Partnership Council (PFPC), the patient voice is considered an integral part of all KHI activities. More information, including a list of current projects, please visit:

www.kidneyhealthinitiative.org

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The **Food and Drug Administration** (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, animal foods & feed and veterinary products.

www.fda.gov

The **National Heart, Lung, and Blood Institute** (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

www.nhlbi.nih.gov

The **European Medicines Agency** is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. It began operating in 1995.

www.ema.europa.eu

The mission of the **International Society of Cardiovascular** Pharmacotherapy (ISCP) is to promote and facilitate strategies to improve cardiovascular health through cooperation among cardiac physicians and surgeons, pharmacologists, pharmacists, scientists, and medical practitioners worldwide.

www.iscpcardio.org

The **International Partnership for Critical Markers of Disease** (CMOD) is an organization established to advance the science of biomarkers used to ideintify, monitor and treat cardiovascular and related diseases.

www.ipcmod.org

EDDH, **European Drug Development Hub** (EDDH) is an academic clinical research organisation, under the aegis of the Foundation Force, a public-interest foundation. EDDH was founded in 2007, from a partnership between the Clinical Investigation Center of the University Hospital of Nancy and the Force Foundation. EDDH provides full-service clinical project management. This enables investigators and promoters to concentrate on their core tasks, while still being actively involved in clinical research.Our clinical project management services cover the planning, coordination and implementation of all types of clinical studies, in France and Europe. EDDH works with a range of partners. These include clinical investigators (institutional clinical trials), pharmaceutical and medical device developers (commercial clinical trials) and EU Framework Programs.

www.eddh-cro.wix.com/fdtsfv

The **European Association for Clinical Pharmacology and Therapeutics** (EACPT) is a learned society in the field of clinical pharmacology. It is the leading society in Europe serving the European and global clinical pharmacology and therapeutics community. The EACPT includes all national organisations for clinical pharmacology in Europe and provides educational and scientific support for the more than 4000 individual professionals interested in clinical pharmacology and therapeutics throughout the European region, with its congresses - the next in Madrid in 2015 - attended by a global audience. The EACPT also holds summer schools and organises other scientific and professional activities.

www.eacpt.org

F-CRIN, **French Clinical Research Infrastructure Network**, hosted by Inserm, is an operational excellence network encompassing the major French academic actors in clinical research. FCRIN aims to support and promote ambitious and competitive multinational academic investigator-driven trials proposed in France and early development proof of concept with industry sponsored trials. FCRIN acts as a multifunctional platform able to provide all necessary services to the duo Investigator/Sponsor and works in tight connection with ECRIN, ERIC of which France is one of the founding member.

www.fcrin.org

The **Investigation Network Initiative** (INI) – **Cardiovascular and Renal Clinical Trialists** (CRCT), coordinated by Pr Patrick Rossignol (Nancy, France) has been approved by the "F-CRIN" (French Clinical Research Infrastructure Network). It has established a national multidisciplinary network of research excellence comprised of the French leaders in the cardiorenal field (nephrology, cardiology, intensivists, internists trialists, epidemiologists, methodologists, basic researchers), an Academic Research Organisation, disease management programs in Chronic Kidney disease (CKD) and heart failure, the French Biomedecine agency, and University of Lorraine Foundation. It aims at designing and realizing research programs both nationally and internationally, to improve cardiovascular and renal outcomes in CKD patients.

www.inicrt.org

Ranked among the top 10 heart programs in the United States, **Duke Heart Center** provides state-of-the-art cardiac care to help thousands of heart patients lead longer, healthier lives. Decades of experience in caring for patients with heart disease have established Duke as one of the world's leading programs in cardiac care, research, and education.

www.dukemedicine.org

Speaker biographies

Marianne Abi-Fadel (Beirut, LBN)

Marianne Abi-Fadel is the elected Dean since 2013 and head of the Biochemistry and Molecular Therapeutics laboratory at the School of Pharmacy at Saint-Joseph University USJ, Beirut. She is also a Senior Researcher associated to the INSERM U1148 at Bichat Hospital, Paris. Born in Lebanon, she received her pharmacy Degree from USJ in 1996, her Clinical Biochemistry Specialization Diploma and her PhD in Molecular Genetics in 2003 with honour and the French accreditation to supervise research (HDR) from the University of Paris-Descartes. Her main scientific achievement is the discovery of the implication of PCSK9 mutations in familial Hypercholesterolemia. This was the seminal paper linking PCSK9 to cholesterol metabolism and was the starting point of the PCSK9 adventure from gene to a new therapeutic class: the anti-PCSK9. She has several papers and was awarded several distinctions in France and Lebanon for her work on familial hypercholesterolemia and familial aortic aneurysms.

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. Dr. Adams has been involved in more than 130 completed grant- and industry-funded research projects, and he is currently leading or participating in multiple drug development trials, several registry and database studies, and NIH/NHLBI-funded trials. Dr. Adams is the principal investigator for the national multicenter database group, UNITE-HF, which focuses on registries of patients with heart failure. In addition to drug development for acute and chronic heart failure, his current research interests are heavily focused on personalized medicine with ongoing projects related to novel biomarkers for heart failure, pharmacogenomics of heart failure therapeutics, and biomarker guided therapy for improving outcomes in CHF. He is very actively involved on the Executive Committee for the NHLBI sponsored trial of NT-proBNP guided therapy known as the GUIDE-IT Trial.

Philip Adamson (Abbott, USA

Phil Adamson is Divisional Vice President, Global Clinical Affairs and Medical Director at Abbott. In this capacity, Dr. Adamson is responsible for global development of Abbott's heart failure formulary spanning cardiac resynchronization therapy to the CardioMEMS HF™ system. Dr. Adamson joined Abbott, formerly St. Jude Medical in February 2015. Dr. Adamson received his M.D. (with distinction) and Masters of Science in Cardiovascular Physiology from the University of Oklahoma Health Sciences Center, where he also trained in internal medicine and cardiology. He joined the faculty at the University of Oklahoma with NIH support to investigate the autonomic mechanisms of sudden cardiac death. Dr. Adamson's clinical interests were to develop more efficient and effective heart failure disease management systems using remote monitoring of physiologic signals from implanted devices. He has served as the Principal Investigator or on the Steering Committees of several large randomized clinical trials.

Angeles Alonso Garcia (EMA, GBR)

Angeles Alonso Garcia is a Senior Medical Assessor in the Medicines and Healthcare products Regulatory Agency (MHRA) Cardiology Member of the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) Active member of the Scientific Advice Working

Party Honorary Consultant in Cardiology. Imperial College Healthcare. NHS. United Kingdom, since 2014.

Dr Alonso graduated from the School of Medicine at the Universidad Autónoma de Madrid (1979). PhD at the Medical School (1991).

Staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid), since 1987 until 2013 with several posititons: Head of the Coronary Care Unit (1987-2000). Senior Consultant as a Clinical Cardiologist (involved in clinical trials on Heart Failure, Ischaemic Heart Disease and Cardiovascular Prevention) 2000-2013. Member of the Committee for Ethics and Clinical Investigation (2000-2009).

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. Nucleus member of Cardiovascular Pharmacology Workin Group.

Elliot Antman (Boston, USA)

Elliott Antman is Professor of Medicine and Associate Dean for Clinical/Translational Research at Harvard Medical School, a Senior Investigator in the Thrombolysis in Myocardial Infarction (TIMI) Study Group, and a Senior Physician in the Cardiovascular Division of the Brigham and Women's Hospital in Boston, Massachusetts. He was President of the American Heart Association (2014-2015). The American Heart Association honored him with the 2016 Paul Dudley White Award.

At Brigham and Women's Hospital, Dr. Antman has been recognized for his active role and interest in education and training. He has been honored for his contributions by the Harvard Medical School when it awarded him the A. Clifford Barger Excellence in Mentoring Award. Dr. Antman is Director of the Harvard Catalyst Program for Education in Clinical and Translational Science and the Skills Development Center at the Boston Biomedical Innovation Center at the Brigham and Women's Hospital.

Paul Armstrong (Edmonton, CAN)

Paul Armstrong is a Distinguished University Professor at the University of Alberta. He serves in a broad range of consultative, editorial, and research leadership roles and is the recipient of numerous awards for scholarly and societal contributions. He publishes extensively, frequently lectures in national and international academic forums, and plays an active leadership role in the conduct of a number of ongoing cardiovascular clinical trials and data safety monitoring boards. He serves as an associate editor for the Journal of the American College of Cardiology and Circulation: Heart Failure, a guest editor for the American Heart Journal, Circulation and JACC Heart Failure, and is a member of several editorial boards including those of the American Heart Journal, the European Heart Journal, JAMA Cardiology and Circulation. Dr. Armstrong's commitment to the education, training, and mentoring of healthcare professionals, research trainees, and faculty spans over 40 years and is a key signature of his career. He is internationally recognized for his expertise in acute coronary disease and heart failure and has a particular interest in novel approaches to the design of clinical trials and their interpretation. Dr. Armstrong is the founding Director of the Canadian VIGOUR Centre (Virtual Coordinating Centre for Global Collaborative Cardiovascular Research), a University of Alberta Research Centre devoted to enhancing cardiovascular health for current and future generations through the conduct of innovative clinical investigations. He was the founding President of the Canadian Academy of Health Sciences (CAHS) and is a Fellow of the Royal Society of Canada.

Patrick Badertscher (Basel, CHE)

Patrick Badertscher, MD, earned his medical degree from the University of Basel. He completed

a residency in internal medicine and joined the cardiology department at the University Hospital Basel in 2015. In 2016 he did a post-doctoral clinical research fellowship at the Cardiovascular Research Institute Basel (Head of Department: Professor Christian Mueller) with a focus on the early diagnosis of acute myocardial infarction and on the rapid and accurate diagnosis of cardiac syncope. Dr. Badertscher will begin a fellowship in electrophysiology at the University of Illinois at Chicago in summer 2018.

George Bakris (Chicago, USA)

George Bakris received his medical degree from the Rosalind Franklin School of Medicine and completed residency in Internal Medicine at the Mayo Graduate School of Medicine where he also completed a research fellowship in Physiology and Biophysics. He then completed fellowships in Nephrology and Clinical Pharmacology at the University of Chicago. Currently, he is a tenured Professor of Medicine and Director of the ASH Comprehensive Hypertension Center in the Department of Medicine at the University of Chicago Medicine. Dr. Bakris has published over 800 peer reviewed articles and book chapters in the areas of diabetic kidney disease, hypertension, and progression of nephropathy. He is the Editor or Co-Editor of 20 books, in the areas of Kidney Disease Progression and Diabetes as well as the new (2017) 3rd edition of Hypertension: A Companion to Braunwald's The Heart. He has served on many national guideline committees including: the JNC 7 executive committee, the American Diabetes Assoc. Clinical Practice Guideline Committee, the National Kidney Foundation (K-DOQI) Blood Pressure and Diabetes Guideline committees, Chair, ADA Blood Pressure Consensus Report and ACC/AHA writing committees for Aortic Aneurysm, Hypertension in the Elderly and Resistant Hypertension Guidelines. He is past-president of the American College of Clinical Pharmacology and the American Society of Hypertension. He is the Editor-in-Chief, Am J Nephrology, Section Editor of Up-to-Date, Nephrology & Hypertension Section and Assoc. Ed of Diabetes Care.

Deepak Bhatt (Boston, USA)

Deepak L. Bhatt MD, MPH, is Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital Heart & Vascular Center and Professor of Medicine at Harvard Medical School. He is also a Senior Physician at Brigham and Women's Hospital and a Senior Investigator in the TIMI Study Group. He was selected by Brigham and Women's Hospital as the 2014 Eugene Braunwald Scholar. He has authored or co-authored over 1000 publications. In 2014, he was listed in the AHA/ASA top ten advances in heart disease and stroke research (for the STAMPEDE and SYMPLICITY HTN-3 trials). He has been listed in Best Doctors in America from 2005 to 2017. He was the inaugural Chair of the AHA-GWTG Quality Oversight Committee. He is a Trustee of the ACC. He is Senior Associate Editor for News and Clinical Trials for ACC.org. He is the Editor of the peer-reviewed Journal of Invasive Cardiology, Chief Medical Editor of Cardiology Today's Intervention for healthcare professionals, and Editor-in-Chief of the Harvard Heart Letter for patients.

Elisabeth Björk (AstraZeneca, SWE)

Elisabeth Björk is Vice President and global head of late phase development for Cardiovascular, Metabolic and Chronic Kidney Disease at AstraZeneca since 2012.

Prior to this, Elisabeth led the development of Dapagliflozin (FORXIGA), a first-in-class diabetes drug and has also been involved in the development of several other key products/ drugs.

In 2014, Elisabeth moved back to Sweden after spending seven years in the US at the AstraZeneca US R&D site. She was then appointed scientific leader for the research site at Gothenburg.

Elisabeth is an endocrinologist by training and

an associate professor of medicine at Uppsala University, and was Head of the Diabetes and Endocrinology Unit at the University Hospital, Uppsala, before joining AstraZeneca in 2002

Donald Black (Dalcore, CAN)

Donald M. Black MD, MBA, FACC is the Chief Medical Officer of DalCor Pharma UK Ltd. He has over 25 years of experience in research, development and business management. During his career, he has held various senior leadership positions including general manager of advanced diabetes care at Becton Dickinson, global leader of research and development as well as general manager of molecular imaging at GE Medical Diagnostics, vice president of global strategic development at Merck and Co, and vice president of clinical research at Parke-Davis from 1990 to 2000, where he was responsible for the clinical development of Lipitor. Dr Black has served on multiple boards of directors and scientific advisory boards, and has over 150 publications, presentations and chapters. His academic appointments include associate professor of paediatric cardiology at the University of Michigan, professor of medicine at the University of Cincinnati, and adjunct professor of medicine, National University of Ireland at Galway.

Dr Black earned his MD from University of Michigan Medical School, his MBA from the University of Cincinnati College of Business, and studied law at University of Cincinnati.

Lucas Boersma (Nieuwegein, NED)

Lucas Boersma received his medical degree in 1994 at Maastricht University, as well as finishing his PhD thesis on Ventricular tachycardia in the Rabbit Heart. He finished his Cardiology training at St.Antonius Hospital in 2000, followed by a Fellowship in Clinical Electrophysiology at Hospital Clinic in Barcelona in 2001. Since then he serves as Electrophysiologist and senior staff member of the Cardiology Department of St.Antonius Hospital. He was Chairman of the Cardiology Department from 2008-2014, Medical Manager of the Cardiology-Cardiac Surgery Unit from 2011-2016. He was the Chairman of the Netherlands Heart Rhythm Association from 2011-2015. In 2017, he was appointed as a special Professor of Innovative Trans-catheter treatment for Arrhyhmias at AMC Amsterdam.

Robert Bonow (JAMA Cardiology, USA)

Robert O. Bonow, MD, MS is the Goldberg Distinguished Professor of Cardiology at the Northwestern University Feinberg School of Medicine, where he is vice chairman of the Department of Medicine. He has authored or co-authored over 550 papers in the medical literature and 110 book chapters. He serves as Editor-in-Chief of JAMA Cardiology and is one of the four editors of Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine. Dr. Bonow is a 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 currently serves on the Board of Scientific Counselors of the NHLBI and has previously served on the Board of Trustees of the American College of Cardiology, the Board of Directors of the American Heart Association, the Subspecialty Board on Cardiovascular Disease of the American Board of Internal Medicine, and the Clinical Research Roundtable of the Institute of Medicine. Among his honors are the the Distinguished Leadership Award, Distinguished Achievement Award, Gold Heart Award, and James B. Herrick Award of the American Heart Association; the Distinguished Fellowship Award and Distinguished Service Award of the American College of Cardiology; the Denolin Award of the European Society of Cardiology; and the John Phillips Memorial Award of the American College of Physicians. 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, Surgery and Public Health at SUNY Downstate Medical Center. For many years he served as Chief of Cardiology and Chairman of Medicine at SUNY, and now directs two research institutes. Dr. Borer received a BA from Harvard, a M.D. from Cornell, trained at the Massachusetts General Hospital, spent 7 years at NHLBI and a year at Guy's Hospital (London) as Senior Fullbright Hays Scholar, completing the first clinical demonstration of nitroglycerin's utility in acute MI. Upon returning to the NIH, he developed stress radionuclide cineangiography, enabling non-invasive assessment of cardiac function with exercise and importantly changing the practice of cardiology. He returned to Cornell for 30 years as Gladys and Roland Harriman Professor and Chief, Division of Cardiovascular Pathophysiology. He has been Advisor to the USFDA for 40 years, was Advisor to NASA for 24 years, is Chairman of the Cardiovascular Devices Committee of the International Standardization Organization (ISO), was founding President, Heart Valve Society of America (2004-2014), has published more than 500 scientific papers and 8 books, has participated in numerous clinical trials, and is editor-in-chief of the journal, Cardiology.

Jackie Bosch (Hamilton, CAN)

Jackie Bosch has focussed her efforts on the conduct of large, multinational clinical trials in the areas of primary and secondary cardiovascular disease and diabetes prevention Dr. Bosch is interested in the design of clinical research and in improving the efficiency of conducting clinical trials, and has been involved in the Sensible Guidelines working group to improve key aspects or research implementation. She co-chaired the Canadian Initiative to Streamline Clinical Trials. She currently oversees the conduct of three large trials, including COMPASS, and numerous smaller projects.

Dr. Bosch's clinical interest is in the area of functional outcomes, and she has worked with colleagues to develop functional outcome measures that can be used in large, international trials. She leads the functional outcome data collection, along with cognitive and physical measures, in two large studies. She is also Co-investigator on two post-stroke intervention trials, one to improve mobility in those with impairments and the other to implement stroke units in low and middle income countries. She is a full time faculty member in the School of Rehabilitation Science as well as an Investigator at the Population Health Research Institute, both at McMaster University.

Robin Bostic (Abbott, USA)

Robin Bostic is Divisional Vice President of Global Health Economics and Reimbursement for Abbott. Robin worked in the insurance industry for eight years before moving into medical device reimbursement and government affairs. She has successfully worked with CMS and private payers to create national and regional coverage policies, coding and payment for new innovative technologies as well as managed global reimbursement, health economic and government affairs departments for medical device companies. Robin serves as the Industry Representative for the Inter agency registry for mechanical assist circulatory services (INTERMACS). Her involvement in reimbursement also includes obtaining positive technology assessments, establishing government and medical society technology guidelines and standards as well as payment. She has presented worldwide to numerous groups regarding health care economics, value propositions and adoption of reimbursement best practices as well as published on topics such as reimbursement, cost comparison, cost effectiveness and health economics. Robin has been recognized by MX Magazines as one of the top executives in the field of reimbursement and is on the speaker faculty for AdvaMed, Center of Business Intelligence, Q1 productions and the Institute for International Research where she has presented business, reimbursement and outcome strategies for medical devices.

Mike Boulware (Medtronic, USA)

Mike Boulware is currently serving as a Sr Clinical Research Manager in the Coronary and Structural Heart Division at Medtronic. He received his Doctorate of Philosophy in Pharmacology at the University of Minnesota researching intracellular calcium signaling and was the recipient of the Bacaner Research Award. He subsequently spent several years in industry designing pharmacokinetic trials before moving to Medtronic. During the course of his seven year tenure at Medtronic his primary focus has been the design and execution of clinical trials evaluating surgical and transcatheter aortic valves.

