FINAL PROGRAM

CVCT WASHINGTON, DC US

15th Global Cardio Vascular Clinical Trialists Forum

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

2018 NOVEMBER THURSDAY 29 DECEMBER SATURDAY 1,

www.globalcvctforum.com

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GENERAL MESSAGE

15th Global Cardio Vascular Clinical Trialists Forum CVCT WASHINGTON, DC US

Welcome to the 15th annual Global CardioVascular Clinical Trialists (CVCT) Forum. A meeting where our faculty members are selected from a list of world renowned global EXPERTS of the highest calibre. They are investigators and trial experts, industry R&D experts, regulatory and health technology experts, health care professional and health insurance experts, major media and medical journal experts and patient advocacy group experts to identify a few. It is this mix of expertise from various backgrounds which makes CVCT meetings unique, a sort of think tank, where faculty and participants alike are more willing to brainstorm and shift the lines than simply lecturing.

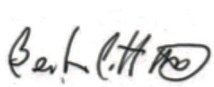
CVCT meetings open up a number of engaging and interactive options, taking our participants on an expedition, making each session more productive and more effective. There is ample time in each session allowing for inspiring and energizing moderated multi-stakeholder expert panel debates ("The Forum"). Moderators interview the experts and engage participants to directly interview and challenge the experts, with the moderator streamlining this process. The moderators are encouraged to structure the discussion and split the timeslot into a few clear chapters.

In addition to its classical features, CVCT Forum 2018 will be experimenting with another new variation to this theme are our Focused CVCT Workshops. Organized as campfire-sessions, fit for smaller groups the expert and the participants sit in a small U shape-table, as equals. The experts are allowed very brief openings, but then it is over to the participants, with the hope that intimacy allows participants to feel freer to talk to the expert and to each other.

Experts are encouraged to share their stories and case studies from real clinical trials, leaving it up to the audience to translate their learnings to their own daily reality, and to bring in more of their own cases.

The real expertise is in the room and during breakouts, mingling and networking among the participants, which is why our CVCT Team encourages all experts to stay for the full forum. Don't hold back in the discussions, it is through these discussions where the CVCT community learns from each other.

Pr Faiez Zannad



Dr Bertram Pitt

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15th Global Cardio Vascular Clinical Trialists Forum

CVCT WASHINGTON, DC US

SCIENTIFIC PROGRAM

Summary

PROGRAM AT-A-GLANCE

DAY 1 – THURSDAY, NOVEMBER 29TH

	9:00 9:30 AM	9:30 11:00 AM	11:00 11:30 AM	11:30 AM 1:00 PM	1:00 2:00 PM	2:00 3:30 PM	3:30 4:00 PM	4:00 6:30 PM
TOQUEVILLE	CVCT – NHLBI JOINT WORKSHOP		Coffee		Lunch		Coffee	
BALLROOM		Stat Master Class (I)		Stat Master Class (II)		Stat Master Class (III)		PATIENTS
AUDITORIUM	ATRIAL FIBRILLATION (I)			ATRIAL FIBRILLATION (II)		ATHEROSCLEROSIS (I)		ATHEROSCLEROSIS (II)

DAY 2 – FRIDAY, NOVEMBER 30TH

	8:00 10:00 AM	10:00 10:30 AM	10:30 AM 12:30 PM	12:40 1:00 PM	1:00 2:00 PM	2:00 3:30 PM	3:30 4:00 PM	4:00 5:30 PM	5:30 7:00 PM
TOQUEVILLE		Career Escalator			Lunch		Coffee	HYPERKALEMIA (I)	HYPERKALEMIA (II)
BALLROOM	THROMBO-CARDIOLOGY (I)	Coffee	THROMBO-CARDIOLOGY (II)			eSOLUTIONS BIG DATA (I)		eSOLUTIONS BIG DATA (II)	eSOLUTIONS BIG DATA (III)
AUDITORIUM	CARDIORENAL TRIALS IN METABOLIC DISORDERS PART (I)		CARDIORENAL TRIALS IN METABOLIC DISORDERS STAKEHOLDERS VIEWPOINT (II)	KEYNOTE ALEX DENNER		CARDIORENAL TRIALS IN METABOLIC DISORDERS PART (III)		STABLE ISCHEMIC HEART DISEASE PART (I)	STABLE ISCHEMIC HEART DISEASE PART (II)

DAY 3 – SATURDAY, DECEMBER 1ST

	8:00 10:00 AM	10:00 10:30 AM	10:30 AM 12:30 PM	12:40 1:10 PM	1:10 2:00 PM	2:00 4:00 PM	4:00 4:30 PM	4:30 7:00 PM
TOQUEVILLE		Career Escalator			Lunch		Coffee	
BALLROOM	REAL WORLD EVIDENCE (I)	Coffee	REAL WORLD EVIDENCE (II)			STENTS TRIALS		GLOBALIZATION
AUDITORIUM	BIOMARKERS (I)		BIOMARKERS (II)	TRIBUTE TO RAY LIPICKY		HEART FAILURE (I)		HEART FAILURE (II)

THURSDAY, NOVEMBER 29TH

TOCQUEVILLE

9:00 – 11:00 AM

MAXIMIZING THE IMPACT OF CLINICAL TRIAL FINDINGS:
NIH FUNDING OPPORTUNITIES FOR DISSEMINATION & IMPLEMENTATION RESEARCH
CVCT – NHLBI Joint Workshop

Moderators: Michael Engelgau (NHLBI, USA); Catherine Stoney (NHLBI, USA)

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.

The goals of this NIH workshop are to highlight the role of dissemination and implementation research in improving and accelerating the translation of evidence-based cardiovascular clinical trials research findings to clinical practice, to provide a high-level review of successes of dissemination and implementation trials in this area, and to share key strategies for successful NIH review and funding of these applications. While early-stage investigators may be especially interested in participation, this seminar will be broadly relevant to cardiovascular researcher's at all professional stages who are interested in dissemination and implementation science. Opportunities for questions and brief discussions will be integrated into the program.

Grand Challenges: Clinical Trial Findings and Quality Cardiovascular Health Care Delivery
Laurence Sperling (Atlanta, USA)

Dissemination and Implementation Research Clinical Trials to the Rescue
Catherine Stoney (NHLBI, USA)

How to Navigate Successful NIH Peer Review of Your D&I Clinical Trial Application
Brian Mittman (Kaiser Permanente, USA)

NHLBI and Other NIH Funding Opportunities for Clinical Trials in D&I Research
David C. Goff (NHLBI, USA)

BALLROOM

9:30 AM – 3:30 PM

CVCT MASTER CLASS
DESIGN, DATA MONITORING AND REPORTING OF CLINICAL TRIALS
Stuart Pocock (London, GBR); Janet Wittes (Washington, USA)
(REQUIRES SPECIFIC REGISTRATION)

Learning Objectives

To provide a comprehensive review of important statistical and scientific aspects of major clinical trials in cardiovascular diseases.

Target audience

The content will be aimed at cardiologists, regulators, academic scientists, and statisticians: indeed all health professionals wanting to expand their knowledge of how to design, conduct, monitor, analyse, report and interpret a major randomized trial.