Eugene Braunwald (Boston, USA)

Eugene Braunwald, M.D. is the Distinguished Hersey Professor of Medicine at Harvard Medical School, and the founding Chair of the TIMI Study Group at the Brigham and Women's Hospital.

He served as Chief of Cardiology and as Clinical Director of the NHLBI. From 1972 to 1996 he was Chairman of the Department of Medicine at the Brigham and Women's Hospital. Dr. Braunwald has served as an editor of Harrison's Principles of Internal Medicine for 12 editions, and is the founding editor of Heart Disease, now in its 10th Edition, the most influential textbooks in their respective fields. Science Watch listed Dr. Braunwald as the most frequently cited author in Cardiology; he has an H index of 204. He has received the Distinguished Scientist and Lifetime Achievement Awards of the ACC, Research Achievement, and Herrick Awards of the AHA, and the Gold Medal of the ESC. He received the honorary Doctor of Science from the University of Oxford and honorary doctorates from twenty two other distinguished universities on three continents. The living Nobel Prize winners in medicine voted Dr. Braunwald as "the person who has contributed the most to cardiology in recent years".

Michael R. Bristow (Aurora, USA)

Michael R. Bristow, MD, PhD is Professor of Medicine (Cardiology) at the University of Colorado Anschutz Medical Campus, and Director of the Section of Pharmacogenomics in the University of Colorado Cardiovascular Institute Dr. Bristow has served as Chairman, National PI or on the Steering Committee of multiple heart failure multicenter clinical trials dating back to 1985, including MDC, BEST, U.S. Carvedilol, COMPANION and GENETIC-AF, and was the DSMB Chairman of TOPCAT. Dr. Bristow has authored more than 450 peer-reviewed papers and chapters on heart failure, cardiac transplantation, pharmacogenomics and other cardiovascular topics. He has received many academic and industry honors, including the Therapeutics Frontiers Award by the American college of Clinical Pharmacy (1993), the Pharmaceutical Research and Manufacturers of America Clinical Trial Exceptional Service Award (2008), the Lifetime Achievement Award by the Heart Failure Society of America (2008), Scientist of the Year by the ARCS Foundation (2008), University of Illinois Alumni Achievement Award, (2009) and the Distinguished Scientist Award (Translational Domain) by the American College of Cardiology (2014).

Javed Butler (New York, USA)

Javed Butler, MD, MPH, MBA, is Professor of Medicine, Professor of Physiology and Biophysics, Chief of Cardiology, and Co-Director of the Heart Institute, Stony Brook University, New York. Prior to joining Stony Brook, he was Professor of Medicine at Emory University, Atlanta, Georgia, and prior to that, the Director of the Cardiac and Heart-Lung Transplant Programs at Vanderbilt University, Nashville, Tennessee.
He received his medical degree at Aga Khan University, Karachi, Pakistan. He completed a residency at Yale University, and then completed

a cardiology fellowship and advanced heart failure and transplant fellowship at Vanderbilt University, and a cardiac imaging fellowship at Massachusetts General Hospital, Boston. He also received a Master of Public Health from Harvard University, Cambridge, Massachusetts, and a Master of Business Administration from Emory University.

Dr. Butler is board certified in cardiovascular medicine, as well as in advanced heart failure and transplant medicine. His research interests include the management and treatment of patients with heart failure. He serves on several American College of Cardiology/American Heart Association committees, on several National Institutes of Health study sections, and is a member of the Heart Failure Society of America Board of Directors. He is the recipient of the Simon Dack Award by the American College of Cardiology as well as the Time, Feeling, and Focus Award by the American Heart Association. Dr. Butler has authored more than 440 peer-reviewed publications. He serves on the editorial board of several peer reviewed cardiovascular journals. He has been cited numerous times in America's Best Doctors list.

Robert Califf (Durham, USA)

Robert M. Califf, MD, MACC, is Vice Chancellor for Health Data Science and Director of the Center for Integrated Health Data Science at Duke Health, Donald F. Fortin, MD Professor of Cardiology in the Duke University School of Medicine, and Chair of the Board of the People Centered Research Foundation. He served as Commissioner of Food and Drugs in 2016-2017 during the Obama administration. Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He was founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in the peer-reviewed literature. Dr. Califf is a member of the National Academy of Medicine (formerly the Institute of Medicine). He has led major initiatives aimed at improving methods and infrastructure for clinical research and served on many NIH advisory committees, including the Institutes of Aging, National Heart, Lung and Blood Institute, National Cancer Institute and National Library of Medicine.

Cynthia Chauhan (Wichita, USA)

Cynthia Chauhan has stage III heart failure with preserved ejection fraction which was diagnosed 3 1/2 years ago and multiple comorbidities including stage III kidney failure secondary to kidney cancer and nephrectomy. There are very few treatment options for heart failure patients with preserved ejection fraction and 50% of us die within the first five years from diagnosis so I enter every clinical trial for HFpEF for which I am eligible. The heart failure has turned my life into having to take twice as long to do things half as well but I remain an active, engaged, contributing member of society including working to increase awareness of HFpEF and bringing the patient perspective to the research table and to professional discussions.

Olivier Chételat (Neuchâtel, CHE)

Olivier Chételat is responsible of the medical technology development at CSEM (a private, non-profit Swiss research and technology organization). His team counts about 40 engineers who have for more than 15 years developed and transferred to the industry new technologies for wearables in the consumer and medical market segments. He is the inventor of cooperative sensors, a new way to measure biopotentials and bioimpedance particularly suited for powerful wearables, i.e., wearables introducing imaging thanks to a large number of electrodes as well as combining multi-signal sensing to get, from comfortable non-obtrusive devices, continuous measurements of multi-lead ECG, SpO2, core

body temperature, cuffless blood pressure, etc. His background is electronics and robotics (master and PhD degrees from the Swiss Institute of Technology EPFL in 1997). He joined CSEM in 2001 as project manager and later led the Signal processing & Control section and finally the Electronics section.

Nancy Cook Bruns (Bayer, GER)

Nancy Cook Bruns, MD, is Vice President and Chief Scientist at Bayer AG in Germany. She is the Global Clinical Leader on the COMPASS trial investigating Rivaroxaban with and without aspiring in patients with CAD and PAD collaborating with with Salim Yusuf at PHRI in Hamilton. Nancy is Canadian, and a graduate of Queen`s University Medical School, Kingston, Canada. She is a board-certified Cardiologist, from the Herzzentrum Bad Krozingen, in Germany. After 20 years of hospital medicine in Canada and Germany, she joined Hoffmann-La Roche in Basel in Switzerland in 1998. She joined Bayer in 2008 to be the clinical lead for Rivaroxaban on the ATLAS TIMI 51 trial for patients with ACS together with development partner Janssen and the TIMI Group in Boston. From 2012 to 2016, she was a group leader responsible for the clinical development programs in heart failure, diabetic nephropathy and renal anemia, with the compounds Finerenone, Vericiguat and Molidustat.

Anthony Costello (Medidata, USA)

Anthony Costello is Vice President of Mobile Health at Medidata. After beginning his clinical research career at Genentech 20 years ago, Anthony Costello has gone on to co-found several clinical trials technology start-up companies including Nextrials (acquired by PRA Health Sciences) and Mytrus (acquired by Medidata). Over his career, he has focused on disruptive and innovative technology that can simplify clinical trials for patients, sites and sponsors. He has been selected as one of the PharmaVoice Top 100 Most Inspiring People in Clinical Research, has served as Chairman of the Board for the Society for Clinical Data Management and is currently a member of the editorial advisory board for Applied Clinical Trials magazine. He is a frequent author and presenter on topics related to the efficient use of technology in clinical research and has a degree in Sociology from UC Berkeley.

Harry Crijns (Maastricht, NED)

Harry Crijns graduated in medicine at the University of Amsterdam in 1981. He completed his cardiology training at the University Medical Center Groningen, The Netherlands in 1987, where he continued working as clinical cardiologist and electrophysiologist. He obtained a PhD at the University of Groningen in 1993 on Changes of Intracardiac Conduction Induced by Anti-arrhythmic Drugs - Importance of Use and Reverse Use-dependence. He currently is Chair and professor of Cardiology, Maastricht University, board member of CARIM and chairman of the Scientific Board of the Netherlands Heart Foundation. His research focuses on epidemiology of atrial fibrillation as well as mechanisms of atrial fibrillation progression. His contributions to the field concern improved rate and rhythm control through the RACE-trials and EuroHeartSurvey - which he chaired - and stroke prevention through development of stroke and bleeding risk scores. Current interests are idiopathic AF, atherothrombotic mechanisms in AF progression, early rhythm control in high risk atrial fibrillation and hybrid AF ablation.

Nirav Dalal (Abbott, USA)

Nirav Dalal leads the Real-World Evidence and Digital Health function at Abbott medical devices. Nirav is interested in methods and tools to improve clinical outcomes and economics

using “Big Data” and machine learning. He has more than twenty years of experience in medical device industry. Prior to his current role, he has held technical leadership roles in R&D and Clinical organizations at St. Jude Medical and Abbott.
He received MS in Electrical Engineering from the California Polytechnic State University, San Luis Obispo and MBA from the Pepperdine University. He has published more than fifty peer-reviewed journal articles, conference abstracts and US patents.

Irene Dankwa-Mullan (IBM, USA)

Irene Dankwa-Mullan is the Deputy Chief Health Officer for IBM Watson Health, and the lead scientific officer for Data and Evidence. IBM Watson Health created a cloud-based data hub that brings together individual, clinical, research and social data from a variety of resources and that is powered by advanced cognitive and analytic technology. In her role, Dr. Dankwa-Mullan is responsible for the global strategy for driving and building a portfolio of studies to prove the clinical evidence for Watson Health cognitive solutions. This is accomplished through clinical studies, promoting research efforts in evidence, and enabling global democratization of data and evidence-based practices to transform healthcare. The efforts at Watson Health highlights an opportunity for advances in delivery of healthcare because of the way in which big data, cognitive computing and technology are working to transform societies and communities.

Dr. Dankwa-Mullan is a physician, researcher and public health leader with nearly two decades of experience in clinical research, public health, disparities and population health. She spent nearly a decade delivering and managing front-line primary care, preventive services, and community-based clinical research as both a primary care physician administrator and Medical Director. Prior to Watson Health, she served as Medical Officer and Deputy Director for Extramural Scientific Programs within the National Institute on Minority Health and Health Disparities at the National Institutes of Health (NIH).

Pieter de Graeff (EMA, NED)

Pieter de Graeff was born in 1950. Following medical training at the University of Groningen, he graduated in 1975. Following his military service, he fulfilled a yearlong internship in internal medicine in the U.S. in Youngstown, Ohio. In October 1977 he started his training as an intern at the department of Internal Medicine, University Hospital, Groningen. In January 1983 he was registered as an internist, practicing up till 2015. Subsequently, he became a clinical advisor for the Dutch Medicines Evaluation Board, keeping a position as associate professor at the depts. of Internal Medicine and Pharmacology/Clinical Pharmacology. In 1989 he finished his thesis, titled “Effects of captopril on the heart. Mechanisms and Therapeutic Potentials.” In 1994 he was co-registered as a clinical pharmacologist. In 1996 he became professor in pharmacotherapeutics. In 2003 he was elected as “teacher of the year”. He maintained a part-time position as senior clinical adviser of the Dutch MEB and as head of the cardiovascular subdivision until 2007. In 2013 he became a full member. In 2007 he became an alternate member of the CHMP and in 2013 a full member from which he retired in 2016. He has fulfilled a number of positions at various organisations, among which the cardiovascular Working Party of the EMA (since 1999), which he is currently chairing. He (co) authored more than 130 publications in peer-reviewed journals with a focus on cardiovascular pharmacology and regulatory science. He has been involved in writing a number of regulatory cardiovascular guidelines, including those on antihypertensive, lipid-lowering, heart failure and anti-arrhythmic agents.

Mehul Desai (Janssen, USA)

Mehul Desai M.D. is a physician scientist and currently a Senior Director within the Cardiovascular-Metabolism Therapeutic area within Janssen Pharmaceuticals. He is a board-certified internist and clinical pharmacologist with

prior drug development experience at US FDA. Mehul has been involved in the Canagliflozin Phase 3 development program since 2010 including the recently completed CANVAS program and the ongoing CREDENCE study.

Holli DeVon (Chicago, USA)

Holli DeVon is Professor and Head of the Biobehavioral Health Science department at the University of Illinois at Chicago, College of Nursing. Her research has focused on multiple aspects of the symptoms of acute coronary syndromes (ACS). Dr. DeVon's ACS symptom checklist has been used by investigators in Australia, Brazil, Iran, Lebanon, the Philippines, Taiwan, and the UK. She was principal investigator of the Think Symptoms study, an NINR funded multi-site study examining the influence of gender on symptom characteristics during ACS. Dr. DeVon received a Fulbright Scholar Award for 2017-2018 to conduct research in Rwanda. She has been honored with several research and writing awards including the Martha N. Hill New Investigator award from the American Heart Association Council on Cardiovascular Nursing, the Harriet Werley New Investigator award from the Midwest Nursing Research Society, and the 2014 best research paper award from the AHA Council on Cardiovascular Nursing. Dr. DeVon has published more than 60 articles in multidisciplinary journals and written commentaries in several journals including, JAMA Internal Medicine, the Canadian Journal of Cardiology, and The Lancet. She is a founding editorial board member for the Journal of the American Heart Association and is chair of the Council for the Advancement of Nursing Science.

Peter M. DiBattiste (Janssen, USA)

Peter M. DiBattiste, M.D., F.A.C.C., F.A.H.A., is the Global Development Head, Cardiovascular at Janssen Research and Development. In this role, he is responsible for establishing the strategy and overseeing the execution of the development programs for all cardiovascular products in development.

After decade in clinical practice as an interventional cardiologist, Pete entered the pharmaceutical industry in 1997. He joined Johnson & Johnson in 2005 as Vice President, Cardiology and assembled and led a clinical team of physicians and scientists who have focused on the development of the oral anticoagulant, rivaroxaban During Pete's tenure as Development Head, he led two of the largest clinical trials in the company's history – ATLAS and ROCKET AF – collectively enrolling more than 30,000 patients. Pete is focused on the continued development of Xarelto, and on the continued exploration and development of novel antithrombotics.

Pete obtained his MD at Harvard Medical School. He completed his internal medicine residency at the University of Texas Southwestern, and his fellowship in cardiovascular disease at the University of Pennsylvania.

Nancy Dreyer (IQVIA, USA)

Nancy Dreyer is global chief of scientific affairs for IQVIA Real-World Insights and is responsible for advanced evidence development for regulators, payers, clinicians, and patients. She leads research using minimally interventional and non-interventional study design that use primary and/or secondary data collection. She has worked with the FDA, most recently helping to plan a medical device evaluation network, and also has worked with the European Medicines Agency testing new methods for pharmacovigilance. She has also participated in the Cardiac Safety Research Consortium in Washington DC, speaking on the role of pragmatic randomized trials. She is a Fellow of both the International Society of Pharmacoepidemiology and the Drug Information Association, and is Adjunct Professor of Epidemiology at the UNC Gillings School of Global Public Health in North Carolina.

Marie-Pierre Dubé (Montreal, CAN)

Marie-Pierre Dubé leads clinical research projects in pharmacogenomics and precision medicine. She received three career awards from the FRQS (Fonds de recherche du Québec en Santé), the Champions in Genetics award from the Canadian Gene Cure Foundation and her research is funded by the Canadian Institutes of Health Research, Genome Quebec, and Genome Canada. She has authored over 140 articles in peer-reviewed journals and is co-author on 11 patents. She teaches and supervises graduate students in the Faculty of Medicine at Université de Montreal. She is director of the Beaulieu-Saucier Pharmacogenomics Centre at the Montreal Heart Institute, where she leads large genomic studies using data from clinical trials of cardiovascular and metabolic diseases. Her research includes the study of the efficacy and safety of lipid medication and medication for the treatment of heart failure. A discovery made by her group has led to the creation of the DalGenE trial, a Phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular risk in a genetically defined population.

Jay Edelberg (Sanofi, USA)

Jay Edelberg is an M.D., Ph.D graduate of Duke University in Durham, North Carolina.
He is a clinical cardiologist and vascular biologist trained at the Massachusetts General Hospital (Internal Medicine), the Beth Israel Deaconess Medical Center in Boston (Cardiovascular Medicine) and Massachusetts Institute of Technology (Biology). From 1999 to 2006, Dr. Edelberg served as an attending coronary care unit (CCU) cardiologist and directed the Cardiac Vascular Biology Research Laboratory at Weill-Cornell Medical Center, with a specific research focus on cardiac stems cells and biomarkers of cardiac aging.

Dr. Edelberg has directed cardiovascular biomarker research at Glaxo Smith Kline and Bristol-Myers Squibb (BMS). In addition, Dr. Edelberg was the US Medical Lead for Eliquis at BMS.
In 2012 he joined Sanofi as the Vice President and Head of the newly formed PCSK9 Development and Launch Unit. In collaboration with Regeneron Pharmaceuticals, he led the development of PraluentTM (Alirocumab) which was the first PCSK9 inhibitor approved by the FDA for the treatment of high LDL cholesterol.
Starting in 2016 Dr. Edelberg has headed Cardiovascular Development at Sanofi. He also serves the deputy head for the Sanofi North American Research & Development Hub as well as the head of Global Cardiovascular Medical Affairs

Justin Ezekowitz (Edmonton, CAN)

Justin Ezekowitz obtained his undergraduate Bachelor of Sciences (Honors Zoology) at the University of Alberta and medical training at the Royal College of Surgeons in Ireland, achieving an honors degree. He completed his internal medicine residency at the University of Texas Southwestern Medical Centre in Dallas, Texas. He then returned to Canada to do a heart failure fellowship and research training, completed a Masters of Science in Clinical Epidemiology at the University of Alberta Public Health Sciences and cardiology fellowship at the University of Alberta. He is currently on faculty as a Professor of Medicine in the Division of Cardiology and Co-Director of the Canadian VIGOUR Centre at the University of Alberta. He is a cardiologist and former Director of the Heart Function Clinic at the University of Alberta Hospital and Mazankowski Alberta Heart Institute.
His research and clinical focus is on heart failure. He is involved in numerous clinical trials in heart failure as a site investigator, and on the steering or executive committee for several multicenter international trials. He is also involved in the design leadership and implementation of several investigator-initiated trials funded through governmental and non-governmental research agencies.
Primary clinical research interests include heart failure with a preserved ejection fraction,

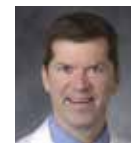
population health of heart failure, and novel processes of care or treatments for acute or chronic heart failure.
Dr. Ezekowitz is involved with the Canadian Cardiovascular Society (Chair of the Heart Failure Guidelines committee), the European Society of Cardiology (primary reviewer of the heart failure guidelines) and has been involved at various levels with the American College of Cardiology, the Heart Failure Society of America, the American Heart Association, the Heart and Stroke Foundation of Canada, and the Canadian Institutes of Health Research.

Joseph Emmerich (EMA, FRA)

Joseph Emmerich, MD, PhD, is Professor of Vascular Medicine at the University Hospital Hôtel-Dieu, Paris, France (University Paris Descartes). He is also working as technical advisor to the French medicine agency (ANSM) and is alternate member to the CHMP (Committee for Medicinal Products for Human Use) of the EMA (European Medicine Agency). He was the director of the INSERM Unit 765 from 2016 to 2012. His main research interests are in the epidemiology of venous thrombosis, genetic and acquired risk factors for venous and arterial thrombosis and rare vascular diseases. He is currently the head of the Vascular Medicine and Cardiology unit in Hôtel Dieu, Diagnostic and Therapeutic centre. He has published more than 250 publications, mainly in the field of cardiology and vascular medicine.

Andrew Farb (FDA, USA)

Andrew Farb, MD, is a medical officer and senior reviewer in the Division of Cardiovascular Devices at the FDA's Center for Devices and Radiological Health (CDRH). He is a graduate of Dartmouth College (BA) and of Cornell University Medical College (MD). He completed an internship and residency in internal medicine, a one-year residency in anatomic pathology, and a fellowship in clinical cardiology at The New York Hospital – Cornell Medical Center. Following a fellowship in cardiovascular pathology at The Armed Forces Institute of Pathology (AFIP), he served as a staff cardiovascular pathologist at AFIP with research interests in and publications on coronary atherosclerosis and mechanisms of thrombosis, coronary artery interventions, and structural heart disease. He joined the FDA in 2004, where he has concentrated on clinical study design and regulatory review of interventional cardiology, structural heart (including left atrial appendage occlusion devices), and peripheral vascular devices as well as providing guidance on pre-clinical animal testing. His most recent work at the Agency has focused on early feasibility and first-in-human studies. He co-authored the FDA's Guidance document entitled "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies," and he is the Clinical Consultant to CDRH's Early Feasibility Study Program. In addition to his position at the FDA, he provides cardiovascular pathology consultations and engages in direct patient care as an attending physician in clinical cardiology.



Michael Felker (Durham, USA)

G. Michael Felker, MD, MHS, FACC, FAHA is a Professor of Medicine with tenure in the Division of Cardiology at Duke University Medical Center. He is Chief of the Heart Failure Section at Duke University School of Medicine. He did his medical training at Duke University School of Medicine, his internal medicine training at Johns Hopkins Hospital where he was chief resident, and his cardiology training at Duke. Dr. Felker has published over 190 peer reviewed articles and book chapters in the field of heart failure. He has served on the Executive and Steering Committees for multiple national and international clinical trials in heart failure. He directs the Advanced Heart Failure Fellowship Training Program at the Duke University School of Medicine. Dr Felker is an editorial board member or peer reviewer for multiple high impact medical

journals, including the New England Journal of Medicine, JAMA, Lancet, Circulation, and JACC. He is the Associate Editor of JACC: Heart Failure and co-editor of Heart Failure: A Companion to Braunwald's Heart Disease, the leading heart failure textbook. His research focus in on clinical trials in acute and chronic heart failure and the use of biomarkers as diagnostics, prognostic, and therapeutic tools in heart failure.

Mona Fiuzat (Durham, USA)

Mona Fiuzat is an Associate Professor of Medicine at Duke University, Scientific Advisor at the FDA, and Executive Editor of JACC: Heart Failure, and Former Senior Scientific Advisor to the FDA Commissioner. She received her PharmD at Mercer University School of Pharmacy in Atlanta, Georgia, and has worked in clinical trials for 20 years. Dr. Fiuzat worked in the pharmaceutical industry for Solvay Pharmaceuticals and SmithKline Beecham Pharmaceuticals, and was Director of Clinical Development at ARCA biopharma, Inc. Her clinical research experience has been in cardiovascular trials with a focus on pharmacogenetics in heart failure, and she helped file an NDA for the first proposed pharmacogenetically targeted heart failure drug. She worked as a Clinical Pharmacist at the West Los Angeles and San Francisco Veterans Affairs Medical Center, and as an Adjunct Assistant Professor at the University of Southern California, University of California, San Francisco, University of Colorado, and University of North Carolina. She worked in the Heart Failure Research Program at Duke on a number of key clinical trials as an investigator and steering committee member, and has authored or co-authored over 100 papers in the field of heart failure. She holds national leadership roles with the American College of Cardiology, and as Program Co-Chair for the Heart Failure Society of America's (HFSA) Scientific Sessions, as well as Membership Co-Chair, and is now on the HFSA Board of Directors, HFSA Task Force for Research Networks and FDA liaison to the HFSA. Most recently, she developed and facilitated the "Heart Failure Collaboratory", a joint effort of government agencies, academicians, stakeholders, patients, societies and advocacy groups to impact heart failure research and therapeutic development.

Thierry Folliguet (Nancy, FRA)

Thierry Folliguet graduated from Paris university in 1983 and received his doctor of Medicine in 1984. He then underwent a general surgery training at St Vincents hospital in New York from 1984 to 1989, then in cardiothoracic surgery in SUNY health in Brooklyn from 1989 to 1992. Successfully passed the American Board of Surgey and American Board of CardioThoracic Surgery, and became Fellow of the American College of Surgery in 1996. After completion of his US training he did a two year fellowship in Marie Lannelongue in adult and pediatric surgery. Became staff surgeon at Institut Mutualiste Montsouris in 1994, he started a mini invasive program with robotic in 2004 for CABG and mitral valve repair.

He then became full Professor of CardioThoracic surgery in 2012 and head of the department of cardiovascular and transplantation of the University of Lorraine in Nancy. His main interest is in the field of minimally invasive valvular cardiac surgery. He the author or coauthor of more than 200 publications.

Pr Folliguet is currently the chairman of the Cardiovascular group of the nucleus of the European Society of Cardiology, and the vice President of the European Society of Endovascular Surgery.

Darrel Francis (London, GBR)

Darrel Francis is a Professor of Cardiology at Imperial College London. His motivation in research is to develop and apply reliable (reproducible) clinical measurements and address questions important to patient care using

bias-resistant methods. As an Interventional Cardiologist, always careful to tell stable angina patients that their PCI would not prevent heart attacks but would reduce their angina, he set up ORBITA with his colleague Rasha Al-Lamee to simply provide bias-resistant evidence for angina reduction from PCI. They thought it would be a slam-dunk win for PCI – but it wasn't. It was a difficult study, but not for the reasons they expected. In his talk, he will explain the surprising challenges and encourage discussion of whether placebo-controlled trials of procedural interventions are necessary or even ethical.

Pierre-Yves Frouin (Bioserenity, FRA)

Pierre Frouin has a Masters in IT Engineering and an MBA from INSEAD. Pierre did his whole career in the Medical Industry. A third in Asia, a third in Europe and a third in North America. With experience in the pharmaceutical industry and medical device business, Pierre founded BioSerenity in 2014, a company that has received many awards for its medical innovation. In 2017, BioSerenity employs over 80 people, has a revenue of over 5 million dollars and recently raised 17 million dollars to support its growth. The company develops continuous recording solutions for clinical trials and diagnostics that include a hardware wearable part and a digital biomarker identification solution.

Alan Fraser (Cardiff, GBR)

Alan Fraser is Consultant Cardiologist at the University Hospital of Wales, Cardiff, UK; Visiting Professor in Cardiovascular Imaging and Dynamics at the University of Leuven; and Emeritus Professor of Cardiology at the Wales Heart Research Institute, Cardiff University. He qualified in Edinburgh, undertook postgraduate training in Scotland and Wales, and was research fellow at the Thoraxcentre in Rotterdam. He is a Past-President of the European Association of Echocardiography, and he chairs the Committee on Regulatory Affairs of the European Society of Cardiology. His research interests include cardiac imaging, heart valve disease, heart muscle disease, and the pathophysiology and diagnosis of heart failure.

Wendy Gattis-Stough (Expert Medical Communication, USA)

Wendy Gattis Stough, PharmD, is Adjunct Professor of Clinical Research and Pharmacy Practice at Campbell University College of Pharmacy and Health Sciences and Owner of Expert Medical Communications and Consulting, LLC, in Cary, North Carolina. Dr. Stough received her doctor of pharmacy degree magna cum laude from Campbell University School of Pharmacy and completed residency and fellowship training at Duke University Medical Center. She spent 10 years in full-time academics at Duke University Medical Center, where she conducted research establishing the role of the pharmacist as a valued member of the heart failure management team and maintained a clinical role on the heart failure service. She also served as a principal investigator, co-principal investigator, and project leader for numerous multicenter Phase II-IV clinical trials at the Duke Clinical Research Institute. In 2005, Dr. Stough established Expert Medical Communications and Consulting, LLC. Dr. Stough has worked with leading professional cardiology organizations including Cardiovascular Clinical Trialists (CVCT), Investigation Network Initiative-Cardiovascular and Renal Clinical Trialists (INI-CRCT), European Society of Cardiology (ESC), Heart Failure Association (HFA) of the ESC, Heart Failure Society of America (HFSA), and the American College of Cardiology (ACC). Dr. Stough has authored or co-authored over 140 papers in peer reviewed medical journals including JAMA, European Heart Journal, Journal of the American College of Cardiology, Circulation, European Journal of Heart Failure, Archives of Internal Medicine, American Journal of Cardiology, among others.

Patrick Gee (Chesterfield, USA)

Patrick Gee had been a peritoneal dialysis patient since December 2013. On April 21, 2017, Patrick

received a kidney transplant at the Hume-Lee Transplant Center at the Medical College of Virginia/Virginia Commonwealth University. After spending 33 days in the hospital, 4 surgeries and a 47 days wait until his kidney began to function, Patrick is back to being active again in the fight against CKD. Since suffering from End Stage Renal Disease, Patrick has become a Health Care Advocate, fighting for a better health care system and better quality of life for those suffering from chronic illness.

Patrick currently serves as Chair for the Quality Insights Network 5 Patient Advisory Committee, Subject Matter Expert for Quality Insights Network 5, Subject Matter Expert for Quality Insights Medical Review Board, Regional Liaison, Center for Patient Engagement and Advocacy, American Association of Kidney Patients, Subject Matter Expert for Kidney Community Emergency Response (KCER) Training Group, Subject Matter Expert for National KCER Patient and Family Engagement Learning and Action Network (N-KPFE-LAN), Subject Matter Expert for The National Kidney Foundation's (NKF) Kidney Advocacy Committee (KAC) and a certified trainer for NKF's You and Your Kidneys, University of Michigan Kidney Epidemiology and Cost Center ESRD PRO Technical Expert Panel member, the APOL1 Study in Kidney Transplantation Consortium Clinical Center through the Cleveland Clinic and an United Network for Organ Sharing Ambassador.

Patrick graduated from the M3 Church School of Ministry in November 2016. Patrick is currently serving in the position of Minister-In-Training and hopes that as part of his ministry, he would visit his peers on in-center hemodialysis, to offer encouragement and support. Patrick also has a Bachelor's and Master's of Science in Criminal Justice from the University of Richmond, Richmond, VA and a Doctor of Philosophy in Justice, Law and Criminology from American University, Washington, DC. Patrick's Advocacy goal is to be a face for the faceless and a voice for the voiceless in regards to fighting for a better quality of life, fair and effective legislation for those suffering from a chronic illness and a cure for all illnesses that lead to kidney disease.

Nancy Geller (NHLBI, USA)

Nancy L. Geller has been the Director of the Office of Biostatistics Research at the National Heart, Lung and Blood Institute of the National Institutes of Health since 1990. She directs a group of 11 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, the ongoing Tailored Antiplatelet Initiation to Lessen Outcomes Due to Decreased Clopidogrel Response after PCI (TAILOR-PCI) and trials of the Cardiovascular Surgery Network. She has published over 200 papers in the statistical and medical literature. She is an Associate Editor of Biometrics and a Fellow of the International Statistics Institute, the American Statistical Association and the Society for Clinical Trials. She was the winner of the 2009 Janet L. Norwood Award for outstanding achievement by a woman in the statistical sciences and was 2011 President of the American Statistical Association.

Jyothis George (Boehringer Ingelheim, GER)

Jyothis George MD PhD is Global Head of Diabetes Clinical Development, Boehringer Ingelheim and Associate Clinical Professor at the University of Warwick, UK.

Leadership roles in CV Outcome Trials include: EMPA-REG-OUTCOME trial (leading to first CV indication for a glucose-lowering drug), CAROLINA (Lina vs. active-comparator), CARMELINA (in a renally enriched type 2 diabetes population) and EMPEROR-Reduced, EMPEROR-Preserved (Empagliflozin trials in

heart failure with reduced and preserved ejection fractions, respectively) and the Empagliflozin outcome trial in CKD.

Fully accredited in Internal medicine with fellowships from the Royal College of Physicians and the American College of Endocrinology, Jyothis served previously as Chief Investigator and member of OCDEM management board at the University of Oxford - an unparalleled opportunity to learn from legendary outcome triallists in diabetes (Holman, Oxford) and cardiovascular disease (Califf, Duke).

Barbara Gillespie (Covance, USA)

Barbara S. Gillespie, MD, MMS, FASN, is a board-certified nephrologist, and Vice President at Covance global CRO where she is the Therapeutic Head of Nephrology. She is an Adjunct Professor at the University of North Carolina, Division of Nephrology and Hypertension, and was recently named to the Board of Directors for the Kidney Health Initiative (KHI). At KHI, she serves on Workgroups for Challenges for CKD patient involvement and EPs in CV trials, and Surrogate EPs for IgA Nephropathy.

Prior to Covance, she was a Global Nephrology Lead at Quintiles for 11 years, and served in positions reporting directly to the CMSO, and heading the NA Internal Medicine Medical Team. She participates in several Advisory Boards and Stakeholder Panels including the FDA/EMA/NKF Workshop on Renal Endpoints, NKF CKD Registry, UNC's PCORI grant on ESRD Symptoms, and the global Standardized Outcomes for Nephrology (SONG) Initiative. She has also served on an Independent Endpoint Adjudication Committee for a global CKD and CV Outcomes program.

Dr. Gillespie completed her fellowship in nephrology at Duke University Medical Center, and residency in internal medicine at the University of North Carolina (UNC) at Chapel Hill, NC.

Claudio Gimpelewicz (Novartis, CHE)

Claudio Gimpelewicz is Sr Global Program Clinical Head at the CV Franchise in the Novartis Pharma Clinical Development Department.
He received his MD diploma at Buenos Aires University, Argentina (1985) and completed his cardiology residence at the Cardiology Department of the Argerich Hospital in Buenos Aires where he also served as instructor of residents (1985-991). He is a certified cardiologist (Argentine Society of Cardiology) and completed a postgraduate course in marketing at San Andres University Buenos Aires (Argentina).
Prior to joining Novartis, he took different positions in the Medical Department in Pfizer Argentina and Pfizer LATAM (1995-2001) where he led several medical initiatives. He joined Novartis Global in Basel Switzerland in 2002 where he assumed positions of increasing responsibility in the CVM franchise, including the completion of outcomes trials (LIPS, ALERT) and submission activities (Lescol indications extension and Vildagliptin-metformin combination) .
Since 2008 he has been responsible of several outcome studies in HF (aliskiren program ATMOSPHERE and ASTRONAUT).From 2013-2017 he has lead the design, execution and reporting of the RLX AHF 2 trial.

Nicolas Girerd (Nancy, FRA)

Nicolas Girerd, MD, PhD, associate professor of Therapeutics, is a cardiologist and biostatistician currently working at the Nancy Plurithematic Clinical Investigation Center (CIC)-Inserm, France.
He completed is Cardiology training in Lyon, France, and completed his Masters degree in Clinical Epidemiology in Québec, Canada. He obtained a PhD in Biostatistics focused on treatment effect evaluation in survival models in Lyon, France.He has participated / is currently participating in several EU FP6-7 programs (MEDIA: Coord.: W. Paulus; HOMAGE & FIBROTARGETS: Coord.: F. Zannad,

Nancy CIC). He is also contributing to the University Hospital "French Government Investment for the Future" Fighting Heart Failure program (2016-2020). He is currently the PI of the REMI (Relationship Between Aldosterone and Cardiac Remodeling After Myocardial Infarction - NCT01109225) and the AHF-CORE (Acute Heart Failure - COngestion Repeated Evaluation - NCT03327532) studies. He is also the methodologist/biostatistician of several randomized clinical trials in the field of heart failure and/or MRA therapy (Effects of Induced Moderate HYPOthermia on Mortality in Cardiogenic Shock Patients Rescued by Veno-arterial ECMO (HYPO-ECMO) NCT02754193; Eplerenone in Patients Undergoing REnal Transplant (EPURE TRANSPLANT) NCT02490904).
His current research interests are mainly focused on the quantification and treatment of congestion in acute and chronic heart failure. He is the author of over 130 publications in international journals.

Robert Golub (JAMA Cardiology, USA)

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

Ida Grundberg (Olink, USA)

Ida Grundberg received her PhD at Uppsala University from the prestigious research group which developed Olink's key technology and founded Olink. She continued as senior scientist at Olink for commercialization of the patented technology developed during her PhD. Following the market release of Olink´s multiplex product, Dr. Grundberg joined the commercial side and in 2015 she transferred to head the U.S. market entry for her scientific understanding of Olink's products, coupled with commercial experience.

Adrian Hernandez (Durham, USA)

Adrian Hernandez is a cardiologist with extensive experience in clinical research ranging from clinical trials to outcomes and health services research. He is the Vice Dean for Clinical Research at the Duke University School of Medicine. He is the Coordinating Center Principal Investigator for multiple networks and clinical trials such as the NHLBI's Heart Failure Research Network, PCORI's National Patient-Centered Clinical Research Network (PCORnet) and NIH's Health System Collaboratory. Dr. Hernandez has over 400 published articles in high-tier journals including the New England Journal of Medicine, Journal of the American Medical Association, and Lancet.

Charles Herzog (Minneapolis, USA)

Charles Herzog is professor of medicine, University of Minnesota, and cardiologist at Hennepin County Medical Center (HCMC) for 33 years. He founded the program in interventional cardiology at HCMC and served as cardiac catheterization

laboratory director from 1985-1991, and cardiac ultrasound laboratory director from 1997-2012. He was director of the United States Renal Data System (USRDS) Cardiovascular Special Studies Center from 1999-2014. He participated in the development of the National Kidney Foundation's K/DOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients, KDIGO Clinical Practice Guidelines on Acute Kidney Injury, and the KDIGO 2017 Clinical Practice Guidelines Update for CKD-Mineral and Bone Disorder. He co-chaired the 2010 KDIGO Controversies Conference, "Cardiovascular Disease in CKD: What is it and What Can We Do About It?" and is co-chair of the KDIGO Kidney, Heart, and Vascular Conference Series. He was an Executive Committee member of the EVOLVE Trial. He chairs the Renal Committee of the ISCHEMIA-CKD Trial and was Co-PI of the WED-HED (Wearable Cardioverter Defibrillator in Hemodialysis Patients) Study. He currently co-chairs the workgroup, "Understanding and Overcoming the Exclusion of Patients with Kidney Disease from Cardiovascular Trials", for the Kidney Health Initiative (KHI). He has over 225 published papers. He has served on the Editorial Boards of the American Heart Journal, the Journal of Nephrology, Clinical Journal of the American Society of Nephrology, and liaison editor for Nephrology, Dialysis and Transplantation. His special interests include cardiac disease and CKD, and echocardiography.