Course Description

The course will comprise three 90 minute sessions, one each on trial design, data monitoring, and reporting.

Topics covered will include the following:

- The two lecturers will actively encourage audience participation in a lively discussion
- Topics will be illustrated by real examples of cardiovascular trials
- All three parts will be full of topical examples to illustrate each point.

- Throughout common sources of bias that arise in designing, monitoring, and reporting about trials, will be pointed out.

The goal is to structure the whole experience to be of direct practical value. Appropriate references to enhance knowledge further will be provided.

Part 1: Designing the Trial and Statistical Fundamentals

Types of trial; choices of patients, treatments and outcomes; randomization, how and why; blinding, how and why; size of trials and power calculations; non-inferiority trials; factorial trials.

Hypothesis testing, including the value and the misuse of P-values; estimation of treatment effects; Kaplan Meier plots; expressing uncertainty using confidence intervals; need for both absolute and relative effect measures.

Part 2: Monitoring the Ongoing Data

The role and function of Data Monitoring Committee: practicalities, ethics and statistics of monitoring accumulating data; stopping for efficacy, for futility or for safety; statistical stopping guidelines; adaptive designs; the reality of decision-making when data suggest it's time to stop a trial.

Part 3: Reporting the Results

Multiplicity of data, hierarchical testing; handling of composite endpoints, subgroup analyses and covariate-adjusted analyses; intention-to-treat and per-protocol analyses; balancing efficacy and safety; Bayesian methods; constructive critical appraisal.

BALLROOM

4:00 – 6:30 PM
PATIENT – TRIALISTS FORUM
HOW TO SECURE PATIENTS' PARTICIPATION AS RESEARCH PARTNERS IN CLINICAL TRIALS?

Moderators: Cynthia Chauhan (Wichita, USA); Annemieke Lenselink (The Hague Area, NED)

The aim of this session is to familiarize the researchers with the contributions, concerns and viewpoints of patients as well as to offer the researchers and patients an opportunity to dialogue meaningfully on the issue of patient engagement in the development of and participation in clinical trials. The outcome of this session would include broader understanding of the issues patients consider in choosing to enter trials and result in the potential for better engagement and accrual with less early withdrawal. When researchers understand and value the unique contribution of the patient perspective they may be more likely to include patients as team members from inception of the concept. No matter their level of engagement, it is important for patients to see themselves and be recognized as research partners or participants, never subjects.

Introduction:

- Cynthia Chauhan (Wichita, USA), HFpEF and Renal Failure
- Annemieke Lenselink (The Hague Area, NED), Stroke

FDA Patient Focused Drug Development: Our Learnings to Date
Theresa Mullin (FDA, USA)

EMA perspective
Angeles Alonso (EMA, GBR)

The Patient Perspective:

- **Patient engagement in trial design**
  - *Heart failure with Reduced EF and Pacemaker with Defibrillator*
    Kirsten Dahlgren (Michigan, USA)
  - *Dilated Cardiomyopathy*
    Natascha van der Post (Nijmegen Area, NED)
- **Enrolment/Accrual and Retention Issues**
  - *Congenital Heart Disease*
    Stefan Teunis (Oldenzaal, NED)
  - *End Stage Hypertrophic Cardiomyopathy*
    Marion van Sinttruije (Zwolle, NED)

Q & A DISCUSSION

Patients with comorbidities, how do they fit into trials?
Patrick Gee (Chesterfield, USA), Kidney disease
Steven Macari (Poitiers, FRA), Heart failure with reduced EF, implanted CRT-D, diabetes

Inclusion of minorities in trials
Sadegh Alikhaani (Los Angeles, USA), Heart Attack and Jacqueline Alikhaani (Los Angeles, USA), ARCA

Q & A DISCUSSION

Patient reported outcomes, how important are they?
Jillianne Code (Vancouver, CAN), Idiopathic Cardiomyopathy and Heart Transplantation

Trial outcomes, what matters to patients
Jayna Williams (New Hampshire, USA), Dilated Cardiomyopathy with Heart Failure with Reduced EF
Robin Martinez (Denver, USA), Kidney Disease

Q & A DISCUSSION

Trialist Perspective
Ileana Piña (New York, USA)

Industry Perspective
Monica Shah (IQVIA, USA)
Helina Kassahun (Amgen, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience

Panelists: Tariq Ahmad (New Haven, USA); Sadegh Alikhaani (Los Angeles, USA); Jacqueline Alikhaani (Los Angeles, USA); Angeles Alonso (EMA, GBR); Cynthia Chauhan (Wichita, USA); Jillianne Code (Vancouver, CAN); Kirsten Dahlgren (Michigan, USA); Patrick Gee (Chesterfield, USA); Larry Husten (Cardiobrief, USA); Stefan James (Upsala, SWE); Nichole Jefferson (Iowa, USA); Mariell Jessup (Philadelphia, USA); Helina Kassahun (Amgen, USA); Carolyn Lam (Singapore, SIN); Anna Maria Langkilde (AstraZeneca, SWE); Annemieke Lenselink (The Hague Area, NED); Gary Lyman (Raleigh, USA); Steven Macari (Poitiers, FRA); Véronique Mahaux (Syneos Health, BEL); Robin Martinez (Denver, USA); Manal Milhem (Atlanta, USA); Rhonda E. Monroe (Washington, USA); Theresa Mullin (FDA, USA); Milton Packer (Dallas, USA); Ileana Piña (New York, USA); Bertram Pitt (Ann Arbor, USA); Adel Rizkala (Novartis, USA); Matt Roe (Durham, USA); Yves Rosenberg (NHLBI, USA); Patrick Rossignol (Nancy, FRA); Juddson Rupp (Charlotte, USA); Rob Scott (Abbvie, USA); Monica Shah (IQVIA, USA); Tabassome Simon (Paris, FRA); Jeff A. Sloan (Rochester, USA); Kenneth Stein (Boston Scientifc, USA); Stefan Teunis (Oldenzaal, NED); Peter van der Meer (Groningen, NED); Natascha van der Post (Nijmegen Area, NED); Marion van Sinttruije (Zwolle, NED); Jayna Williams (New Hampshire, USA); Faiez Zannad (Nancy, FRA)

AUDITORIUM

9:00 – 11:00 AM
ATRIAL FIBRILLATION ABLATION (I)
HOW TO INTERPRET CABANA?
CVCT – HRS Joint Session

Moderators: Thomas Deering (Atlanta, USA); Gerhard Hindricks (Leipzig, GER)

The Catheter Ablation versus Standard Conventional Therapy in Patients with Left Ventricular Dysfunction and Atrial Fibrillation (CASTLE-AF) trial randomized 398 patients with paroxysmal or persistent atrial fibrillation and NYHA class II-IV HFrEF (LVEF ≤35%) to catheter ablation or medical therapy.

- Fewer patients in the catheter ablation group experienced the primary composite outcome of death or hospitalization for worsening heart failure (28.5% vs. 44.6%, P=0.006).
- Crossovers occurred in 9.8% of patients in the medical therapy group and 15.6% of the catheter ablation group.