Karen Hicks (FDA, USA)

Karen A. Hicks, M.D. is a senior medical officer in the Division of Cardiovascular and Renal Products at the Food and Drug Administration (Center for Drug Evaluation and Research). Dr. Hicks received her undergraduate degree from Duke University and MD degree from the Georgetown School of Medicine. She completed her internship and residency in Internal Medicine and fellowship in Cardiovascular Disease at Walter Reed Army Medical Center. She completed her Interventional Cardiology training at The Johns Hopkins Hospital and subsequently was Director of the Cardiac Catheterization Laboratory at Madigan Army Medical Center. After completing her military commitment, she was in private practice in the Washington, D.C. area and joined the FDA in December 2003. She remains clinically active at Walter Reed National Military Medical Center. She leads two large multi-stakeholder Initiatives to Standardize Data Collection for Cardiovascular Trials. In addition to chairing the Writing Committee for the 2014 American College of Cardiology (ACC)/American Heart Association (AHA) Key Data Elements and Definitions for Cardiovascular Endpoint Events in Clinical Trials, Dr. Hicks has participated in other ACC/AHA writing committees. Her interests include interventional cardiology, definition and harmonization of cardiovascular endpoints, clinical trial design, cardiovascular outcome trials, and cardiovascular risk factor modification.

Ziad Hijazi (Uppsala, SWE)

Ziad Hijazi is a faculty researcher at Uppsala Clinical Research Center (UCR) at Uppsala University and a senior consultant in cardiology and head of the cardiovascular outpatient services at Uppsala University Hospital, Sweden. The research of Dr. Hijazi focuses on biomarkers, risk stratification, and antithrombotic treatment in atrial fibrillation. His formal research training includes a Ph.D. in medical sciences with emphasis on cardiovascular biomarkers in atrial fibrillation. He has participated in clinical events committees for many central large-scale multi-national clinical trials and several subcommittees for biomarkers in clinical trials on new treatment interventions.

Joseph A. Hill (Circulation, USA)

Joseph Hill is a cardiologist-scientist whose research focuses on molecular mechanisms of remodeling in the stressed oral scientific training at the Institut Pasteur in Paris, followed by clinical training in Internal Medicine and Cardiology at

the Brigham and Women's Hospital, Harvard Medical School. Dr Hill served on the faculty of the University of Iowa for five years before moving in 2002 to the University of Texas Southwestern Medical Center to assume the role of Chief of Cardiology and Director of the Harry S. Moss Heart Center. Dr Hill's research group strives to decipher mechanisms of structural, functional, and electrical remodeling in heart disease with an eye toward therapeutic intervention. Dr Hill serves on numerous committees, boards, and study sections, and he lectures widely. In addition, he serves on several editorial boards, including Circulation, Circulation Research, Journal of Biological Chemistry, and American Journal of Cardiology. He serves as editor-in-chief of a recently published textbook entitled Muscle: Fundamental Biology and Mechanisms of Disease. He has received numerous recognitions and awards, including election to the Association of American Professors. He recently served as President of the Association of University Cardiologists and chair of the Academic Council of the American College of Cardiology. Presently, he serves as Editor-in-Chief of Circulation. Dr Hill maintains an active clinical practice focusing on general cardiology, hypertension, and heart failure.

Jakub Hlávka (Rand Corporation, USA)

Jakub P. Hlávka, MA MPhil is a health policy researcher at the RAND Corporation, a doctoral fellow at the Pardee RAND Graduate School, and a visiting fellow in health economics at the USC Schaeffer Center for Health Policy & Economics. His research addresses biotechnology, health care financing and R&D investment by the public and private sector, with a focus on innovative payment models for high-cost medical treatments in cardiology, neurology and oncology. He is currently investigating outcome-based, deferred payment and time-varying payment approaches for regenerative treatments and specialty drugs, including PCSK9 inhibitors. He has completed fellowships and internships at Genentech, the Fraunhofer Society and the Hoover Institution at Stanford. Jakub holds a graduate degree from Georgetown University Edmund A. Walsh School of Foreign Service and an undergraduate degree from the University of Economics in Prague.

Narimon Honarpour (Amgen, USA)

Narimon Honarpour MD, PhD obtained his MD and PhD from the University of Texas Southwestern Medical Center at Dallas and completed clinical training at UCLA for both Internal Medicine and Cardiovascular Disease. In transitioning from a career path in academic cardiology to industry, Narimon was involved in the design and execution of several late phase Repatha clinical studies at Amgen, including FOURIER. He currently is an Executive Medical Director and Global Product Areal Lead for heart failure at Amgen Inc, where he helps oversee late phase clinical activities in Amgen's heart failure franchise.

Larry Husten (CardioBrief, USA)

Larry Husten is a veteran medical journalist who writes the CardioBrief blog, which appears on CardioBrief.Org and MedPage Today. Prior to starting CardioBrief early in 2009 he was the editor of TheHeart.Org, from its inception in 1999 until December 2008. Following the purchase of TheHeart.Org by WebMD in 2005 he also served as the editorial director of WebMD professional news, encompassing TheHeart.Org and Medscape Medical News. From January 2010 until June 2015 he was a consulting editor and news director at CardioExchange, an online cardiology community published by the New England Journal of Medicine.

Before helping to start TheHeart.Org he was a freelance medical journalist who wrote for the Lancet, the New York Times, Discover, and many other medical and computer publications. In 1994-1995 he was a Knight Science Journalism Fellow at MIT. He has a PHD in English from the State University of New York at Buffalo and drove a taxicab in New York City before falling into a career in medical journalism.

Jula Inrig (IQVIA, USA)

Jula Inrig is a Senior Medical Director and Global Medical Strategic Lead in Nephrology at Iqvia. Dr. Inrig is Board certified in Nephrology and Internal Medicine from Duke University. Prior to joining Iqvia, she had a 10 year tenure as an academic clinical scientist with 50+ publications in peer-reviewed literature and PI and consultant for numerous clinical trials. She is an Adjunct Associate in Medicine at Duke University/DCRI where she previously worked on and designed nephrology and cardiovascular outcomes trials. She also is an Associate Professor of Medicine at UC Irvine where she teaches and manages dialysis patients part-time. Dr. Inrig is an Inaugural member of the Board of Directors for the Kidney Health Initiative, a member on the KDOQI work group for Dialysis Adequacy Guidelines, Chair of American Heart Association Kidney Council in Cardiovascular Disease, and serves on editorial boards for National Kidney Foundation and Kidney International.

As the Head of the Renal Center of Excellence, Dr. Inrig oversees the entire portfolio of Nephrology trials at IQVIA and provides scientific and strategic insight and ongoing consultation to both internal and external teams through the lifecycle of the trials. In her role, Dr. Inrig provides a full range of pre- and post-marketing nephrology strategic support such as formulation of clinical development plans, planning and designing trials, clinical endpoint committees, executive steering committees, global regulatory submissions, FDA// EMA/PMDA meetings, DSMB/CEC planning and oversight, protocol writing, global medical oversight, feasibility and global country selection, steering committee/advisory boards, publications, market analysis, and commercialization scenarios.

Julie Ishida (San Francisco, USA)

Julie Ishida, MD, MAS is an Assistant Professor of Nephrology at the University of California, San Francisco (UCSF). Dr. Ishida is a graduate of UC Berkeley (BA), Stanford University (MD), and UCSF (Master of Advanced Study in Clinical Research). She completed her internal medicine residency and nephrology fellowship at UCSF. She has performed research and provided consultation on drug development programs for Genentech/Roche.

Dr. Ishida's research focuses on improving the quality of medication prescribing for patients with kidney disease, and her long-term goal is to develop and implement strategies to promote appropriate medication use in this population. Her interests include the persistent underrepresentation of patients with kidney disease in cardiovascular trials. She has authored an invited commentary for JAMA Internal Medicine on this topic and is co-chair of a Kidney Health Initiative project aimed at understanding and overcoming the challenges to involving patients with kidney disease in cardiovascular trials.

Stefan James (Uppsala, SWE)

Stefan James is Professor of Cardiology at Uppsala University and Scientific Director of Uppsala Clinical Research Center. He is a Senior Interventional Cardiologist at Uppsala University Hospital Sweden. He graduated from Uppsala University Medical School and completed specialist training in Uppsala. He has previously held positions at the Karolinska Hospital and Duke Clinical Research Institute, Duke University. A Fellow of the European Society of Cardiology (ESC), Professor James co-chaired the previous and current 2017 ESC guidelines for ST-elevation myocardial infarction, co-author of several of the recent European guidelines on ACS and revascularization. He is the also Society's official representative for the European Commission for Evaluation of Medical Devices.

Stefan James has served as PI on steering committees for numerous international trials in cardiology including PLATO, Early-ACS trial, EVOLUTION, APPRAISE II, GUSTO IV-ACS, GEMINI and THEMIS. He has served as the chairman of the Swedish Coronary and Angioplasty registry and a member of the steering committee of SWEDEHEART. He has pioneered the concept of registry based randomized clinical trials and served as the study chair for large outcome trials TASTE and VALIDATE.

John Jarcho (NEJM, USA)

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

David Kallend (The Medicine Company, USA)

David Kallend graduated from Kings College Hospital School of Medicine in London and worked in various hospital departments in the United Kingdom, predominantly at the Royal Postgraduate Medical School Hammersmith Hospital, London, where his final post was Research Fellow in the Department of Surgery. In 1995 he joined the pharmaceutical industry, where he initially worked as an International Clinical Research Physician on imaging studies for Schering AG in Berlin, predominantly in the area of magnetic resonance contrast media. Over the last 22 years, David has held leadership roles at AstraZeneca and Roche, and has been involved with clinical studies and regulatory approvals in the cardiovascular and metabolism area, including that of rosuvastatin and dalcetrapib. In his current role, based in Switzerland, David is Senior Vice President and Global Medical Director focusing on inclisiran, the PCSK9si, at The Medicines Company.

Pieter Kappetein (Rotterdam, NED)

Pieter Kappetein, MD, PhD, is a Consultant Cardiothoracic Surgeon, is Professor at the Thoraxcenter at the Erasmus Medical Center in Rotterdam, The Netherlands. He is board certified in Cardiothoracic Surgery. Before he joined Medtronic as Chief Medical Officer, Vice-President, he was Secretary General of the European Association for Cardio-thoracic Surgery for 9 years, President of CTSnet and member of the Board of the Society of Thoracic Surgeons and chairman of the International Cooperation committee of the STS in the USA.

Besides this he was member of the Editorial Board of the Annals of Thoracic Surgery and Eurointervention.

His clinical interests include aortic valve surgery, indications, outcome; percutaneous aortic and mitral valve replacement and repair, coronary surgery, and new techniques in the field, education, and epidemiology. He is co-principal investigator of the SYNTAX and EXCEL trial (comparing coronary surgery with drug eluting stents) and member of the steering committee of the REPRISE III and SURTAVI trial on percutaneous valves and the RESHAPE trial: the evaluation of the Mitraclip in patients with heart failure. He was also member of the steering committee of the Re-align trial on Dabigatran in patients with mechanical heart valves.

His current research efforts are focused on the evaluation of new surgical techniques and the comparison of new techniques in cardiothoracic surgery with new techniques in interventional cardiology. He is project leader of the 'One valve for life" research program, a study together with the Technical University in Eindhoven and the University Hospital in Utrecht developing a tissue engineered heart valve.

Helina Kassahun (Amgen, USA)

Helina Kassahun is a Clinical Research Medical Director within the Cardiovascular and Metabolic Therapeutic Area at Amgen. She joined the team in 2014 as a Senior Medical Scientist on the Repatha program, supporting the GLAGOV (Global Assessment of Plaque Regression with PCSK9 Antibody as measured by Intravascular Ultrasound) study and leading other clinical trials. Currently, she is the clinical development lead for a new molecule in the early phase of development.

Helina earned her medical degree from Harvard Medical School and completed her internal medicine internship and residency at Johns Hopkins. She completed a fellowship in cardiovascular medicine at Weil Medical College, New York Presbyterian Hospital in New York City. Prior to joining Amgen, Helina was Assistant Professor of Medicine at the University of Minnesota and developed its PET imaging program in addition to her contribution of launching a cardiovascular CT program.

Allen Kindman (IQVIA, USA)

Allen Kindman MD, FACC is currently Vice President of Clinical Planning and Analytics at IQVIA. Before joining IQVIA in 2013, he was a Clinical Professor of Medicine at the University of North Carolina, where he focused on Clinical and Interventional Cardiology. His group's responsibilities include finding the best countries and sites for clinical trials covering all therapy areas. The group employs analytics to mine vast data sets incorporating information from around the world, as well as more traditional approaches. His interests include the development of enhanced automated analytics to facilitate precision site selection and enrollment.

Paulus Kirchhof (Birmingham, GBR)

Paulus Kirchhof is Deputy Director of the Institute of Cardiovascular Sciences and Professor of Cardiovascular Medicine at the College of Medical and Dental Sciences, University of Birmingham, UK.

His appointment includes a position as consultant cardiologist at SWBH NHS and UHB NHS trusts. He has worked on several guidelines of the European Society of Cardiology including as chair of the 2016 ESC guidelines for atrial fibrillation.

Professor Kirchhof chairs the board of the Atrial Fibrillation NETwork (AFNET), is a member of the Board of the European Heart Rhythm Association, and sits on the board of the European Society of Cardiology.

Professor Kirchhof researches mechanisms and management of cardiovascular diseases with a special interest in atrial fibrillation and cardiomyopathies.

He also has a long-standing experience in the planning and conduct of international multi-centre investigator-initiated trials, including work as Chief Investigator, steering committee member, and data monitoring committee member.

His research is funded by British Heart Foundation, Leducq Foundation, European Union, and others.

Working closely with international collaborators, his research group uses genetically modified models, controlled clinical trials and trial data bases, imaging data and biosamples from trial participants, and observational cohorts in a translational team approach to science and health care. He uses these resources to improve the management of patients with atrial fibrillation and cardiomyopathies, to develop personalized therapies for AF patients, and to improve cardiovascular health in general.

Professor Kirchhof runs a large atrial fibrillation service based at SWBH NHS trust and coordinates the interdisciplinary Inherited Cardiac Conditions Clinic at UHB NHS trust.

Wolfgang Koenig (Munich, GER)

Wolfgang Koenig is a Professor of Medicine/ Cardiology at the University of Ulm Medical School, Germany. He is a board-certified internist and interventional cardiologist specialised in intensive care medicine and has extensive experience in the molecular epidemiology of cardiovascular diseases. A former Director of the WHO-MONICA Augsburg Myocardial Infarction Register, Professor Koenig has held multiple clinical positions at the University of Ulm Medical Center. In April 2015 he joined the Deutsches Herzzentrum München, Technische Universität München and became an established investigator of the Munich Heart Alliance within the German Centre for Cardiovascular Research (DZHK) and is the Head of the Cardiometabolic Unit. Professor Koenig also serves on the steering committee of multiple large, international randomised clinical trials testing innovative targets in cardiovascular medicine. His research investigates the molecular basis of atherothrombogenesis including the interrelationship between hemostasis, inflammation, and atherothrombotic complications. He also has a particular interest in 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. Between 2008 and 2012, he ranked sixth in the most frequently cited German speaking researchers in cardiovascular disease and has an H-Index of 89. In 2014 he received the Rudolf Schönheimer Award from the German Atherosclerosis Society.

Annemieke Lenselink (The Hague, NED)

Annemieke Lenselink's life changed dramatically in 2012 when she got a CVA at 47, now 5 years ago. Before that she had a successful career in HR in international companies, like Interpay, Nokia, Centocor (JNJ) and NIBC. She just started my own company and as a mom of two beautiful girls she had to keep on going. She had to rethink her goals in her life and decided to make the best out of a bad situation (thanks to her husband and the wonderful team of doctors and therapists at the hospital and rehab centre) and decided to help science with her experiences as a CVA patient. She has participated in many clinical trials and is still doing that. Her experience in biotech helps in reviewing research proposals. It is satisfying to know that her illness is not in vain and that she can help others with their research and hopefully in finding better treatment of illnesses.

Peter Libby (Boston, USA)

Peter Libby, MD, is a cardiovascular specialist at Brigham and Women's Hospital in Boston, Massachusetts, and holds the Mallinckrodt Professorship of Medicine at Harvard Medical School. His areas of clinical expertise include general and preventive cardiology. His current major research focus is the role of inflammation in vascular diseases such as atherosclerosis. Dr. Libby has a particular devotion to translate laboratory studies to pilot and then large-scale clinical cardiovascular outcome trials.
An author and lecturer on cardiovascular medicine and atherosclerosis, Dr. Libby has published extensively in top ranked medical journals. He is an Editor of Braunwald's Heart Disease. He has held numerous visiting professorships and delivered more than 100 major named or keynote lectures throughout the world.

Dr. Libby has received numerous awards and recognitions for his research accomplishments, including a number of lifetime achievement awards. Most recently he was awarded: the Gold Medal of the European Society of Cardiology (2011), Anitschkow Prize of the European Atherosclerosis Society (2013), the Ernst Jung Gold Medal for Medicine (2016) and the Earl Benditt Award from the North American Vascular Biology Organization (2017).
Dr. Libby's elected professional memberships include the Association of American Physicians, the American Society for Clinical Investigation, and honorary memberships in the British Atherosclerosis Society, the Japan Circulation Society, and the Japanese College of Cardiology.

He has served in many roles as a volunteer for the American Heart Association. He served a 5-year term on the Board of Scientific Councilors of National Heart, Lung, and Blood Institute (NHLBI). He has received continuous funding from the NHLBI for several decades.

Dr. Libby earned his medical degree at the University of California, San Diego, and completed his training in internal medicine and cardiology at the Peter Bent Brigham Hospital (now Brigham and Women's Hospital). He also holds an honorary MA degree from Harvard University, and an honorary doctorate from the University of Lille, France.

Renato Lopes (Durham, USA)

Renato D. Lopes, MD, MHS, PhD is a Professor of Medicine of the Department of Medicine of the Division of Cardiology at Duke University Medical Center, in Durham, North Carolina, USA, as well as an Professor of Medicine of the Divisions of Internal Medicine and Cardiology in the Federal University of Sao Paulo, in Sao Paulo, Brazil. He completed his clinical training at the Federal University of Sao Paulo, Sao Paulo, Brazil and his Cardiology Fellowship at the Duke Clinical Research Institute (DCRI), serving as Chief Fellow for the research training program during his senior year.

After finishing his Fellowship, Dr. Lopes joined the Faculty at Duke as an Assistant Professor at the Division of Cardiovascular Medicine, in the Department of Medicine of the Duke University, in Durham, NC. He is currently the Director of Clinical Events Classification (CEC) and the Co-Director of the Integrated Clinical Events-Safety Surveillance Group. His primary research interests include investigating the impact and outcomes of atrial fibrillation complicating acute coronary syndromes.