The Catheter Ablation versus Antiarrhythmic Drug Therapy for Atrial Fibrillation (CABANA) trial was a multicentre, prospective, randomized, open-label study comparing percutaneous left atrial catheter ablation to pharmacologic rate or rhythm control. The results were reported in May at the Heart Rhythm Society.

- Among the 2,204 patients were enrolled, there was no difference in the primary outcome of total mortality, disabling stroke, serious bleeding, or cardiac arrest after 5 years of follow-up for patients randomized to ablation compared to drug therapy (8% vs. 9.2%, HR 0.86, 95% CI 0.65-1.15, P=0.3).
- In this open-label trial, a high crossover from the drug therapy arm to ablation (27.5%) occurred. In an as treated analysis, ablation was superior to drug therapy on the primary composite outcome, as well as for all-cause mortality alone, and the composite of death or cardiovascular hospitalization.

These findings raise important questions that will be discussed during the session:

- How should the on-treatment analysis be used and/or applied in practice?
- Do the results of CASTLE-AF and other data provide more confidence in the as-treated analysis of CABANA?
- What accounts for the higher crossover in CABANA vs. CASTLE-AF?
- Are sham-controlled trials always necessary to avoid the potential for crossovers? Would sham-controlled be ethical in light of CASTLE-AF?
- Will physicians in practice (non-researchers) recognize the limitations of as treated analyses?

CABANA Key Outcome Points
Kerry Lee (Durham, USA)

CABANA newest results (Quality of Life and Cost Analyses)
Dan Mark (Durham, USA)

Statistician Viewpoint
Brian Claggett (Boston, USA)

NHLBI perspective
Yves Rosenberg (NHLBI, USA)

CASTLE-AF and other recent and ongoing trials
Nassir Marrouche (Salt Lake City, USA)

Electrophysiologist Viewpoint
EU: Gerhard Hindricks (Leipzig, GER)
US: Conor Barrett (Boston, USA)

Non-Electrophysiologist Viewpoint
EU: Lars Lund (Stockholm, SWE)
US: Bernard Gersh (Rochester, USA)

Q & A DISCUSSION

AUDITORIUM

11:30 AM – 1:00 PM
ATRIAL FIBRILLATION ABLATION (II)
STAKEHOLDERS VIEWPOINTS
CVCT – HRS Joint Session

Moderators: Thomas Deering (Atlanta, USA); Gerhard Hindricks (Leipzig, GER)

Regulatory viewpoint
Jun Dong (FDA, USA)

Industry viewpoint
Kenneth Stein (Boston Scientifc, USA)

Media Viewpoint
Larry Husten (Cardiobrief, USA)

Patient Viewpoint:
Kirsten Dahlgren (Michigan, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
WHAT'S NEXT? INTERPRETATION AND IMPLEMENTATION ISSUES

Panelists: Conor Barrett (Boston, USA); Brian Claggett (Boston, USA); Nikolaos Dagres (Leipzig, GER); Kirsten Dahlgren (Michigan, USA); Thomas Deering (Atlanta, USA); Jun Dong (FDA, USA); Bernard Gersh (Rochester, USA); Gerhard Hindricks (Leipzig, GER); Larry Husten (Cardiobrief, USA); Kerry Lee (Durham, USA); Lars Lund (Stockholm, SWE); Dan Mark (Durham, USA); Nassir Marrouche (Salt Lake City, USA); Yves Rosenberg (NHLBI, USA); Kenneth Stein (Boston Scientifc, USA)

AUDITORIUM

2:00 – 3:30 PM
ATHEROSCLEROSIS TRIALS (I)
TARGETING THE APPROPRIATE MECHANISM

Moderators: Wolfgang Koenig (Munich, GER); Robert S. Rosenson (New York, USA)

Residual risk still represents an important issue in patients with manifest cardiovascular disease despite standard of care treatment with approximately 20% of patients experiencing a recurrent event within 5 years after an ACS. Several additional strategies are presently in place or are being investigated 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 PPAR-□ modulator). But novel strategies are at the horizon.

The recently presented ODYSSEY trial showed a 15 % relative risk reduction (RRR) (absolute risk reduction 1,6%) of the primary efficacy endpoint consisting of CHD, death, non-fatal MI, ischemic stroke or unstable angina requiring hospitalization in post-ACS patients thus extending the results from FOURIER to a higher risk cohort. However, there are several issues that need clarification, such as the reported decrease in all-cause deaths without a significant decrease in CHD death or cardiovascular death and the increase in LDL-C over the study's duration both in the ITT group (40 mg/dl to 66 mg/dl) and the on-treatment group (38 mg/dl to 53 mg/dl). At present, it is still unclear what the reasons for these changes are. By contrast, FOURIER reported a flat 30 mg/dl level throughout the whole study period. In addition, recent post-hoc analyses from FOURIER have highlighted specific high-risk subgroups, such as patients with peripheral arterial disease (PAD), multi-vessel disease, or a recent MI, that may derive greater benefit compared to the overall study population. Similarly, in ODYSSEY, those with a baseline LDL-C > 100 mg/dl showed a 29% RRR compared to 15% in the total study population. Thus, although basically confirming the results of FOURIER, there are still a number of remaining questions that require further discussion, including the observation that in every day clinical practice there appears to be a number of patients that either demonstrate an inadequate response or experience an attenuation of the effect over time.

Lp(a) has been identified as an additional risk factor based among others on convincing results from Mendelian Randomisation Studies. Yet, is is still unclear whether additional Lp(a) lowering on top of aggressive LDL-C lowering confers any clinically relevant benefit. Options to selectively lower Lp(a) are under way.

On the other hand, the positive CANTOS study clearly has paved the way for the introduction of anti-inflammatory treatment in high-risk patient's post-ACS. Several recent additional analyses have identified high-risk groups and in particular high responders based on robust changes of the biomarker hs-CRP three months after the first injection. In addition data from CIRT, a trial investigating low-dose methotrexate in high risk patients will probably be presented during AHA this year. Still, in CANTOS as well as in FOURIER and ODYSSEY, a significant number of patients went on to have a second event. Thus, additional strategies are needed.

Most recently, two studies have reported that even at extremely low levels of LDL cholesterol, <20 mg/dl, hs-CRP still is able to modify risk in these patients suggesting that inflammation might play a role even in these patients and we should not alternatively choose between a residual cholesterol risk or a residual inflammatory risk but rather consider a combination of these two strategies.

PCSK9 inhibitor trials

- **ODYSSEY: Did it achieve its goals?**
  Shaun Goodman (Toronto, CAN)
- **FOURIER: Identifying very high-risk groups**
  Marc Sabatine (Boston, USA)
- **Statistical and meta-analytical viewpoint**
  Usman Baber (New York, USA)

Q & A DISCUSSION

Trials of agents targeting inflammation

- **CANTOS: Recent Analyses Paving the way for Individualized Treatment**
  Peter Libby (Boston, USA)
- **CIRT Trial: Implications for an Anti-Inflammatory Strategy**
  Ahmed Hasan (NHLBI, USA)

Q & A DISCUSSION

AUDITORIUM

4:00 – 6:30 PM
ATHEROSCLEROSIS TRIALS (II)
TARGETING THE APPROPRIATE MECHANISM AND STAKEHOLDERS VIEWPOINTS

Moderators: Wolfgang Koenig (Munich, GER); Robert S. Rosenson (New York, USA)

Residual cholesterol risk vs. residual inflammatory risk or combining both?