He also has an interest in novel antithrombotic therapies for the management of patients with atrial fibrillation and acute coronary syndromes as well as in the discovery of new biomarkers in the field of Cardiology. Dr. Lopes has led several national and international clinical trials and registries. He has also participated in clinical events committees (CECs) for many important clinical trials, serving as CEC chair or Principal Investigator for several of these trials.

Dr. Lopes has worked with other colleagues to establish a Clinical Research Institute in Sao Paulo, Brazil: the Brazilian Clinical Research Institute (BCRI), an academic research organization (ARO). Dr. Lopes is the current BCRI Executive Director and is involved in the conductance of several clinical studies, both national and internationally. In addition, Dr. Lopes has also been working closely with the Duke Global Health Institute (DGHI), in helping to expand the DGHI to other parts of the world. As a result of this work, he has created the Brazilian Global Health Institute (BGHI) at the Federal University of Sao Paulo, in Sao Paulo, Brazil.

Carol Maguire (San Francisco, USA)

Carol Maguire is the Director of Clinical Research for the Division of Cardiology at the University of California, San Francisco and the Project Director for the Eureka Research Platform. She specialized in cardiovascular critical care nursing for 9 years before transitioning to research. Since 2008 she has been managing multiple clinical and investigator initiated trials including international multi-site trials.

With a staff of 18 and growing on the Eureka Research Platform Project, she is helping to pave the way in streamlining the clinical trial process by helping to create a digital infrastructure to facilitate mobile-health research for investigators around the world.

Marilyn Mann (Patient Advocate, USA)

Marilyn Mann has family members with familial hypercholesterolemia, including her daughter who was diagnosed in 2001 at age eight. There is a family history of early heart attacks in her

husband's family. She moderates an online community of FH patients and their family members, responding to questions and providing information. She is patient advisor for Circulation: Cardiovascular Quality and Outcomes, and edits a series of articles written by patients with cardiovascular disease or their family members. She was an attorney at the U.S. Securities and Exchange Commission for 23 years, until her retirement in 2014.

Lorenzo Mantovani (CESP, ITA)

Lorenzo G Mantovani holds a degree in Economics (Milan) and a Doctorate in Epidemiology (Rotterdam). He is Associate Professor of Public Health at the University of Milan - Bicocca, Italy. His main research interests include cost, outcomes, compliance and persistence to chronic cardio-metabolic treatments.

Recipient of several international service and scientific awards, he is member of the Steering Committee of international registries, including Xamos, Xalia, Xalia-LEA, COSIMO, Garfield-AF, Garfield-VTE and collaborates with the Global Burden of Disease Study. In the last two decades he has been serving as HTA advisor to several Public Authorities.

Member of the editorial board of PLOS ONE, of the Open Diabetes Journal and of Health Policy in Non-communicable Diseases, he co-authored more than 200 HTA Reports and scientific articles, including papers published in Blood, Circulation, European Heart Journal, American Heart Journal, Europace, European Journal of Heart Failure, International Journal of Cardiology, Lancet, Lancet Haematology and The New England Journal of Medicine.

Nassir Marrouche (Salt Lake City, USA)

Nassir Marrouche has dedicated his career to developing innovative research and clinical practices to advance patient care, diagnosis and treatment of heart arrhythmias. In 2009, at the University of Utah, he created the Comprehensive Arrhythmia Research and Management Center (CARMA) bringing together a cross-departmental team of physicians, scientists, researchers, MRI and imaging specialists dedicated to working collaboratively to answer the questions: What if we treated patients proactively instead of reactively? Moreover, what if we could predict and prevent a stroke in a patient before it happens?

Under his guidance, the CARMA Center developed the Utah Classification System enabling electrophysiologists and cardiologists to deliver individualized care to arrhythmia patients. The CARMA Center also conducted the international DECAAF study. The standard of care was to ablate around the pulmonary vein. The DECAAF study showed that ablation of the veins did not predict outcome. In fact, the most important predictor of outcome, along with stage of atrial fibrosis, was the degree of ablation of the fibrotic tissue. Rather than targeting the pulmonary veins, procedures which ablated fibrotic tissue produced better outcomes.

Steven Marso (Kansas City, USA)

Steven Marso is the Medical Director for Cardiovascular Services for HCA Midwest Health Heart and Vascular Institute in Kansas City Missouri. He is a clinician and clinical investigator. His clinical interests include caring for patients diabetes and heart disease and for patients with complex coronary artery disease. Dr. Marso' research interests include evaluating the cardiovascular safety and efficacy of therapies to treat diabetes mellitus. He is involved in several ongoing large cardiovascular outcome trials. Dr. Marso also has a research interest in evaluating the outcomes following PCI using large national databases. Dr. Marso earned his medical degree at the University of Kansas and trained in Internal Medicine at the University of Virginia. He went on to complete a fellowship in Cardiovascular Medicine and serve as Chief Cardiology Fellow at the Cleveland Clinic Foundation. Professor Marso has published over 140 peer-reviewed

manuscripts, edited four textbooks, mentored over 30 Interventional Cardiology fellows and is a frequent invited lecturer on the topics of PCI and diabetes and cardiovascular disease.

Felipe Martinez (Cordoba, ARG)

Felipe Martinez graduated from Cordoba National University where he is currently distinguished as Emeritus Professor of Medicine. He attended post graduate training at Brussels University, Belgium and Toronto University, Canada. He is the Director of Rusculleda Foundation and Damic Institute where in addition to patient care and Academic activities, many Phase II and III international trials have been coordinated in South America as SMO/ARO. Dr Martinez is a former President of the Argentinean Federation of Cardiology and the International Society of Cardiovascular Pharmacotherapy and Immediate Past Governor of the Argentina Chapter of the American College of Cardiology. He has edited three books about Cardiovascular Therapeutics, the last two were sold out in less than 6 months in Spanish Speaking Countries. He published more than 200 articles in international Journals. As an invited speaker he has participated in more than 150 international meetings, in 26 Countries distributed in the five continents, including four of the largest Congresses in the world. And also has chaired the Scientific Committee of the World Congress of Cardiology 2008 in Buenos Aires. His main fields of interest are Heart Failure and Hypertension with special focus in drug treatment and clinical research. In this particular area he has participated as Member of Executive, Steering and Endpoint Committees in 43 multinational trials. CVCT has invited him as a Faculty Member every year since 2010.

Antoni Martinez-Rubio (Barcelona, ESP)

Antoni Martínez-Rubio studied Medicine at the Universitat Autònoma of Barcelona (Spain). He specialized in Internal Medicine and in Cardiology in Münster (Germany) where he also got his Doctor medicinae ("magna cum laude"). He is Magister in Health Management (Univ. Autònoma de Barcelona). Actually, he is the director of the Dept. of Cardiology of the University Hospital of Sabadell (Barcelona). Under his leadership, this department has been twice nominated one of the three best Cardiology Departments of Spain. He also teaches at the Universitat Autònoma de Barcelona. He has served in several boards, including the Catalan Society of Cardiology or the European Commission. He is president elect of the International Society of Cardiovascular Pharmacotherapy. He is reviewer of several scientific journals and societies.
He is first-author and co-author of more than 130 and 230, respectively, publications and presentations in international congresses and international journals (e.g. European Heart Journal, Circulation, American Journal of Cardiology, Journal of the American College of Cardiology, etc.), monographs and textbooks. He has given several invited lectures in Argentina, Australia, Canada, Chile, China, Finland, Germany, Italy, Israel, Portugal, Rumania, Russia, Spain, USA.

Debbe McCall (Murrieta, USA)

Debbe McCall is an active patient leader in the heart disease community, specifically atrial fibrillation. She is the administrator of the Atrial Fibrillation Support Forum, with >8,000 international members. She has spoken about the patient experience at ACC, HRS, patient conferences and industry symposia. She has also been interviewed many times about patient engagement and research, and attending medical conferences.
In 2010, she was nominated to be a Patient Representative (SGE) to the FDA's Cardiovascular Drug and Device Advisory Committee, and has served on over 18 AdComms including drugs, devices, reclassifications, biologics and think tanks. In 2013 she joined the Health eHeart Alliance, and in March of 2015 was elected as their first Chair and Co-PI. She is a co-author of «Ethical responsibilities toward indirect and collateral participants in pragmatic clinical

trials» in Clinical Trials Journal. She is on the Data Safety Monitoring Board (DSMB) of the ADAPTABLE Aspirin Trial, a patient lead or Co-PI on multiple funded grants and a patient peer reviewer for manuscripts.

Twitter: @DebbeMcCall

Darren McGuire (Dallas, USA)

Darren K. McGuire, MD, MHSc completed medical school at Johns Hopkins, residency at UT Southwestern, and Cardiology Fellowship at Duke. He is Professor of Medicine at UT Southwestern in the Division of Cardiology, holding the Dallas Heart Ball Chair for Research on Heart Disease in Women and is a Distinguished Teaching Professor. Dr. McGuire's expertise is in global CV outcomes trials with a focus in the area of diabetes.

Dr. McGuire has been received Outstanding Teacher awards from the UT Southwestern medical students, medicine housestaff, and cardiology fellows, as well as the UT System Board of Regents Outstanding Teacher Award in 2013.

Dr. McGuire is a previous member of the FDA Cardiovascular and Renal Drugs Advisory Committee; is Deputy Editor of Circulation and co-editor of: Diabetes in Cardiovascular Disease: A Companion to Braunwald's Heart Disease. Dr. McGuire has co-authored over 260 peer-reviewed publications.

Alexandre Mebazaa (Paris, FRA)

Alexandre Mebazaa, MD, PhD, FESC, is Professor of Anaesthesiology and Critical Care Medicine at the Hôpital Lariboisière, University Paris 7, France. His research interests include mechanisms of contractile impairment during acute heart failure and global studies on biomarkers in acute heart failure. He acted as member or Chair of several Steering Committees including SURVIVE, COMPOSE, TRUE-HF. He is also involved in several European and global registries on circulatory failure. He has authored or co-authored more than 200 papers and is Lead-Editor of the Acute Heart Failure textbook. Dr Mebazaa also serves as the Chair of Department of Anesthesiology and Critical Care in Paris.

Roxana Mehran (New York, USA)

Roxana Mehran is Professor of Medicine, Cardiology and Professor of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai is internationally renowned in the field of interventional cardiovascular disease. As Director of Interventional Cardiovascular Research and Clinical Trials at Mount Sinai, she has developed a globally-respected data and clinical coordination center. A prolific researcher and author, she has served as principal investigator for numerous large global studies, developed risk scores for bleeding and acute kidney injury, and authored >800 peer-reviewed articles. Dr. Mehran has received numerous prestigious awards, most recently the 2017 Bernadine Healy Leadership in Women's CV Disease Award. She is co-founder of the Academic Research Consortium (ARC) and Women in Innovation (WIN), and a founding physician of the Cardiovascular Research Foundation, where she is currently Chief Scientific Officer. Prior to her position at Mount Sinai, Dr. Mehran held appointments at Columbia University Medical Center and Washington Hospital Center. She completed internal medicine training at University of Connecticut and fellowships in cardiovascular disease and interventional cardiology at Mount Sinai Medical Center.

Cyrus Mehta (Boston, USA)

Cyrus Mehta is President and co-founder of Cytel Corporation and Adjunct Professor of

Biostatistics, Harvard University. Cytel (www.cytel.com) is a leading provider of software, clinical services and strategic consulting on the design, interim monitoring and implementation of adaptive clinical trials, with offices in the United States, Europe and India. Dr. Mehta consults extensively with the biopharmaceutical industry on group sequential and adaptive design, offers workshops on these topics, and serves on data monitoring and steering committees for trials in many therapeutic areas. He has over 110 publications in leading statistics and medical journals. He is a past co-winner of the George W. Snedecor Award from the American Statistical Association, is a Fellow of the American Statistical Association, and an elected member of the International Statistical Institute. He was named Mosteller Statistician of the Year by the Massachusetts Chapter of the American Statistical Association in 2000, and Outstanding Zoroastrian Entrepreneur by the World Zoroastrian Chamber of Commerce in 2002. He has received the Lifetime Achievement Award from the International Indian Statistical Association (2015) and the Distinguished Alumi Award from the Indian Institute of Technology, Bombay (2016).

Marissa Miller (NHLBI, USA)

Marissa Miller serves as the Chief of the Advanced Technologies and Surgery Branch (ATSB), National Heart, Lung and Blood Institute, National Institutes of Health in the U.S. The ATSB is responsible for managing government supported research programs directed at diagnosis, prevention and treatment of cardiovascular disease. Dr. Miller also oversees the Cardiothoracic Surgical Trials Network that promotes the evaluation of novel cardiac surgical techniques, technologies, devices and innovative pharmaceutical and bioengineered products through a collaborative clinical trials enterprise.
Dr. Miller is board certified in Veterinary Preventive Medicine and Public Health; she received her DVM degree from The Ohio State University and MPH with an emphasis in Epidemiology, from the Uniformed Services University of the Health Sciences. Over thirty plus years, she has served in numerous capacities in the U.S. government with experience spanning regulatory medicine, biodefense, biomedical research, vaccine policy, human substance abuse epidemiology and prevention and treatment of infectious diseases.

Carl Moons (Utrecht, NED)

Carl G.M. Moons is Professor of Clinical Epidemiology at the Julius Center for Health Sciences and Primary Care, UMC Utrecht, The Netherlands. He is Director of Research in the management team of the Julius Center and heading the research programme 'Methodology'. Since 2005 he also has an Adjunct Professorship at VanderBilt University, Nashville, USA. He also is affiliated to the Cochrane Collaboration and Cochrane Netherlands. He is editor in chief of BMC Diagnostic & Prognostic Research.
Carl Moons is principal investigator in numerous international clinical (epidemiology) studies funded by various organisations (EU, NHS, NIH). His experience covers the full range of conduct, data analysis, reporting and disseminaton of such studies, varying from studies on the evaluation of medical devices and tests for diagnosis, prognosis, screening and monitoring, to etiological studies and randomised therapeutic trials, to meta-epidemiological studies both on aggregate and individual participant data. His main focus concerns improving the methods and approaches for evaluation and implementation of medical devices and technology. His major expertise is introducing innovations for the design, conducting, analysis and reporting of evaluations of diagnostic and prognostic tests, devices, (bio) markers and prediction models. Clinical topics include cancer, deep vein thrombosis, stroke, heart failure and peri-operative risk assessment. He teaches graduate and postgraduate students in all aspects of clinical (epidemiological) research design, conducting, analysis and reporting, throughout the world. He has published over 450 scientific papers and book chapters and obtained numerous research grants, including large prestigious personal grants.

Gillian Murtagh (Abbott, USA)

Gillian Murtagh is Associate Medical Director of Medical and Scientific Affairs for Abbott Diagnostics. Dr. Murtagh directs and implements clinical research activities, internal and external educational programs and business development projects in the cardiac space. Dr. Murtagh received her MD from Trinity College Dublin in 2003 before completing residency in Internal Medicine and specialty training in Cardiology (Advanced Cardiovascular Imaging and Cardio-Oncology at Northwestern Memorial and the University of Chicago). Dr. Murtagh has been involved in cardiovascular biomarker research for over ten years. She was co-chair of the ACC Working Group in Cardio-Oncology and has authored and co-authored multiple publications on biomarkers and imaging. She joined Abbott Diagnostics Division as Associate Medical Director in 2015.

Michael Nassif (Kansas City, USA)

Michael Nassif completed his cardiology training at Washington University in Saint Louis. Upon the completion of his clinical training he completed a two year NIH T32 outcomes research fellowship under the mentorship of John Spertus at Mid American Heart Institute in Kansas City, Mo. Dr. Nassif's research focuses on methods for assessing patients' health outcomes, measuring healthcare quality, and the use of information technology to effectively collect and track patient reported outcome metrics so that healthcare can be, more cost-effective, evidence-based and patient-centered.

Bruce Neal (Sydney, AUS)

Bruce Neal is a Deputy Executive Director at The George Institute for Global Health in Australia, Professor of Medicine at UNSW Sydney and Professor of Clinical Epidemiology at Imperial College London. Bruce completed his medical training at Bristol University in the UK in 1990 and spent four years in clinical posts. Prior to taking up his position at the Institute in 1999 he worked as an epidemiologist at the Clinical Trials Research Unit in Auckland, New Zealand, where he completed his PhD in Medicine. Bruce has a longstanding interest in the management of high blood pressure and diabetes and has played lead roles in multiple large-scale clinical trials. He currently chairs the Steering Committees for the recently completed CANVAS and CANVAS-R trials of the SGLT2 inhibitor canagliflozin and an ongoing 21,000 patient trial examining the effects of salt reduction on stroke.

Johannes Neumann (Hamburg, GER)

Johannes T. Neumann studied medicine at the University of Hamburg with residencies in Zurich, Helsinki, and Brisbane. Currently, he is a resident at the Clinic for General and Interventional Cardiology at the University Heart Center Hamburg. His scientific interest focuses on the use of biomarkers in acute cardiac care and for risk prediction. He is the leader of the Biomarkers in Acute Cardiac Care (BACC) study, which investigates patients with suspected myocardial infarction. Furthermore, he is the study coordinator for a worldwide randomized clinical trial investigating high-sensitivity troponin in acute cardiac care.

Steven Nissen (Cleveland, USA)

Steven Nissen, MD, is the Chairman of the Robert and Suzanne Tomsich Department of Cardiovascular Medicine at Cleveland Clinic's Sydell and Arnold Miller Family Heart & Vascular Institute. He was appointed to this position in 2006 after serving nine years as Vice Chairman of the Department of Cardiology and five years

as Medical Director of the Cleveland Clinic Cardiovascular Coordinating Center (C5), an organization that directs multicenter clinical trials. Dr. Nissen's research during the last two decades has focused on the application of intravascular ultrasound (IVUS) imaging to study the progression and regression of coronary atherosclerosis. He has served as International Principal Investigator for several large IVUS multicenter atherosclerosis trials.
Dr. Nissen has more than 35 years of experience as a physician. He is world-renowned for his work as a cardiologist, patient advocate and researcher. Equally as significant is his pioneering work in IVUS technology and its use in patients with atherosclerosis.

Richard Nkulikiuinka (Bayer, GER)

Richard Nkulikiyinka holds a Medical Degree from the University of Cambridge in the UK. He received his Membership of the Royal College of Physicians (MRCP) of London after completing his post-graduate training in general internal medicine at the Royal London and the Northwest London NHS Trusts, with a focus on emergency medicine and intensive care. He also holds a M.Sc. in Epidemiology from the London School of Hygiene and Tropical Medicine. He joined Bayer Pharmaceuticals in 2008, where he has held positions in Pharmacovigilance and Clinical Development, with responsibility for the planning and oversight of Phase 2-3 clinical studies, leading to NDA/MAA submissions in several indications. He is currently focused on new therapies for Heart Failure and Diabetic Kidney Disease, with a special interest for HFpEF and the cardio-renal axis.

Chistopher O'Connor (Washington, USA)

Christopher O'Connor is the Executive Director and CEO of the Inova Fairfax Heart and Vascular Institute, a 5-hospital center in the Northern Virginia / Washington, DC area. He is a Professor of Medicine in Cardiology at Duke University, and was previously the chief of the Division of Cardiology and director of the Duke Heart Center. Under his leadership, Duke Heart Center was ranked the #4 Heart Center in the country by U.S. News and World Report. Dr. O'Connor, who first joined the Duke faculty in 1989, is an internationally recognized cardiologist and authority on heart failure. His clinical investigations have dramatically expanded the understanding of numerous aspects of cardiac function and dysfunction, including the influence of depression and stress on heart failure patients. His research has led to profound insights into both pharmacologic and non-pharmacologic therapies to treat heart failure and has had a direct impact on the lives of thousands of patients.

Dr. O'Connor was one of the first investigators to lead initiatives to study therapies in acute decompensated heart failure, which has led to a number of novel therapeutic interventions. He was the Principal Investigator of the landmark HF-ACTION clinical trial, which studied exercise training in more than 2,000 heart failure patients, and eventually led to a change in the international guidelines, change in the national reimbursement of cardiac rehabilitation for heart failure patients by CMS, and validation of two novel biomarkers that were later approved by the FDA. Dr. O'Connor was an editor of the textbook, Managing Acute Decompensated Heart Failure, the first one published on the topic. He is currently the editor-in-chief of the Journal of the American College of Cardiology: Heart Failure, and serves on the editorial boards for several journals, including the New England Journal of Medicine, Journal of the American Medical Association, and Journal of the American College of Cardiology. Dr. O'Connor is a Fellow of the American College of Cardiology (ACC), the European Society of Cardiology (ESC), and the Heart Failure Society of America (HFSA). He has served on over 90 CEC and DSMC committees in 25 years and served as Chair or Co-Chair on more than 15 of these committees. He has an extensive record of successful mentorship of trainees and has published over 500 manuscripts. He has served as Principal Investigator (PI) or Co-PI for over 20 national and international clinical trials with an extensive record of NIH/NHLBI and industry grants. His commitment to mentoring students, residents, and fellows at Duke has been recognized with the Joseph C. Greenfield Research Mentoring Award in 2006 and the 2013 Research Mentoring Award

for clinical science research by the Schools of Medicine and Nursing. He currently serves as Editor-in-Chief of JACC: Heart Failure and is President of the HFSA.

Milton Packer (Dallas, USA)

Milton Packer is the Distinguished Scholar in Cardiovascular Science at the Baylor University Medical Center in Dallas. He has been the principal investigator of 20 multicenter trials that have evaluated novel interventions for the treatment of acute and chronic heart failure. He has served frequently as a member of government advisory committees, study sections, task forces or Data and Safety Monitoring Boards for the NIH. He served as a member of the Cardiac and Renal Drugs Advisory Committee to the US Food and Drug Administration from 1986-1992 and then as its Chair from 1997-2001, and he continues to serve on various FDA advisory committees. Dr. Packer was President of the Heart Failure Society of America from 2000-2002 and has served on numerous guidelines and standards committees for the American Heart Association and American College of Cardiology. He has received many teaching awards and has mentored dozens of young clinical investigators, many of whom have become leaders in basic and clinical research

Peter Pang (Chicago, USA)

Peter S. Pang MD MS FAHA FACC FACEP is an Associate Professor of Emergency Medicine and an Affiliated Regenstrief Scientist at the Indiana University School of Medicine. He is the Director of Clinical Research in the Department of Emergency Medicine and also the Chief Science Officer for Mobile Integrated Health with Indianapolis EMS. He recently became a Hoosier after spending 10 years at Northwestern University in Chicago as Associate Chief and Associate Director of Experimental Therapeutics in the Center for Cardiovascular Innovation. Dr. Pang went to medical school at the University of Texas Health Science Center at San Antonio and then completed residency and chief residency at the Brigham and Women's / Massachusetts General Hospital combined program in Emergency Medicine. His primary research area is acute heart failure. He has published extensively in this area and also serves as an Associate Editor of the Journal of the American College of Cardiology-Heart Failure and a member of the editorial board of the Journal of Cardiac Failure.

Bakul Patel (FDA, USA)

Bakul Patel is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.

Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort.

Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations.

Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

Gail Pearson (NHLBI, USA)

Gail D. Pearson is an Associate Director of the Division of Cardiovascular Sciences at NHLBI, Director of NHLBI's Office of Clinical Research, and Adjunct Professor of Pediatrics at Children's National Medical Center.

She oversees the Pediatric Heart Network, established in 2001, and the Bench to Bassinet Program, a comprehensive translational research program in pediatric cardiovascular diseases.

Gail also helped develop and oversee the Children and Clinical Studies web site and campaign to inform parents about clinical research.

In her role as Director of NHLBI's Office of Clinical Research, Dr. Pearson is responsible for ensuring the appropriate stewardship of NHLBI-funded clinical research. Her research interests focus on clinical trials and clinical research in congenital and acquired pediatric cardiovascular disease.

At Children's, she sees outpatients in the Heart Institute, proctor a cardiology fellow's clinic, interpret echocardiograms, lead an educational conference for the fellows, and provide mentoring about research for fellows and junior faculty.

Vlado Perkovic (Sydney, AUS)

Vlado Perkovic is Executive Director of The George Institute, Australia, Professor of Medicine at UNSW Sydney, and a Staff Specialist in Nephrology at the Royal North Shore Hospital. His research focus is in clinical trials and epidemiology, in particular in preventing the progression of kidney disease and its complications. He leads several major international clinical trials, serves on the Steering Committees of several others, and has led the development of George Clinical, the global clinical trials arm of The George Institute. He has been involved in developing Australian and global guidelines in kidney disease, cardiovascular risk assessment and blood pressure management.

Vlado holds a Doctor of Philosophy from the University of Melbourne and completed his undergraduate training at The Royal Melbourne Hospital. He is a member of the National Health and Medical Research Council Principal Committee on Research Translation; is Chair of the International Society of Nephrology Action for Clinical Trials (ISN-ACT) group; and is a Fellow of the Royal Australasian College of Physicians, of the Australian Academy of Health and Medical Sciences and of the American Society of Nephrology

Bertram Pitt (Ann Arbor, USA)

Bertram Pitt is a professor of medicine emeritus at the University of Michigan, School of Medicine. Dr Pitt obtained his MD degree from the University of Basel in Switzerland in 1959.
He completed a fellowship in cardiology at the Johns Hopkins University School of Medicine and remained on the faculty until 1977, when he left to direct the division of cardiology at the University of Michigan. He has been chairman or co-chairman of a number of clinical trials in cardiology including: SOLVD; ELITE I and II; Prevent; Rales and Ephesus.
He is currently chairman of the steering committee of the NHLBI TOPCAT trial examining the effect of spironolactone in patients with HF and preserved LV systolic function; co-chairman of the Emphasis-HF trial examining the role of eplerenone in patients with NYHA Class II HF, chairman of Break- DHF, co-chairman of STOP-CKD, co-chairman of Exceed, co-chairman of Escape-SHF and Escape-DH F, chairman of a study evaluating the role of an aldostereone synthase inhibitor in patients with HF and is a member of the executive committee of the Accomplish trial. In addition, he serves as the chairman of the DSMB for the NHLBI HF-Action trial and has over 500 articles in peer reviewed journals.
Dr Pitt has been a member of a number of medical organizations and has served as an advisor to the clinical trials branch of the NHLBI and a member of the FDA cardio-renal advisory board.

He has been awarded the James B. Herrick Award by the Council of Clinical Cardiology of the American Heart Association and has been elected to the Society of Scholars of the Johns Hopkins University.

Aruna Pradhan (Boston, USA)

Aruna D. Pradhan is Assistant Professor of Medicine at Harvard Medical School, staff physician in the Division of Preventive Medicine (DPM), Brigham and Women's Hospital and cardiologist in the Division of Cardiovascular Diseases, VA Boston Healthcare System. Dr. Pradhan's research focus has been the evaluation of novel biomarkers in the prediction, progression, and treatment of type 2 diabetes (T2D), coronary and peripheral artery disease (PAD). She is or has been the recipient of numerous research grants sponsored by the American Heart Association, National Heart, Lung, and Blood Institute and industry. She is currently principal investigator of several large ongoing studies:

- Anti-inflammatory Therapy with Low Dose Methotrexate for Reduction of PAD; NHLBI R01
- Diabetes Prevention in the Vitamin D and Omega-3 Trial; NIDDK R01
- Pemafibrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes (PROMINENT); Kowa Research Institute.

Dr. Pradhan is Chair of the American Heart Association's Council on Peripheral Vascular Diseases. She completed her cardiovascular medicine fellowship at the Brigham and Women's Hospital in 2004 and subspecialty training in echocardiography at the Massachusetts General Hospital in 2005.

Krishna Prasad (EMA, GBR)

Krishna Prasad is a Group Manager at the UK Regulatory Agency with direct management responsibility for 3 therapy areas (Cardiovascular-Diabetes, Anti-infectives and Oncology) and an Honorary Cardiologist at St. Thomas' hospital, London. He has worked for MHRA, since 2002 initially as reviewer, progressing to the current post. His is a long-standing member of European Society of Cardiology with special interest in heart failure, CV risk factors, arrhythmias, cardiomyopathies and sudden death. Dr Prasad is a regular participant in the regulatory roundtable dialogues with European Society of Cardiology and European Heart Failure association. An active member of two EMA/CHMP working groups- cardiovascular-Diabetes WP (2008) and the Pharmacogenomics WP (2005), he has coordinated several regulatory guidelines in these areas. He is closely involved in the International Committee of harmonisation expert groups for E-14 and E-18 guidelines as Regulatory chair/ Rapporteur.

Susan Quella (Rochester, USA)

Susan Quella, RN, BSN, had a 37 year career at Mayo Clinic, first as a Physician Extender in Urology for 11 years, then as a clinical trial nursing chair for a 35 U.S. clinic Oncology research group (NCCTG, North Central Cancer Treatment Group), then became the Project Manager for international clinical trials, and finally Lead RN for Nicotine Research Clinical Trials.

Susan has been published in several U.S. medical journals and has received the Literary Award from the BritishJournal of Medicine. Susan had developed the Oncology Patient Advocate Committee for Mayo Clinic and since retirement has volunteered for research committees at Mayo as a patient advocate herself.

Ileana Piña (New York, USA)

Ileana L. Piña, MD, MPH is a Professor of Medicine, Epidemiology & Population Health at the Albert Einstein College of Medicine in the Bronx, NY. Dr. Piña also serves as advisor/

consultant to the Food and Drug Administrations' (FDA) Center for Devices and Radiological Health and their section of Epidemiology. Dr. Piña earned her undergraduate degree in Chemistry from the University of Miami in Florida. She completed her medical degree and cardiology fellowship at the University of Miami School of Medicine, an internal medicine residency at the University of South Florida Tampa, where she was Chief Resident, and fulfilled a surgery internship at the University of Miami Hospitals and Clinics. She earned a master's degree in public health from Case Western Reserve University School of Medicine in Cleveland, OH. Dr. Piña's research interests include transition of care in heart failure patients, and the role of natriuretic peptide-guided management for patients hospitalized for heart failure, biomarkers of myocardial stress and fibrosis in chronic heart failure, and the clinical implications of chronic heart failure phenotypes. She is the author/co-author of more than 100 publications.

Paul Ridker (Boston, USA)

Paul M. Ridker MD, MPH, FACC is a Eugene Braunwald Professor of Medicine at Harvard Medical School and serves as a Director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital. Prof. Ridker specialized in therosclerosis and cardiovascular disease including the role of inflammation in the disease process and the role of CRP.

Prof. Ridker's particular areas of interest involve molecular and genetic determinants of hemostasis, thrombosis, and inflammation with a focus on «predictive medicine», early disease diagnosis, and the underlying causes and prevention of acute coronary syndromes. His research efforts are primarily supported by RO1 research grants from the National Heart, Lung, and Blood Institute (NHLBI), a Distinguished Clinical Scientist Award from the Doris Duke Charitable Foundation, and through philanthropic research grants from the Leducq Foundation and the Donald W Reynolds Foundation.

Dr. Ridker has been the recipient of a Clinician Scientist Award (1992-1997), an Established Investigator Award (1997-2002), and a Distinguished Scientist Award (2013) from the American Heart Association. His pioneering work on inflammation, CRP, and atherothrombosis, was also recognized by Time Magazine who named him among America's Ten Best Researchers in Science and Medicine in 2001 and as one of the «Time 100» in 2004.

Lothar Roessig (Bayer, GER)

Lothar Roessig received his MD form the Hannover Medical School, Germany. He is board certified in Cardiology and in Internal Medicine, and Lecturer in Medicine at the Goethe University of Frankfurt, Germany. As senior cardiologist and member of the faculty at the University Hospital Frankfurt he participated as clinical investigator in numerous cardiovascular trials until 2007 when he moved into clinical research industry. Since October 2009 he is appointed at Bayer as Global Clinical Leader in heart failure development.

Claudio Ronco (Vicenza, ITA)

Claudio Ronco is director of the Department of Nephrology and the International Renal Research Institute (IRRIV) of San Bortolo Hospital, Vicenza, Italy. He graduated in 1979 and specialised in nephrology at the University of Padua in 1979. He has been Director of the Laboratory of the RRI and Beth Israel MC in New York and professor of Medicine at the Albert Einstein College of Medicine. He is external professor at the University of Virginia of Charlottesville and the University Fudan and Jaotong of Shanghai. He authored 1246 papers, 65 books and 106 book chapters and delivered more than 850 lectures at international meetings. He is Editor-in-Chief of Blood Purification and Contributions to Nephrology, Editor emeritus of the International Journal of Artificial Organs. He has received several international awards. He is considered the pioneer in many areas of nephrology including peritoneal dialysis, critical care nephrology,

CRRT, cardiorenal syndromes and wearable dialysis technology. He invented the first CRRT machine for neonates CARPEDIEM (Cardio Renal Pediatric Dialysis Emergency Machine)

Yves Rosenberg (NHLBI, USA)

Yves Rosenberg is Chief of the Atherothrombosis and Coronary Artery Disease Branch at the National Heart, Lung, and Blood Institute, a part of the United States National Institutes of Health (Bethesda, Maryland). Dr. Rosenberg obtained his MD from the University of Lyon, France, and is Board certified in Preventive Medicine. He also has an MPH from the Johns Hopkins School of Hygiene & Public Health. Dr. Rosenberg's main research interests are the design and conduct of large multicenter phase III clinical trials, especially trials of treatment strategies, comparative effectiveness and pragmatic trials. As a Program Director at NHLBI for over 20 years he has led and participated in the development, conduct, analysis and reporting of more than a dozen major international clinical trials, the results of which have usually been incorporated in clinical guidelines and are influencing today's practice of cardiovascular medicine in the United States and all over the world.

Heather Ross (Tempe, USA)

Heather M. Ross, PhD, DNP, is a Clinical Assistant Professor in the School for the Future of Innovation in Society and College of Nursing and Health Innovation, and a Research Scientist in the Global Security Initiative at Arizona State University. She has a clinical practice as a nurse practitioner at Arizona Arrhythmia Consultants. Dr. Ross's research centers on human-technology interaction with a focus on wearable sensors for health and biomedical applications. She has previously studied innovation in atrial fibrillation ablation technologies. She is currently conducting clinical research related to sensor-enabled patient-centered management of atrial fibrillation, heart failure, asthma, and real-time detection of traumatic brain injury. Additionally, Dr. Ross is engaged in research related to health education in under-resourced regions, wearable robotic devices in low-gravity and microgravity environments, and individual decision-making based on water quality sensor data. She hosts the Future Out Loud podcast, examining social and policy implications of emerging technologies. Dr. Ross serves as a Trustee of the Heart Rhythm Society, and is the Chair of the Cardiovascular Team Advocacy Committee of the American College of Cardiology. She is a candidate for U.S. Congress in Arizona's sixth district.

Patrick Rossignol (Nancy, FRA)

Patrick Rossignol was born 1969, married, 3 children, Patrick Rossignol, MD, PhD, is professor of Therapeutics, Nephrologist and Vascular medicine specialist, Deputy Director of Nancy Plurithematic Clinical Investigation center (CIC)-Inserm. He has participated/is participating in several EU FP6-7 programs (Ingenious Hypercare: Coord A; Zanchetti; MEDIA: Coord: W. Paulus ; HOMAGE & FIBROTARGETS : Coord F. Zannad , Nancy CIC). He is coordinating a French network of excellence endorsed by F-CRIN (French Clinical research Infrastructure Network, the French affiliate of ECRIN/ERIC: Cardiovascular and Renal Clinical Trialists (INI-CRCT www.inicrct.org) since 2014. He is coordinating the University Hospital "French Government Investment for the Future" Fighting Heart Failure program (2016-2020). He is the PI of the ongoing largest double blind (spironolactone vs. placebo) academic cardiovascular outcome randomized controlled trial in hemodialysis (ALCHEMIST: ClinicalTrials.gov Identifier: NCT01848639) and steering committee member of several international randomized clinical trials. He is a EURECA-m (cardiorenal working group of ERA-EDTA: The European Nephrology Dialysis Transplantation Association) member since its creation in 2009 and got elected as board member (2013-2016) and he is now serving as scientific advisor. Since 2016 is a Heart

Failure Association of the European Society of Cardiology "Translational" and "Cardiorenal" board member. He is CardioRenal cofounder.

Sébastien Roux (Idorsia, CHE)

Sébastien Roux, MD, studied cardiology in both France (Paris) and Canada (Montreal Heart Institute). He did his MSc. in cell biology in the French research institute INSERM. He started his career in the pharmaceutical industry at F. Hoffmann La Roche (Switzerland) where he was leading drug discovery laboratories focused on antithrombotic research, vascular tone, atherosclerosis and angiogenesis. He moved to Actelion Pharmaceuticals Ltd. in 2000 to lead the clinical program for bosentan which eventually allowed the worldwide registration of the first orally active endothelin receptor antagonist for the treatment of pulmonary arterial hypertension. He led the pulmonary arterial hypertension development program that resulted in successful worldwide registrations of other oral therapies for pulmonary arterial hypertension such as macitentan and selexipag. This year, he moved to Idorsia Pharmaceuticals Ltd. where he is currently Head of Clinical Science Early Clinical Projects with a special interest in the early treatment of myocardial infarction. Idorsia is an independent biopharmaceutical company based on science and innovation. Idorsia was established in June 2017, when Actelion demerged its drug discovery and early clinical pipeline business as part of the acquisition by Johnson & Johnson. The company is specialized in the discovery and development of small molecules and develops drugs in multiple therapeutic areas such as, resistant hypertension, Lupus, insomnia, Fabry disease and acute coronary syndrome.

Prabir Roy-Chaudhury (Tucson, USA)

Prabir Roy-Chaudhury MD, PhD, FRCP (Edin) is a Professor of Medicine at the University of Arizona Health Sciences. He is also the Director of the Division of Nephrology and the Director of the Arizona Kidney and Vascular Center. After graduating from the Armed Forces Medical College, Pune, India, he trained in Internal Medicine and Nephrology at the University of Aberdeen, Scotland and at the Beth Israel Hospital, Harvard Medical School, Boston, USA. In addition to being an active transplant nephrologist, Dr. Roy-Chaudhury's main research interest is in uremic vascular biology (including both dialysis vascular access dysfunction and cardiovascular disease in kidney disease patients) and he currently directs the Arizona Kidney and Vascular Center.This translational research program is funded through the National Institutes of Health, the Veterans Administration research program and through industry grants.