- **Inflammation does play a significant role even at very low LDL levels**
  Erin Bohula (Boston, USA)
- **Inflammation is no longer relevant in patient on very low LDL levels**
  Erin Michos (Baltimore, USA)

Q & A DISCUSSION

Selective reduction of Lp (a)

- **Lp (a) in FOURIER**
  Michelle O'Donoghue (Boston, USA)
- **Still clinically relevant in patients after MI on an optimized LDL-C lowering strategy**
  Brian Ference (Cambridge, GBR)

Q & A DISCUSSION

Industry Viewpoints
Jean Marc Guettier (Sanofi, FRA); Andrew Hamer (AMGEN, USA)

Regulatory Viewpoints
William Chong (FDA, USA); Alar Irs (EMA, EST)

Payers Viewpoints:
Alejandro Arrieta (Miami, USA)

Patient Viewpoints:
Cat Davis Ahmed (The FH Foundation, USA); Wanda F Moore (Arizona, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
APPROVAL, IMPLEMENTATION AND REIMBURSEMENT CHALLENGES

Panelists: Cat Davis Ahmed (The FH Foundation, USA); Alejandro Arrieta (Miami, USA); Usman Baber (New York, USA); Erin Bohula (Boston, USA); William Chong (FDA, USA); Brian Ference (Cambridge, GBR); Augusto Gallino (ISCP, CHE); Shaun Goodman (Toronto, CAN); Jean Marc Guettier (Sanofi, FRA); Andrew Hamer (AMGEN, USA); Ahmed Hasan (NHLBI, USA); Alar Irs (EMA, EST); Wolfgang Koenig (Munich, GER); Peter Libby (Boston, USA); Erin Michos (Baltimore, USA); Wanda F Moore (Arizona, USA); Michelle O'Donoghue (Boston, USA); Robert S. Rosenson (New York, USA); Marc Sabatine (Boston, USA)

FRIDAY, NOVEMBER 30th

TOCQUEVILLE

4:00 – 7:00 PM
ASN-KHI-CVCT Joint Focused Workshop
POTASSIUM BINDERS ENABLING OPTIMIZATION OF RAAS INHIBITOR THERAPY. WHAT EVIDENCE IS NEEDED?

ON INVITATION ONLY – CLOSED WORKSHOP
Focused CVCT Workshops are organized as campfire-sessions, fit for smaller groups: The expert and the participants sit in a small U shape-table, as equals. The experts are allowed very brief openings, but then it is over to the participants, with the hope that intimacy allows participants to feel freer to talk to the expert and to each other.

ACE inhibitors, ARBs, MRAs and ARNi have shown significant clinical benefit in a variety of diseases including heart failure, patients at high CV risk, diabetes, and CKD.
Yet they are under-prescribed, frequently discontinued and/or under-dosed in real world registry data.
Suboptimal use is associated with poor outcome
One major driver of under use, discontinuation or under dosing is hyperkaliemia, a consistent and frequent adverse event.
Patients at risk of hyperkalemia are those very patients at most need for RAAS inhibitors, i.e elderly, CKD, diabetes pts, and pts with history of hyperkalemia episodes.
Whether the use of potassium binders may help enabling optimal use of life saving RAASi therapies, and therefore improve outcome in pts at risk is a question which needs to be based on appropriate evidence.
The objective of this focused workshop is to assemble a think tank of critical stakeholders discussing unmet needs, evidence to be generated, data to be collected, potential studies, registries, and trials to be developed, and implementation strategies to be designed for an optimal use of potassium binders enabling optimization of RAAS inhibitor therapy.

4:00 – 5:00 PM
ASN-KHI-CVCT Joint Focused Workshop
POTASSIUM BINDERS ENABLING OPTIMIZATION OF RAAS INHIBITOR THERAPY. WHAT EVIDENCE IS NEEDED?

Moderators: Ileana Piña (New York, USA); Patrick Rossignol (Nancy, FRA)

Registries and Real World Evidence: Value, Feasibility, Design, Translatability

- **Nephrology Viewpoint**
  Prabir Roy Chaudhury (Tucson, USA)
- **Cardiology Viewpoint**
  Lars Lund (Stockholm, SWE)

Challenges in Clinical trials: Defining Novel Endpoints in RAASi Enabling Trials
Aliza Thompson (FDA, USA)

Q & A DISCUSSION

5:00 – 6:00 PM
Implementation issues

Moderators: Moderators: Prabir Roy Chaudhury (Tucson, USA); James Januzzi (Boston, USA)

How to better streamline cardiologist – nephrologist collaboration in the management of hyperkalemia?

- **Cardiologist Viewpoint**
  Charles Herzog (Minneapolis, USA)
- **Nephrologist Viewpoint**
  George Bakris (Chicago, USA)

The Way to Guidelines
Ileana Pina (New York, USA

Patient Viewpoint

- **Kidney disease**
  Patrick Gee (Chesterfield, USA)
- **Heart failure with reduced EF, implanted CRT-D, diabetes**
  Steven Macari (Poitiers, FRA)

Q & A DISCUSSION

6:00 – 7:00 PM
Panel Discussion - Industry Viewpoint

Moderators: Colin Baigent (Oxford, GBR), Bertram Pitt (Ann Arbor, USA)

Panelists: William Abraham (Columbus, USA); Colin Baigent (Oxford, GBR); George Bakris (Chicago, USA); Justin Ezekowitz (Edmonton, CAN); Patrick Gee (Chesterfield, USA); Jyothis George (Boehringer, GER); Charles Herzog (Minneapolis, USA); James Januzzi (Boston, USA); Csaba Kovesdy (Nashville, USA); Lars Lund (Stockholm, SWE); Steven Macari (Poitiers, FRA); Alexandre Mebazaa (Paris, FRA); Robert Mentz (Durham, USA); Carol Moreno Quinn (AstraZeneca, SWE); Claudio Mori (Vifor Pharma, SWI); Milton Packer (Dallas, USA); Bertram Pitt (Ann Arbor, USA); Ileana Pina (New York, USA); Prabir Roy Chaudhury (Tucson, USA); Wilson Tang (Cleveland, USA); Aliza Thompson (FDA, USA); Peter van der Meer (Groningen, NED); Fred Yang (KBP Biosciences, USA); Faiez Zannad (Nancy, FRA); Emmanouil Zouridakis (EMA, GBR)

BALLROOM

8:00 – 10:00 AM
THROMBOCARDIOLOGY TRIALS (I)

Moderators: Roxana Mehran (New York, USA); Tabassome Simon (Paris, FRA)

Anti-Thrombotic Strategies: Latest Findings from NOACs Clinical Trials

1. **In Atrial Fibrillation**
   Elaine Hylek (Boston, USA)
2. **In Coronary and Peripheral Vascular Disease**
   Kelley Branch (Washington, USA)
3. **In Heart Failure**
   Faiez Zannad (Nancy, FRA)
4. **After Hospital Discharge for Medical Patients**
   Jeffrey Weitz (Hamilton, CAN)
5. **In Oncology**
   Gary Raskob (Oklahoma, USA)

Is There Room for yet Another Anticoagulant?
Jeffrey Weitz (Hamilton, CAN)

DAPT Post-ACS: Twice as Nice, or Double the Trouble?
Shaun Goodman (Toronto, CAN)

Q & A DISCUSSION

BALLROOM

10:30 AM – 12:30 PM
THROMBOCARDIOLOGY TRIALS (II)

Moderators: Roxana Mehran (New York, USA); Tabassome Simon (Paris, FRA)

Polypharmacy Anticoagulation: How to Study and Treat Combined Disorders Effectively and Safely?

1. **ACS, Atrial Fibrillation, DES, TAVR**
   David Moliterno (Lexington, USA)

2. **Phenotype-Guided Strategies (Platelet Function and Whole-Blood Clotting)**
   Tabassome Simon (Paris, FRA)

3. **Biomarker and Risk Score Guidance (HASBLED, CHADSVASC, biomarkers)**
   Jonas Oldgren (Uppsala, SWE)

Regulatory Viewpoint
Ellis Unger (FDA, USA); Emmanouil Zouridakis (EMA, GBR)

Industry Viewpoint
Efthymios Deliargyris (PLX Pharma Inc, USA); Pete Di Battiste (Janssen, USA); Melanie Goth (Bayer, GER), Martin Unverdorben (Daiichi Sankyo, USA)

Patient Viewpoint
Annemieke Lenselink (The Hague Area, NED))

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
HOW CAN WE BEST ADAPT TO THE FAST CHANGE IN LANDSCAPE?

Panelists: Kelley Branch (Washington, USA); Efthymios Deliargyris (PLX Pharma Inc, USA); Pete Di Battiste (Janssen, USA); Shaun Goodman (Toronto, CAN); Melanie Goth (Bayer, GER); Elaine Hylek (Boston, USA); Annemieke Lenselink (The Hague Area, NED); Roxana Mehran (New York, USA); David Moliterno (Lexington, USA); Jonas Oldgren (Uppsala, SWE); Gary Raskob (Oklahoma, USA); Tabassome Simon (Paris, FRA); Ellis Unger (FDA, USA); Martin Unverdorben (Daiichi Sankyo, USA); Jeffrey Weitz (Hamilton, CAN); Faiez Zannad (Nancy, FRA); Emmanouil Zouridakis (EMA, GBR)

BALLROOM

2:00 – 3:30 AM
eSOLUTIONS: BIG DATA – SMART DATA AND HOW THESE MAY HELP WITH CLINICAL EVIDENCE GENERATION
CVCT- Duke Think Tank Joint Session (II)

Moderator: Martin Cowie (London, GBR); Matt Roe (Durham, USA)

The increasing availability of large quantities of data from multiple sources, coupled with advances in computing technology, have created opportunities to transform observational research and complement the evidence generated by randomized clinical trials. Big data compiled from single or multiple sources (e.g., registries, biobanks, electronic health records, claims or billing databases, implantable devices, mobile platforms) may provide some solutions to the challenges facing cardiovascular clinical research and the limitations of randomized trials (e.g., generalizability, resource availability, practicality for common clinical questions). However, best practices for the application or interpretation of data from these sources is often uncertain. Leaders in the field have an opportunity to guide the evolution of big data and its application to cardiovascular research and practice.

Use of Big Data and AI in Clinical Trials
Tariq Ahmad (New Haven, USA)
Dan Riskin (Verantos, USA)

Example of a Virtual Trial
Matt Roe (Durham, USA)

mHealth solutions, health apps and e-Tools for clinical trials
Helina Kassahun (Amgen, USA)

Risk Based Monitoring
Jennifer Schumi (Astrazeneca, SWE)

Q & A DISCUSSION

BALLROOM

4:00 – 5:30 PM
eSOLUTIONS: BIG DATA – SMART DATA AND HOW THESE MAY HELP WITH CLINICAL EVIDENCE GENERATION
CVCT- Duke Think Tank Joint Session (II)

Moderators: Martin Cowie (London, GBR); Matt Roe (Durham, USA)

What is Patient-Centered Research?
Pamela Tenaerts (Durham, USA)

The Transcelerate Initiative
Rob Scott (Abbvie, USA)

Data-driven Solutions: Data-Driven Protocol Design, Approaches to Optimize Site Selection and Trial Implementation.
Allen Kindman (IQVIA, USA)

Q & A DISCUSSION

BALLROOM

5:30 – 7:00 PM
eSOLUTIONS – BIG DATA – SMART DATA AND HOW THESE MAY HELP WITH CLINICAL EVIDENCE GENERATION
CVCT & Duke Think-Tank Joint Session (III)
STAKEHOLDER VIEWPOINT

Moderator: Martin Cowie (London, GBR); Matt Roe (Durham, USA)

Will Digital Make My Life Easier?
Javed Butler (Jackson, USA)

Industry Viewpoint
Helina Kassahun (Amgen, USA)

Academic CRO Viewpoint
Matt Roe (Durham, USA)

CRO Viewpoint
Gadi Cotter (Momentum Research, USA)

NHLBI Viewpoint
Gail Pearson (NHLBI, USA)

Media Viewpoint
Larry Husten (Cardiobrief, USA)

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

Patient Viewpoint
Robin Martinez (Denver, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
HOW SHOULD WE BRING THE DIGITAL REVOLUTION INTO CLINICAL TRIALS?

Panelists: Tariq Ahmad (New Haven, USA); Javed Butler (Jackson, USA); Gadi Cotter (Momentum Research, USA); Martin Cowie (London, GBR); Adrian Hernandez (Durham, USA); Larry Husten (Cardiobrief, USA); Helina Kassahun (Amgen, USA); Allen Kindman (IQVIA, USA); Robin Martinez (Denver, USA); Gail Pearson (NHLBI, USA); Dan Riskin (Verantos, USA); Matt Roe (Durham, USA); Jennifer Schumi (Astrazeneca, SWE); Rob Scott (Abbvie, USA); Pamela Tenaerts (Durham, USA)

AUDITORIUM

8:00 – 10:00 AM
CVCT & INI – CRCT Joint Session
CARDIORENAL OUTCOME TRIALS IN METABOLIC DISORDERS (I)
NEW TRIALS - NEW PARADIGMS

Moderators: Colin Baigent (Oxford, GBR); Milton Packer (Dallas, USA)

Cardiovascular outcome trials in patients with type 2 diabetes mellitus and cardiovascular disease (or with major cardiovascular risk factors) have shown that some glucose lowering drugs reduce the composite risk of CV death, MI, and stroke when added to standard of care, compared to standard of care alone. These findings reinforce the importance of moving beyond a glucocentric approach to the management of type 2 diabetes mellitus to reduce cardiovascular risk. Although cardiovascular outcome trials were initially required to rule out cardiovascular harm of glucose lowering drugs, the findings from these trials support a position that clinical trials in patients with cardiometabolic disease should be evaluating efficacy (superiority). Conducting trials only to rule out harm (non-inferiority) without other evidence of meaningful clinical benefit should be re-evaluated. Not all cardiovascular outcome trials conducted in patients with type 2 diabetes mellitus have yielded superior results compared to standard therapy, raising the possibility that pharmacologic differences among agents may translate into tangible differences in clinical efficacy. The implications of these differences on the need to conduct cardiovascular outcome trials with every agent in a drug class needs further discussion. Cardiovascular outcome trials in type 2 diabetes mellitus also signal an opportunity to explore the treatment effects of these and other cardioprotective agents in patients with other cardiometabolic and cardiorenal diseases.