Dr. Roy-Chaudhury has also been actively involved in the public policy and administrative aspects of dialysis vascular access care and kidney disease as a board member/councilor/committee chair for the American Society of Diagnostic and Interventional Nephrology, the Renal Network, the Interventional Nephrology Advisory Group of the American Society of Nephrology (ASN), the Cardio-Renal Society of America, the Cincinnati chapter of the National Kidney Foundation and the Medical Advisory Board of the Life Center (Ohio). He is a member of the ASN Board of Advisors and Capitol Hill advocacy team, the ASN Post Graduation Education Committee and the International Society of Nephrology-India and South Asia Committees, as well as being the President of the American Nephrologists of Indian Origin (ANIO).

Dr. Roy-Chaudhury is also the American Society of Nephrology co-chair of the Kidney Health Initiative which is a public-private partnership between the ASN and the FDA.

Marc Sabatine (Boston, USA)

Marc S. Sabatine, MD, MPH is Chairman of the Thrombolysis in Myocardial Infarction (TIMI) Study Group, the Lewis Dexter, MD, Distinguished Chair in Cardiovascular Medicine at Brigham and Women's Hospital (BWH), and a Professor of Medicine at Harvard Medical School (HMS). As

Chairman of the TIMI Study Group, Dr. Sabatine leads an Academic Research Organization whose mission over the past 30+ years has been to advance the knowledge and care of patients suffering from cardiovascular disease and its risk factors. To that end, Dr. Sabatine has led several large-scale, international, randomized controlled trials of novel antithrombotic, lipid-lowering, and other pharmacotherapies. A pioneer in the multimarker approach to risk stratification, Dr. Sabatine has several NIH grants supporting the application of proteomics and metabolomics for discovery of novel biomarkers. He has a long-standing interest in pharmacogenetics and has made seminal observations on the ability to use genetics for personalized medicine. Dr. Sabatine has authored over 200 original research, peer-reviewed articles including in the New England Journal of Medicine, JAMA, and the Lancet and is on the writing committees for several ACC/AHA practice guidelines.

Naveed Sattar (Glasgow, GBR)

Naveed Sattar is a clinically active academic experienced in biomarker studies/trials investigating the causes, prevention and management of diabetes, obesity and heart disease. He has authored or co-authored over 650 published papers, has received several national and international prizes for his research, and is in the top 1% of cited clinical academics in the world according to the Thomson Reuters 2016 Highly Cited Researcher list.

He has been on several national and international guideline committees, including: European Society of Cardiology (ESC) Task Force to develop 2019 Guidelines on diabetes, pre-diabetes, and cardiovascular diseases; Joint British Societies 3 CVD prevention recommendations; SIGN obesity and CVD prevention guidelines (as Chair); and European CVD prevention guidelines. He is currently involved in several lifestyle and drug trials in diabetes and CVD and leads on biomarker initiatives in other trials. He is also on editorial or international advisory boards for Diabetologia, Lancet Diabetes and Endocrinology, BMC Medicine and UK Biobank, and is an Associate Editor for Circulation.

Dan Schaber (Medtronic, USA)

Dan Schaber PharmD is Vice-President Heart Failure Clinical Research, Medtronic Inc. Dan has more than 30 years of experience in the pharmaceutical and medical device industry and 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 joined Medtronic in 1987 from the University of Minnesota and Minneapolis Children's Medical Center where he taught respiratory and cardiovascular clinical pharmacology. He has held management positions in the clinical research, product development, regulatory and marketing organizations of Cardiac Rhythm Management in the US and in Europe. Dan is a Bakken Fellow the highest scientific and technical honor bestowed by Medtronic. He has a Doctor of Pharmacy degree from the University of Minnesota and was Pediatric Clinical Pharmacy Fellow at Minneapolis Children's Medical Center.

Heribert Schunkert (Munich, GER)

Heribert Schunkert, MD is Professor of Cardiology of the Technische Universitaet Munich, Director of the Cardiology Department, German Heart Centre Munich. He completed a research fellowship at Brigham and Women's Hospital, Boston, USA and clinical fellowships at Beth Israel Hospital and at the Universitaetsklinikum, Regensburg and the Massachusetts General Hospital, Boston, USA. From 2002-2012 Prof. Schunkert was Director of Internal Medicine and Cardiology at the University of Luebeck. He conducts research in the molecular genetics of multifactorial cardiovascular disease, coordinates several EU- and BMBF-sponsored projects as well as the European-American Leducq network CADgenomics to identify the genetic roots of myocardial infarction. He is the author of more than 600 publications in international journals.

Abhinav Sharma (Stanford, USA and Nancy, FRA)

Abhinav Sharma has finished hid medical school and internal medicine training at McMaster University. He completed my cardiology fellowship at the University of Alberta and he is currently completing my PhD in Medicine with Dr. Justin Ezekowitz at the University of Alberta. His research focuses on the intersection of heart failure and diabetes, evaluating optimal management strategies, risk prediction, and biomarker expression. Furthermore he is interested in the use of mobile device to accelerate clinical care and clinical trial conduct. He has also concurrently completed a cardiovascular research fellowship at Duke University under Dr. Michael Felker. He is currently undergoing a clinical advanced heart failure and transplantation fellowship at Stanford University which is expected to finish in July 2018.

Kaori Shinagawa (PMDA, JPN)

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 in clinical trial consultations and reviews of new drugs, assessments of cardiac safety of new drugs, and in creating new guidelines for Japanese drug applications. 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 published in a variety of prestigious cardiovascular journals. Dr. Shinagawa's findings have been featured in Circulation, J Am Coll Cardiol, PACE, Cardiovasc Drugs Ther, and Cardiovascular Res. She also received Kimura Memorial Award from the Japanese Heart Rhythm Society in 2000.

Tabassome Simon (Paris, FRA)

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

Dr Simon is currently the Director of the Clinical Research platform of the East of Paris, including the Clinical Research Unit, the clinical Research Center, and the BioBank Research Center, that coordinates several multicenter national and international studies throughout centers in France. In addition to teaching pharmacology for medical students, T. Simon coordinates the Master Diploma of Clinical Research for physicians, pharmacists, and scientists, the university diploma for pharmacogenetics and personalized medicine, and the university diploma for the education of research nurses in France.

Dr Simon has received several awards from the French Society of Cardiology, the French Society of Pharmacology, the French Society of Angiology, and the EACPT. The editors of Circulation have chosen one of her publications as Groundbreaking Studies in the Practice of Cardiovascular Medicine in 2009.

She has published more than 185 original articles in international peer-reviewed journals, including The New England Journal of Medecine, The Lancet, JAMA, Nature Med, Circulation, JACC, European Heart Journal, Hypertension, Atherosclerosis, Arterioscler Thromb Vasc Biol, Clinical Pharmacology and Therapeutics, Heart, J Clin Endocrinol Metab, etc.

Shalabh Singhal (BMS, USA)

Shalabh Singhal is the Worldwide Medical Lead for early assets for the Cardiovascular Research and development efforts at Bristol-Myers Squibb. In this role, he is part of the team responsible for the development of the BMS Cardiovascular strategy. He also continues to see patients regularly and be a part of the cardiovascular teaching curriculum for the senior internal medicine residents at a local hospital and sees patients on a regular basis.

Dr. Singhal earned a Medical Degree from the SUNY Upstate Medical University in Syracuse, NY. He completed his internal medicine residency at Thomas Jefferson University Hospital and a cardiovascular fellowship at the University of Cincinnati.

His passion is in evolving our country's healthcare system into a modern, scientifically grounded, outcomes driven system that is patient centric at heart. Dr. Singhal lives in NJ with his family. He enjoys traveling, skiing, running, cycling, spending time with his twin sons and helping them develop into positive contributors to society.

James Smith (FDA, USA)

James P. Smith, MD, MS, is the Deputy Director of the Division of Metabolism and Endocrinology Products (DMEP) within the Office of New Drugs, Center for Drug Evaluation and Research (CDER), at the FDA. In this capacity, he primarily oversees development programs targeting lipid disorders and obesity. Prior to joining FDA in February 2011, he was a faculty member in the Division of Nephrology of the University of Michigan Health System. Dr. Smith is a graduate of the University of Michigan Medical School, and he completed his residency in Internal Medicine at the same institution. Subsequently, he completed fellowships in both nephrology and clinical pharmacology at Vanderbilt University Medical Center, as well as a master's degree in Clinical Research Design and Statistical Analysis at the University of Michigan School of Public Health.

Scott Solomon (Boston, USA)

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

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

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

Associate Editor at Circulation.

Stuart Spencer (The Lancet, London, GBR)

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

After graduating Stuart moved into research which started at the Brompton Hospital, London, looking at scoliosis in children before moving to the Veterinary School site at Bristol University. During this period he was invited to establish a research unit in The Netherlands. Later he set up a research team for a major pharmaceutical company in Switzerland for a year, and then spent 9 years as a senior researcher in New Zealand. He has also had two senior research fellowships at Leuven University, Belgium, and visiting professorships at King's College, London and Hong Kong University, and a doctorate of medicine from Umea University, Sweden. Stuart's research expertise includes such diverse topics as, growth, neuroendocrinology, immunology and fetal development. He also had a Senior Fellowship in bioethics for 5 years. This broad research base in front-line research has given a clear understanding of principles in research and publications applicable across disciplines.

Stuart is also a Trustee of the Scoliosis Association (UK), is on the British Scoliosis Research Fund grants committee and the steering Committee of the Swedish National GP Research School.

Kenneth Stein (Boston Scientific, USA)

Kenneth Stein, MD, FACC, FHRS, is Senior Vice President and Chief Medical Officer for Rhythm Management and Global Health Policy at Boston Scientific. Dr Stein is a Phi Beta Kappa graduate of Harvard College (in Economics), and earned his MD from New York University School of Medicine. He completed his medical internship and residency at The New York-Presbyterian Hospital/Weill Cornell Medical Center, where he also completed his cardiology and cardiac electrophysiology training.

In 2009 Dr Stein held the position of Associate Director of Clinical Cardiac Electrophysiology at Weill Cornell Medical Center and Associate Professor of Medicine at Cornell University where he was widely published, authoring over 125 peer-reviewed scientific publications in the areas of cardiac electrophysiology with special interest in cardiac resynchronization therapy and risk stratification for sudden cardiac arrest. Dr Stein oversees the clinical trials, medical safety, and medical education and clinical communications for Boston Scientific's Cardiac Rhythm Management, Electrophysiology and Watchman Left Atrial Appendage Closure businesses as well as leading the corporate Global Health Policy team tasked with shaping the company's policies with respect to global health care delivery and reimbursement.

Dr Stein serves on the board of the Boston Scientific Political Action Committee and on the Scientific Advisory Board of Optum Labs. Since 2013, he has served on the board of Childrens HeartLink, a registered 501c(3) nonprofit organization that trains and mentors medical teams in underserved parts of the world to diagnose and treat children with heart disease.

Norman Stockbridge (FDA, USA)

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

James Strait (Merck, USA)

James Strait is a Cardiologist and head of the Cardiovascular Therapeutic Area for European

Clinical Development at Merck, Sharpe, Dohme (MSD) where he oversees trials in heart failure, pulmonary hypertension, atherosclerosis, and thrombosis. Prior to joining industry, he was the head of Human Cardiovascular Studies at the National Institute on Aging, National Institutes of Health in the United States.

He has served as a Principal Investigator on several interventional and observational trials with a focus on the development of therapeutic approaches to the decline in aging-associated declines cardiovascular function. As an outgrowth of this background he has maintained an interest in the delay and reversal of cardiovascular fibrosis focusing on the development of surrogate endpoints which would enable the study of these changes in humans within large scale development programs and production of effective therapies for afflicted patients. In addition to his current work in Clinical Development, he has had a broad based research career which has included study of cardiomyocyte signal transduction using adenoviral-gene construct approaches, genetic underpinnings of common diseases using GWAS, changes in extracellular matrix composition, preserved and reduced ejection fraction associated heart failure, and changes in arterial-ventricular coupling via echocardiographic and pulse wave velocity modalities.

Julia Stubben (CVRx, CHE)

Julia Stubben is the Vice President of European Sales & Marketing of CVRx, a private med tech company that has developed the only implantable device approved for the treatment of heart failure and hypertension. Julia had previously spent five years at Medtronic, where she helped the cardiac rhythm management group conceptualize and launch a disruptive business model, NayaMed, throughout Europe. NayaMed was the first company to exclusively offer online distribution and support of implantable cardiac devices. Prior to this, Julia held positions in business development at a private biotech company in Canada and in sales for Novartis Pharmaceuticals in the United States.

Julia is a regular speaker on strategic innovation at the London Business School, and holds an MBA from INSEAD in France & Singapore and a Bachelor of Arts degree in Psychology from McGill University in Canada.

Karl Swedberg (Goteborg, SWE)

Karl Swedberg, MD, PhD, FESC, is Senior Professor of Medicine, Department of Molecular and Clinical Medicine, Sahlgrenska Academy, University of Gothenburg, Sweden. He is also Professor of Cardiology, National Heart and Lung Institute, Imperial College, London.

He was the first to report on survival benefits of a beta-blocker (1979), an ACE-inhibitor (1987), an angiotensin receptor blocker (2003), an if-channel inhibitor (ivabradine 2010) and recently an ARNI (angiotensin receptor antagonist and neprilysin inhibitor 2014) in chronic heart failure. He has published widely with more than 600 publications in peer-reviewed journals, 340 original research papers and over 48,000 citations.

He was Chairman of the Task Force on the Diagnosis and Treatment of Chronic Heart Failure that updated the ESC Guidelines 2005. He has participated in Steering Committees in numerous outcome trials in myocardial infarction and heart failure.

Recipient of the 2004 Kaufman Award of heart failure research from Cleveland Clinics, USA.

Awarded European Society of Cardiology Gold medal 2007 for outstanding contributions to the cardiovascular field. He gave the Paul Dudley White international lecture, AHA annual meeting in Orlando 2009. He received a Life-time Achievement Award from the Heart Failure Association (HFA) of ESC in 2016

He served as Editor-in-Chief of the European Journal of Heart Failure as between 2005 to 2009. And is the Associate Editor European Heart Journal since 2012.

Jean-Claude Tardif (Montreal, Canada)

Jean-Claude Tardif is the Director of the Research Centre at the Montreal Heart Institute and Professor of Medicine at the University of Montreal. Dr Tardif graduated from the University of Montreal with his medical degree in 1987 and completed his training in cardiology and research in Montreal and Boston in 1994. Dr Tardif holds the Canada Research Chair (tier 1) in translational and personalized medicine and the University of Montreal endowed research chair in atherosclerosis. He founded the Montreal Health Innovations Coordinating Centre (MHICC) and is the Chairman of the steering committees of the CIHR funded Canadian Atherosclerosis Imaging Network (CAIN) and Medical Imaging Trials NEtwork of Canada (MITNEC).

Dr Tardif and his team have created the Beaulieu-Saucier Pharmacogenomics Center at the Montreal Heart Institute and he has created the Center of Excellence in Personalized Medicine (CEPMed), the latter funded by the Network of Centers of Excellence (NCE) of Canada and which is also supported by multiple pharmaceutical and biotechnological companies.

Dr Tardif has won multiple awards during his career, including the Research Achievement Award of the Canadian Cardiovascular Society, the Distinguished Lecturer Award of the Canadian Institutes for Health Research, the Genesis Award of Bio-Québec (for his outstanding contributions to life sciences) and the Armand-Frappier Award of the Government of Quebec, the highest scientific award in Quebec. He was also named scientific personality of the year by La Presse newspaper. Because of his accomplishments,

In 2014, he was inducted into the Order of Canada, the highest distinction in the country.

John Teerlink (San Francisco, USA)

John R. Teerlink, FACC, FAHA, FESC, FHFSA, FRCP (UK) is Director of Heart Failure and of the Echocardiography Laboratory at the San Francisco Veterans Affairs Medical Center and Professor of Medicine at the University of California San Francisco (UCSF, USA). He received a BA with Highest Honors from Swarthmore College (Comparative Religious Studies; Cellular Biology) and an MD from Harvard Medical School, completing Internal Medicine residency and Cardiology fellowship at UCSF, as well as postdoctoral research fellowships at Hoffman-LaRoche (Basel, Switzerland) and UCSF (Howard Hughes), subsequently joining the faculty. Dr Teerlink is actively involved in the design and execution of many acute and chronic heart failure clinical trials, serving on endpoint, data safety monitoring, and steering committees. He was a permanent member of the FDA Cardiovascular and Renal Drugs Advisory Committee, and frequently serves as an ad hoc member of multiple other FDA advisory committees and panels for medical devices, diagnostics, biologics and drugs. Dr Teerlink is a clinical scholar presenting many lectures and publications, including a chapter on Acute Heart Failure in Braunwald's Heart Disease textbook, and was profiled in The Lancet as an internationally recognized leader in heart failure. He serves as a consultant on clinical development programs in all areas of cardiology, as well as in cardiovascular safety for multiple non-cardiovascular indications.

Robert Temple (FDA, USA)

Robert Temple has been Deputy Center Director for Clinical Science at FDA's Center for Drug Evaluation and Research since 2009, participating in the direction of the Center's operations. He is also Acting Deputy Director of the Office of Drug Evaluation I (ODE-I). ODE-I is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr Temple served as Director, Office of Medical Policy from 1999-2009. The Office of Medical Policy is responsible for regulation of promotion through the Office of Prescription Drug Products (formerly, Division of Drug Marketing, Advertising, and Communication) and for assessing quality of clinical trials. Dr Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical

trials, evaluation of active control and non-inferiority trials, trials to evaluate dose-response, and trials using “enrichment” designs.

Stefan Teunis (Oldenzaal, NED)

Stefan was born with VSD and has had two open heart surgeries so far, the first at two mons old an the second was 7 years ago. He knows that he will need surgery in the future, but he is not sure when and of what type

Martyn Thomas (Edwards, USA)

Martyn Thomas, qualified from St Bartholomew’s Hospital, London 1982 and trained in Cardiology at Kings College Hospital, London.
He became Director of Cardiology Services at Kings College Hospital from 2003 to 2006 and moved to St Thomas Hospital London in 2007 where he was the Director of Cardiovascular Services from 2007 to October 2014. He was the President of the British Cardiovascular Intervention Society (BCIS) 2004-2008.
Martyn Thomas has a specialised interest with the academic assessment and introduction of new technologies and is a P.I. of a number of European trials. He has been involved in the assessment of many innovative technologies including brachytherapy and laser myocardial revascularisation therapies and has taught various novel therapies throughout the world. He performed the first case of Edwards Sapien Valve implantation in the United Kingdom. He was previously the co-PI of the SOURCE Registries of TAVI using the Edwards Sapien THV device. And is the Chairman and founder of PCR London Valves and Member of the PCR Board.
He has trained in TAVR centres in South Africa (Cape Town, Durban and Johannesburg) along with his surgical colleague Mr Vinnie Bapat. He is currently a programme committee member of TCT and TVT.
Martyn Thomas has had publications in pier reviewed journals on the topic of TAVI and is the lead for a team who performed first three cases of the Edwards Fortis Mitral Valve implants in the world in February 2014. He has left practice in October 2014 to become VP of Medical Affairs at Edwards Lifesciences.