SGLT-2 Inhibitors Cardiovascular Outcome Trials
Marc Sabatine (Boston, USA)

Other SGLT-2 Inhibitors Renal Outcome Trials
Colin Baigent (Oxford, GBR)

Any value in a cardiorenal composite outcome?
Faiez Zannad (Nancy, FRA)

GLP1RA Trials

Robert Mentz (Durham, USA)
Salim Janmohamed (GSK, GBR)
Jeff Riesmeyer (Lilly, USA)

DPPIV Inhibitors
Jacob Udell (Toronto, CAN)

Q & A DISCUSSION

AUDITORIUM

10:00 AM – 12:30 PM
CVCT & INI – CRCT Joint Session
CARDIORENAL OUTCOME TRIALS IN METABOLIC DISORDERS (II)
STAKEHOLDERS VIEWPOINTS

Moderators: Colin Baigent (Oxford, GBR); Milton Packer (Dallas, USA)

Mechanistic Speculations About the Cardiorenal Benefits of New Glucose Lowering Agents
Milton Packer (Dallas, USA)

Should Metformin Remain First-Line Medical Therapy? What is the Preferred Second Line Glucose Lowering Agent for Patients with Type 2 Diabetes Mellitus and Atherosclerotic Cardiovascular Disease?
Muthu Vaduganathan (Boston, USA)

CV Protection Trials in Obesity: CV Safety or Efficacy Trials?
Donna Ryan (Baton Rouge, USA)

CV Protection Trials in NASH: CV Endpoints for CV Claims?
Arun Sanyal (Richmond, USA)

Q & A DISCUSSION

AUDITORIUM

12:40 – 13:00 PM
KEYNOTE
READING THE TEA LEAVES: WHERE IS HEALTHCARE | BIOTECH HEADED IN THE FUTURE
Alex Denner (Greenwich, USA)
Founder, Managing Director and Chief Investment Officer at Sarissa Capital, USA.

AUDITORIUM

2:00 – 3:30 PM
CVCT & INI – CRCT Joint Session
CARDIORENAL TRIALS IN METABOLIC DISORDERS (III)
IS R&D AND REGULATORY LANDSCAPE EVOLVING?

Moderators: Colin Baigent (Oxford, GBR); Milton Packer (Dallas, USA)

Statistician Viewpoint
Stuart Pocock (London, GBR)

Industry Viewpoint
Jyothis George (Boehringer, GER)
Anna Maria Langkilde (AstraZeneca, SWE)
Francesca Lawson (Sanofi, FRA)

Funding Agencies Viewpoint
Judith Fradkin (NIDDK, USA)

Regulatory Viewpoints
Kristina Dunder (EMA, SWE)
Kimberly Smith (CDER-FDA, USA)
Lisa Yanoff (FDA, USA)

Patient Viewpoint
Cynthia Chauhan (Wichita, USA)
Patrick Gee (Chesterfield, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience

Panelists: Colin Baigent (Oxford, GBR); Cynthia Chauhan (Wichita, USA); Kristina Dunder (EMA, SWE); Judith Fradkin (NIDDK, USA); Patrick Gee (Chesterfield, USA); Jyothis George (Boehringer, GER); Salim Janmohamed (GSK, GBR); Francesca Lawson (Sanofi, FRA); Anna Maria Langkilde (AstraZeneca, SWE); Barbara Linder (NIDDK, USA); Robert Mentz (Durham, USA); Milton Packer (Dallas, USA); Stuart Pocock (London, GBR); Donna Ryan (Baton Rouge, USA); Marc Sabatine (Boston, USA); Arun Sanyal (Richmond, USA); Kimberly Smith (CDER-FDA, USA); WH Wilson Tang (Cleveland, USA); Jacob Udell (Toronto, CAN); Muthu Vaduganathan (Boston, USA); Lisa Yanoff (FDA, USA); Faiez Zannad (Nancy, FRA)

AUDITORIUM

4:00 – 5:30 PM
STABLE ISCHEMIC HEART DISEASE TRIALS (I)

Moderators: Shaun Goodman (Toronto, CAN); David Moliterno (Lexington, USA)

Endpoint Related Issues

- **How to Best Design Clinical Trials in SIHD?**
  David Moliterno (Lexington, USA)
- **Defining the Right Endpoints (soft versus hard) for Regulators, Companies, Physicians, and Patient**
  Don Cutlip (Boston, USA)

Are Results of Slow Enrolling Trials Relevant with Current Practice? ISCHEMIA, OAT, COURAGE
Roxana Mehran (New York, USA)

Sham design: Feasibility, Ethics and Late Crossover Issues
Darrel Francis (London, GBR)

Q & A DISCUSSION

AUDITORIUM

5:30 – 7:00 PM
STABLE ISCHEMIC HEART DISEASE TRIALS (II)
STAKEHOLDER VIEWPOINT

Moderators: Shaun Goodman (Toronto, CAN); David Moliterno (Lexington, USA)

Statistical: Methodological Considerations
Peter Jüni (Toronto, CAN)

Funding Agencies Viewpoint
Yves Rosenberg (NHLBI, USA)

Regulatory Viewpoint
Bram Zuckerman (FDA, USA)

Patient Viewpoint
Cynthia Chauhan (Wichita, USA)
Susan Quella (Rochester, USA)

Q & A DISCUSSION

7:00 – 7:30 PM
Cheese & Wine Poster Session

7:30 – 9:00 PM
Networking Reception

SATURDAY, NOVEMBER 1ST

BALLROOM

8:00 – 10:00 AM
REAL WORLD DATA (I)
IS IT REAL WORLD EVIDENCE?

Moderators: John Jarcho (NEJM, USA) ; Mariell Jessup (Philadelphia, USA)

The 21st Century Cures Act requires the FDA to develop a framework and guidance for evaluating real world evidence (RWE) to support approvals of new indications for previously approved drugs and to support or fulfil post-approval study requirements. This needs to be done within the next 2 years.

How can we help to support and input into this process?
The four main stakeholder groups with influence in the drug development process, i.e. trialists, regulators, payers, practitioners and patients may have different insights on how RWE can be made highly credible, if at all possible.