Aliza Thompson (FDA, USA)

Aliza Thompson is a Clinical Team Leader in the Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research (CDER), at the U.S. Food and Drug Administration (FDA). Dr. Thompson joined the FDA in 2007; her team focuses on products being developed to treat renal-related indications. Dr. Thompson has served on several CDER biomarker qualification review teams and has been involved in larger efforts to define an evidentiary framework for CDER biomarker qualification. She received her medical degree from Johns Hopkins Medical School and completed her Internal Medicine and Nephrology training at Columbia University/New York-Presbyterian Hospital. She holds a Master of Science in Biostatistics/Patient Oriented Research Track from the Columbia University Mailman School of Public Health.

Sotirios Tsimikas (Ionis Pharmaceutical, USA)

Sotirios Tsimikas is Professor of Medicine and the Director of Vascular Medicine at the University of California San Diego School of Medicine. He obtained his MD degree in 1988 from the University of Massachusetts Medical School. He completed Internal Medicine training at the University of Massachusetts Medical Center in 1991, and fellowships in Cardiovascular Disease, Atherosclerosis and Molecular Medicine and Interventional Cardiology at the University of California San Diego from 1992-1997. Dr. Tsimikas’ clinical interests include running the Vascular Medicine Program which encompasses

treating patients in the continuum of high-risk primary prevention to endovascular intervention. In 2014, he established the world's first dedicated "Lp(a) Clinic". Dr. Tsimikas' research interests focus on two major areas: 1-"biotheranostics"-biomarkers, molecular imaging and therapeutics targeted to oxidation-specific epitopes, and 2-Lp(a) pathophysiology and therapeutics. He has published in all of the major medical journals, including NEJM, Lancet, Nature, Cell and has over 260 original manuscripts, review articles and book chapters. He currently has a dual appointment at UCSD and as Vice President of Global Cardiovascular Development at Ionis Pharmaceuticals, Carlsbad, CA.

Mintu Turakhia (Stanford, USA)

Mintu Turakhia M.D. M.A.S. is a cardiac electrophysiologist, outcomes researcher, and clinical trialist. Dr. Turakhia has an active, highly-funded multidisciplinary program in Atrial Fibrillation, where uses large datasets to examine quality, outcomes, and risk prediction for heart rhythm disorders. As the Executive Director of Stanford's new Center for Digital Health, he is the principal investigator of several multi-center trials to test digital health tools and wearable devices to screen and manage heart rhythm disorders. In his clinical role as Director of EP at the VA, Dr. Turakhia performs invasive procedures such as catheter ablation and device implantation to treat heart rhythm disorders. Dr. Turakhia is a Fellow of the American Heart Association, American College of Cardiology, and Heart Rhythm Society.

Ellis Unger (FDA, USA)

Ellis F. Unger is the Director, Office of Drug Evaluation-I, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), US FDA. His Office oversees the regulation of drugs for cardiovascular, renal, neurological, and psychiatric disorders. Dr. Unger obtained his medical degree from the University of Cincinnati, and received post-doctoral training in internal medicine at the Medical College of Virginia. He completed a fellowship in Cardiovascular Diseases at The Johns Hopkins Hospital. Dr Unger was a Senior Investigator in the Cardiology Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, from 1983 to 1997 where he led efforts in translational science on experimental promotion of angiogenesis. From 1997 to 2003, Dr Unger served as a Medical Officer, Team Leader, and subsequently Branch Chief in the Center for Biologics Evaluation and Research, FDA. When regulatory authority for therapeutic biologics was transferred from CBER to CDER in 2003, Dr Unger joined the Division of Cardiovascular and Renal Products in CDER, and became Deputy Director of that Division. Dr Unger was promoted to Deputy Director, Office of Drug Evaluation-I, in July, 2009, and promoted to Director in July, 2012.

Martin Unverdorben (Daiichi Sankyo, USA)

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

Natascha Van der Post (Nijmegen, NED)

Natascha van der Post is 37 years old and mother of two boys, living together with them and my boyfriend in a beautiful home in Apeldoorn, the Netherlands.
In 2010 she started her own daycare which is now a daycare organization with four daycare locations.
After her second pregnacy she became ill. During a hospitalization she was diagnosed with dilated cardiomyopathy. Her ejection fraction was at that time 15%. Three years later she is recovered until an EF of 49% with the help of medication and a balans in food and rest. She is still working, being a mom and participating at the Hart en Vaatgroep. With her expercience and the experience of other patients she reads research proposals. After reading them she will suggest improvements in the importance of patients. They hopes to improve research with a little of their help.

Bernard Vasseur (FDA, USA)

Bernard Vasseur MD has been a cardiothoracic surgeon for 20 years. Early on in his education at the Broussais hospital, he developed an interest in the study of mechanical heart devices. He completed his general surgery residency at the Yale University School of Medicine and his cardiothoracic surgery fellowship at The Cleveland Clinic Foundation. Dr Vasseur began a clinical practice, first at the University of Medicine and Dentistry of New Jersey and then in private practice in Pennsylvania. He then spent one year in France working as both a senior cardiac surgeon and a percutaneous valve fellow in the department of cardiology at the European Hospital and has witnessed the closing gap between the surgical and medical specialties. This has complemented his lifelong interest in the understanding of cardiac valves. He joined the Office of Device Evaluation at the FDA in 2015.

Yves Verboven (MedTech Europe, BEL)

Yves Verboven is the Director Access & Economic Policies at MedTechEurope. He graduated in 1987 as Electro-Mechanical-Engineer at the KULeuven, and MBA. He is the holder of five patents in field of cardiac stimulation in health failure.
In 1999, he was the head of Medtronics' European Heart Failure clinical outcomes & research department responsible for Clinical and Health Economic Outcome Evidence.
Publications and acknowledgements in Int'l journals as New England Journal of Medicine, Circulation resulting in: a class I indication level for Cardiac Resynchronization therapy and positive Health Technology appraisals
In 2008, he was assistant Director Health Economics, EurMEA at Alcon- (Ophthalmology) responsible for reimbursement and co-developed PRO IDEEL. In 2012, head of "access and economic policies for MedTech Europe", Europe's trade association striving for pro-innovation policies and a shift to a Value based Access model in dialogue with procurers, payers, etc.
Key enablers include MEAT-Value Based Procurement, Value of (Diagnostic) Information, modern HTA and new value driven evidence and financing schemes to invest in value for patients, healthcare, society and our economy.

David Whellan (Durham, USA)

David J. Whellan, MD, is the James C. Wilson Professor of Medicine in the Division of Cardiology at Sidney Kimmel Medical College, Senior Associate Provost for Clinical Research at Thomas Jefferson University, Associate Dean for Clinical Research for Sidney Kimmel Medical College, and the Executive Director of the Jefferson Clinical Research Institute.

He received his BS from the University of Pennsylvania, his Master of Health Sciences from Duke University, and MD degree from Washington University School of Medicine. He completed Internal Medicine Residency at the University of Pennsylvania and a Fellowship in Cardiology at Duke University and the Duke Clinical Research Institute. Dr. Whellan was the Co-Principal Investigator of the HF-ACTION study. In addition, he has served on the executive committees and the steering committees for a number of clinical trials. He is currently the Jefferson Regional Clinical Center PI for the NHLBI HF Clinical Research Network. He has authored over 150 peer-reviewed articles, reviews, abstracts, and book chapters on cardiomyopathy; and is an associate editor for JACC-HF.

John Whyte (FDA, USA)

John J. Whyte, MD, MPH is currently the Director of Professional Affairs and Stakeholder Engagement at the Center for Drugs Evaluation and Research at the U.S. Food and Drug Administration. In this role, Dr. Whyte works with health care professionals, patients, patient advocates, and others involved in the use of medicines. His office provides them with a focal point for advocacy, enhanced two-way communication, and collaboration, and assists them in navigating the FDA on issues concerning drug development, review, and drug safety. He also oversees the Safe Use program and supports the ongoing partnerships and activities under the Safe Use Initiative.

Dr. Whyte was in the Immediate Office of the Director at the Agency for Healthcare Research Quality. He served as Medical Advisor/Director of the Council on Private Sector Initiatives to Improve the Safety, Security, and Quality of Healthcare. Prior to this assignment, Dr. Whyte was the Acting Director, Division of Medical Items and Devices in the Coverage and Analysis Group in the Centers for Medicare & Medicaid Services (CMS). In his role at CMS, Dr.Whyte made recommendations as to whether or not the Medicare program should pay for certain procedures, equipment, or services. As Division Director as well as Medical Officer/Senior Advisor, Dr. Whyte was responsible for more national coverage decisions than any other CMS staff.

Dr. Whyte is a board-certified internist. He completed an internal medicine residency at Duke University Medical Center as well as earned a Masters of Public Health (MPH) in Health Policy and Management at Harvard University School of Public Health. His book Is This Normal? The Essential Guide to Middle Age and Beyond has won numerous awards. His most recent book, AARP New American Diet: Lose Weight, Live Longer is a national best-seller.

Harindra Wijeysundera (Canadian Agency for Drugs and Technologies in Health, CAN)

Harindra Wijeysundera is the Vice-President, Medical Devices and Clinical Intervention at CADTH. He continues an active practice as an interventional cardiologist and clinician scientist at the Schulich Heart Center in Sunnybrook Health Sciences Center. He is the director of research for the division of cardiology, and a scientist at Sunnybrook Research Institute as well as an adjunct scientist at the Institute for Clinical Evaluative Sciences (ICES). He is an associate professor in the Department of Medicine and the Institute for Health Policy, Management and Evaluation (IHPME) at the University of Toronto. His clinical practice is focused on transcatheter aortic valve implantation (TAVI) and coronary chronic total occlusions. His research program focuses on health technology assessments predominantly in cardiovascular disease using decision analytic models, which are populated and validated using real-world administrative data for both clinical outcomes and health care costs.

Ron Winslow (Freelance Journalist, USA)

Ron Winslow is a freelance journalist who recently retired from The Wall Street Journal where he was a reporter and editor for nearly 34 years. During his WSJ career, he covered the development of statins, stents and other technologies that have transformed treatment of heart disease over the past 25 years. He is a winner of the Victor Cohn Prize for Excellence in Medical Science Reporting. His work has also been recognized by the Association of Health Care Journalists (AHCJ), the New York Press Club, the American Heart Association and other groups. He was co-chair of the 10th World Conference of Science Journalists, held in San Francisco in October 2017. He is a past president of the National Association of Science Writers and a founding board member of the AHCJ. Most recently his work has appeared in STAT, the online medicine and health publication owned by the Boston Globe.

Janet Wittes (Washington, USA)

Janet Wittes, PhD is President of Statistics Collaborative, Inc. which she founded in 1990. Previously, she was Chief, Biostatistics Research Branch, National Heart, Lung, & Blood Institute (1983–89). Her 2006 monograph, "Statistical Monitoring of Clinical Trials – A Unified Approach" by Proschan, Lan, and Wittes, deals with sequential trials. Her research has focused on design of randomized clinical trials, capture recapture methods in epidemiology, and sample size recalculation. She has served on a variety of advisory committees and data monitoring committees for government (NHLBI, the VA, NEI, and NCI) and industry. For the FDA, she has been a regular member of the Circulatory Devices Advisory Panel and has served as an ad hoc member of several other panels. Currently, she is a regular member of the Gene Therapy Advisory Committee. She was formerly Editor in Chief of Controlled Clinical Trials (1994-98). She received her Ph.D. in Statistics from Harvard University.

Nadim Yared (CVRx, USA)

Nadim Yared is the President and Chief Executive Officer of CVRx. CVRx has developed the BAROSTIM NEO, a minimally-invasive implantable system designed to trigger the body's main cardiovascular reflex to treat patients suffering from chronic heart failure.
Nadim had previously served as Vice President and General Manager of Medtronic Navigation, the leading supplier of integrated image-guided surgery products in the world, from 2002 – 2006. He also worked at GE Medical for 10-years, where he had been Vice President of Global Marketing for the OEC Medical Systems and Vice President and General Manager of GE's European X-ray business based in Paris. Nadim has an engineering degree from Ecole Nationale Supérieure des Télécommunications, and an MBA from INSEAD, France.
Mr. Yared is currently serving as the chairman of the board of directors of AdvaMed. He also serves on the board of MDIC and CVRx.

Faiez Zannad (Nancy, FRA)

Faiez Zannad is Professor of Therapeutics at the University of Lorraine, Head of the Division of Heart Failure and Hypertension and Director of the Inserm Clinical Investigation Center at "Institut Lorrain du Coeur et des Vaisseaux", Nancy, France. He is a cardiologist and heart failure (HF) specialist with a PhD in clinical pharmacology (Oxford, UK).

Professor Zannad leads two EU FP7 granted programs: HOMAGE (omics biomarkers for mechanistic phenotyping and prediction of drug response [www.homage-hf.eu]) and FIBROTARGETS (fibrosis as a biotarget [www.fibrotargets.eu]). As the primary investigator, or member, of oversight committees of major clinical trials, he pioneered and/or made significant contributions to evidence-based therapy for HF

(mainly mineralocorticoid receptor antagonists [RALES, EPHESUS, EMPHASIS-HF] and beta-blockers [CIBIS]) as well as for major comorbid diseases in HF (such as sleep disordered breathing [SERVE-HF], autonomic nervous dysfunction [NECTAR-HF, BEAT-HF], diabetes [EXAMINE, EMPEROR], hyperkalemia [PEARL-HF], chronic kidney disease [FOSIDIAL, AURORA, ALCHEMIST], and thrombosis [COMMANDER-HF]).

He served as Chairman of the French Society of Hypertension, Chairman of the European Society of Cardiology (ESC) Working Group on pharmacology and drug therapy, and board member of the Heart Failure Association (HFA) of the ESC. He is the founder of, and is currently organizing, the Global CardioVascular Clinical Trialists (CVCT) Forum and Workshop; an annual international think tank gathering, dedicated to the science of clinical trials, with meetings in Paris and Washington DC, and in the Middle East and Asia. Professor Zannad has published more than 600 peer-reviewed papers, and several books and book chapters. He was awarded the 2014 European Society of Hypertension Paul Milliez Award and the 2017 Lifetime Achievement Award from the HFA of the ESC.

Bram Zuckerman (FDA, USA)

Bram Zuckerman is a graduate of the Boston University Medical School. He completed postgraduate training in internal medicine at Baltimore City Hospital and cardiology at the John's Hopkins program. Prior to joining the FDA in 1992, he was involved in basic research in emodynamics at the University of Colorado Medical School and practiced noninvasive and invasive cardiology in Denver, Colorado and Northern Virginia. He joined the FDA Division of Cardiovascular Devices (DCD) as a Medical Officer in 1992 and has been actively involved in development and review of clinical trials for many new cardiovascular devices. In May 2001 he was appointed a Deputy Director in DCD. Then in September 2002 he was appointed to his current position as Director of the FDA Division of Cardiovascular Devices.

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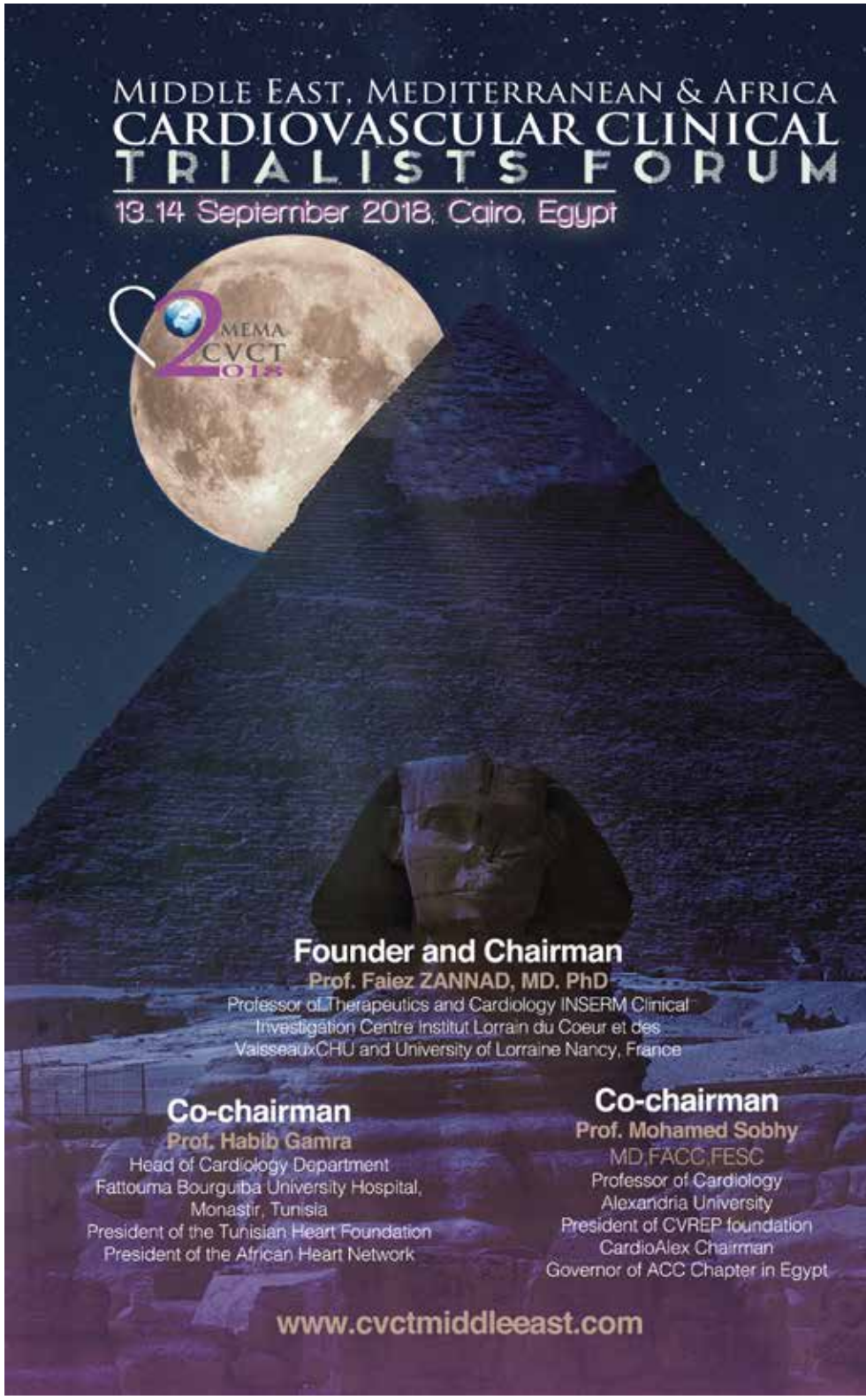
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- Lunches on Nov 30-Dec 2, 2017
- Daily coffee breaks
- Networking Reception on December 1, 2017 on invitation only. Please ask as the congress desk.

Opening hours of the welcome desk

- Thursday, November 30th: 7:30am - 7:30pm
- Friday, December 1st: 7:30am - 7:30pm

CLINICAL GATHERING SPACE

The clinical gathering space, located in the Foyer, will showcase the latest results and findings of ongoing clinical trials.

OFFICIAL LANGUAGE

The official language of the meeting is English.

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