Potential Implications of the 21st Century Cures Act in Relation to the Use of RWE: The Changing Regulatory Landscape

- **US:** Robert Califf (Durham, USA)
- **Europe:** Martin Cowie (London, GBR)

How the Increasing Use of RWE Will Impact Future Designs and Implementation of Phase II-III Clinical Development Programs?
Phil Galtry (Syneos Health, BEL)

Registry Data and How these May Help Evidence Generation
Kirkwood Adams (Chapel Hill, USA)
Stefan James (Upsala, SWE)

Can Registry-Based Randomized Clinical Trials Bridge the Evidence Gap?
Stefan James (Upsala, Sweden)

From Frequentist to Bayesian to RWE
Bernard Vasseur (FDA, USA)

Q & A DISCUSSION

BALLROOM

10:30 AM – 12:30 PM
eREAL WORLD DATA (II)
STAKEHOLDERS VIEWPOINT

Moderators: John Jarcho (NEJM, USA); Mariell Jessup (Philadelphia, USA)

Trialist Viewpoint: Only Trials Can Tell the Truth!
Milton Packer (Dallas, USA)

Industry Viewpoint
Anna Maria Langkilde (AstraZeneca, SWE); Nirav Dalal (Abbott, USA)

CRO Viewpoint
Jennifer Christian (IQVIA, USA)

Issues with Clinical Research Publication: What to Trust or Not to Trust?
Joseph Hill (Dallas, USA)

Journal Editors Viewpoint
John Jarcho (NEJM, USA)
Stuart Spencer (The Lancet, GBR)

Regulatory Viewpoint: What is "Regulatory Grade" Real World Evidence?
David Martin (FDA, USA); Alar Irs (EMA, EST)

Patient Viewpoint
Jeff A. Sloan (Rochester, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
REAL WORLD EVIDENCE VS. CLINICAL TRIAL EVIDENCE. HOW TO MAKE THE BEST OF BOTH WORDS?

Panelists: Kirkwood Adams (Chapel Hill, USA); Robert Califf (Durham, USA); Jennifer Christian (IQVIA, USA); Martin Cowie (London, GBR); Nirav Dalal (Abbott, USA); Efthymios Deliargyris (PLX Pharma Inc, USA); Phil Galtry (Syneos Health, BEL); Joseph Hill (Dallas, USA); Alar Irs (EMA, EST); Stefan James (Upsala, SWE); John Jarcho (NEJM, USA); Mariell Jessup (Philadelphia, USA); Anna Maria Langkilde (AstraZeneca, SWE); Véronique Mahaux (Syneoshealth, BEL); David Martin (FDA, USA); Milton Packer (Dallas, USA); Monica Shah (IQVIA, USA); Jeff A. Sloan (Rochester, USA); Stuart Spencer (The Lancet, GBR); Bernard Vasseur (FDA, USA)

BALLROOM

2:00 – 4:00 PM
DRUG ELUTING AND BIORESORBABLE VASCULAR STENTS TRIALS

Moderators: Roxana Mehran (New York, USA); David Moliterno (Lexington, USA)

DES trials: What Trials and How to Conduct?
Don Cutlip (Boston, USA)

DES in High Bleeding Risk Patients
Christopher Granger (Durham, USA)

BVS Trial Conduct and Results Implementation Issues
Alexandre Abizaid (Sao Paulo, BRA)

Endpoint Related Issues: Death, MI and Stent Thrombosis Events?
David Moliterno (Lexington, USA)

Regulatory Viewpoint
Andrew Farb (FDA, USA), P.F. Adrian Magee (FDA, USA)

Industry Viewpoint
Martin Unverdorben (Daiichi Sankyo, USA)

Patient Viewpoint
Steven Macari (Poitiers, FRA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
EVIDENCE GENERATION AND IMPLEMENTATION ISSUES IN INTERVENTIONAL CARDIOLOGY. HOW TO DO A BETTER JOB?

Panelists: Alexandre Abizaid (Sao Paulo, BRA); Don Cutlip (Boston, USA); Andrew Farb (FDA, USA); Christopher Granger (Durham, USA); Steven Macari (Poitiers, FRA); P.F. Adrian Magee (FDA, USA); Roxana Mehran (New York, USA); David Moliterno (Lexington, USA); Martin Unverdorben (Daiichi Sankyo, USA)

BALLROOM

4:00 – 7:00 PM
GLOBALIZATION OF CV CLINICAL TRIALS
OPPORTUNITIES, CHALLENGES AND UNMET NEEDS
CVCT & ISCP Joint Session

Moderators: Koji Hasegawa (Kyoto, JPN); Felipe Martinez (Cordoba, ARG)

There are important potential advantages of conducting clinical research in a wider global setting such as better generalizability and lower cost. However, there are also important complexities and challenges that need to be considered.

Research priorities may differ in global clinical trials. There are important regional differences including disease states (e.g. Chagas or rheumatic heart disease), therapeutic approaches (e.g. the polypill, lower dose requirements); patient populations (low economic development, younger patients, etc.) or genetic variations to therapeutic response (i.e. ACE-I).

Variations in clinical setting and "usual care" may also influence the conduct of global clinical trials. Important country level differences may exist in the availability of established therapies; the use of non-standard treatments such as traditional Chinese medicine, and nutrition and lifestyle patterns (i.e. smoking).

Additional challenges in developing countries may include unfamiliarity with clinical research standards and paradigms, difficulty with enrolment and monitoring; loss to follow-up etc. In contrast, in developed countries challenges may include reluctance of physicians and/or patients to enrol in trials, or scepticism related to big pharma. Such challenges may explain why the US is increasingly listed among the lowest contributors in large global trials. Yet, globalization of trials has so many advantages.

The objective of the session is to gain insight in local/regional conditions with the aim of maximizing quality and efficiently of CV trials and improve generalizability of the results of these trials.

Income inequality and trial performance and outcomes.
Pooja Dewan (Glasgow, GBR)

Regional Perspectives

- **Africa and Middle East:** Faiez Zannad (Nancy, FRA)
- **Eastern Europe:** Simon Matskeplishvili (Moscow, RUS)
- **Asia:** Carolyn Lam (Singapore, SIN); Lijing Yan (Kunshan, CHN)
- **LATAM Countries:** Felipe Martinez (Cordoba, ARG)

Industry Viewpoint
Adel Rizkala (Novartis, USA)

Regulatory Viewpoint
Robert Temple (FDA, USA)

Patient Viewpoint
Stefan Teunis (Oldenzaal, NED)

THE FORUM
Moderated Multi-Stakeholder ExpertPanel Debate with the Audience

Panelists: Ashraf El Fiky (Washington, USA); Koji Hasegawa (Kyoto, JPN); Larry Husten (CardioBrief, USA); John Jarcho (NEJM, USA); Carolyn Lam (Singapore, SIN); Felipe Martinez (Cordoba, ARG); Simon Matskeplishvili (Moscow, RUS); Manal Milhem (Atlanta, USA); Stuart Spencer (The Lancet, GBR); Lijing Yan (Kunshan, CHN); Faiez Zannad (Nancy, FRA)

AUDITORIUM

8.00 – 10:00 AM
PRIMARY AND SECONDARY PREVENTION USING CARDIAC BIOMARKERS (I) WILL RESEARCH TRANSLATE INTO IMPROVED OUTCOMES?

Moderators: James Januzzi (Boston, USA), Jean-Claude Tardif (Montreal, CAN)

Biomarker tests remain the primary diagnostic paradigm with huge potential for innovation and hold the potential to better tailor medications to patients and monitor treatment response. Yet, despite thousands of publications on biomarkers published each year and with these numbers continuously increasing, the anticipated outcome with the transformation of the published findings into improvements in clinical practice is not immediately evident. The vast-majority of blood tests in use currently are decades old and specifically in the cardiovascular space over the past two decades there has been only one new plasma biomarker introduced as a diagnostic test for routine clinical use.

To achieve implementation, well-powered clinical studies are required in the appropriate population, addressing a specific clinical need and with a clear context of use. Efforts towards implementation must be supported by the key players, i.e. industry, regulators, clinical scientists, sponsors, etc. Patient advocacy groups should lobby stakeholders in order to make CV precision medicine catch up with oncology.

In addition to discovery studies, well-designed prospective trials should be able to demonstrate the practical value of actionable biomarkers. It is therefore imperative that all major CV outcome trials systematically collect bio-samples. Practice of collecting samples in such industry trials and making little or no use of them should not occur anymore.

Precision medicine will likely be possible based on multi-marker panels, not on single markers. While the cost of diagnosis/patient assessment may increase, the overall cost and effectiveness of disease management may actually decrease, by avoiding unnecessary exposure to potential non-responders or to patients who might be intolerant to a specific treatment.

Intellectual property protection of biomarkers already seems impossible, even worse for multi-marker panels. Following the landmark Mayo v. Prometheus, case the US Patent and Trademark Office (USPTO) 2014 guidance denies claims directed to laws of nature, natural phenomena, and abstract ideas. It is under those circumstances that a patent application that aimed to seek IP protection for measuring PCSK9 in plasma to support medical decision-making under various circumstances was rejected. Until the patent law may be challenged, specific algorithms, and trial data that demonstrate significant added value, may confer protection. A large database of multiple parameters together with clinical information and especially follow up may well be the key to IP protection; as long as the database is not shared, this is almost as good, probably even better as IP protection.

The objective of this session is to discuss the value and validity of recent biomarker findings, assess how little implementation has progressed and discuss how progress may be sought, in the interest of useful innovations and patient care.

Identifying Subclinical Cardiovascular Disease Using Cardiac Biomarkers: Do We Need to Refine Existing Risk Models? Which Marker Should We Use?
Torbjorn Omland (Lørenskog, NOR)

How Can Biomarkers Help to Better Understand Cardiovascular Risk?

- **In the US Population**
  Dan Levy (Boston, USA)
- **In EU Population**
  Peter van der Meer (Groningen, NED)

Multimarker Strategies in the Prediction of MACE in Patients with Known CAD
Arshed Quyyumi (Atlanta, USA)

Multimarker Strategies in the Prediction of New Onset Heart Failure (HOMAGE and other results)
Faiez Zannad (Nancy, FRA)

How can Causal Integrative Analysis of Biomarkers and Genomic Data Inform Therapeutic Approaches in Heart Failure?
Tom Lumbers (London, GBR)

Recent and Ongoing Biomarker Precision Medicine Trials

- **In CAD**
  Patrick Lawler (Toronto, CAN)

- **In Heart Failure**
  Alexandre Mebazaa (Paris, FRA)

Case: Cohort and Extensive Proteomics for CV Surrogate Endpoint Discovery and Validation
Stephen Williams (Somalogic, USA)

Statistician Viewpoint
Brian Claggett (Boston, USA)

Q & A DISCUSSION

AUDITORIUM

10:30 AM – 12:30 PM
PRIMARY AND SECONDARY PREVENTION USING CARDIAC BIOMARKERS (II)
STAKEHOLDER VIEWPOINT

Moderators: James Januzzi (Boston, USA), Jean-Claude Tardif (Montreal, CAN)

State of the State in Cardiovascular Diagnostics: Does the Current System Allow Innovation?
Kristin Pothier (EY-Parthenon, Ernst & Young LLP, Boston, USA)

Industry Viewpoint: Gillian Murtagh (Abbott Diagnostics, USA); Josh Porter (Olink, USA); André Ziegler (Roche, CHE)

Regulatory Viewpoint: What is it needed to Approve the Clinical Use of a Biomarker?

- **Qualification Process**
  Robert Hemmings (EMA, GBR); Christopher Leptak (FDA, USA)

- **Scientific Basis for the Regulatory Adoption**
  Norman Stockbridge (FDA, USA)

Patient Viewpoint
Jayna Williams (New Hampshire, USA)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
WHAT IS IT NEEDED TO APPROVE AND USE A NEW BIOMARKER FOR RISK PREDICTION AND THERAPEUTIC ACTION IN CLINICAL PRACTICE?

Moderators: James Januzzi (Boston, USA), Jean-Claude Tardif (Montreal, CAN)

Panelists: João Ferreira (Nancy, FRA); Robert Hemmings (EMA, GBR); Anne Cécile Huby (Nancy, FRA); James Januzzi (Boston, USA); Christopher Leptak (FDA, USA); Gillian Murtagh (Abbott Diagnostics, USA); Josh Porter (Olink, USA); Kristin Pothier (EY-Parthenon, Ernst & Young LLP, Boston, USA); Norman Stockbridge (FDA, USA); WH Wilson Tang (Cleveland, USA); Jean-Claude Tardif (Montreal, CAN); Jayna Williams (New Hampshire, USA); André Ziegler (Roche, CHE)

AUDITORIUM

12:40 – 1:10 PM
KEYNOTE
Tribute to Ray Lipicky
Rob Califf (Durham, USA), Milton Packer (Dallas, USA), Robert Temple (FDA, USA)

AUDITORIUM

2:00 – 4:00 PM
ONGOING HEART FAILURE TRIALS (I)
LOOKING INTO THE CRYSTAL BALL
CVCT & HFSA Joint Session

Moderators: Michael Felker (Durham, USA); Christopher O'Connor (Washington, USA)

Many trials of new therapies for patients with heart failure are ongoing. Trials that demonstrate a benefit on clinical outcomes have the potential to change practice, but the uptake of evidence from clinical trials can be variable, even when the trial has been rigorously conducted and the data are robust. This heterogeneity in uptake can be related to other factors such as cost or delays in payer approval, concerns about adverse effects or polypharmacy, skepticism about the clinical relevance of treatment effects (if they are relatively small), a belief that the study population is not representative, or physician inertia. This session will discuss what may happen in clinical practice depending on hypothetical scenarios and predictions of whether or not ongoing trials will demonstrate a beneficial effect on outcomes

Discussion on varying scenarios based on prediction of the trial achieving or not its primary result

- With live audience interaction
- Internet interaction using the App
- Audience opinion poll pre- and post- debate to determine shift in results

Sacubutril Entresto Trials (PARAGON-HF, PARADISE-MI)
Scott Solomon (Boston, USA)

Omecamtiv mecarbil GALACTIC – HF
John Teerlink (San Francisco, USA)

Vericiguat VICTORIA
Paul Armstrong (Edmonton, CAN)

SGLT2 Inhibitors EMPEROR, DAPA-HF
Javed Butler (Jacksonville, USA)

Endothelin Antagonists, the Right Ventricle and HFPEF with Pulmonary Hypertension Trials SERENADE
Sanjiv Shah (Chicago, USA)

Iron Deficiency Trials
Stefan Anker (Berlin, GER)

Mineralocorticoid Receptor Antagonists, SPIRRIT
Lars Lund (Stockholm, SWE)

Toresamide
Robert Mentz (Durham, USA)

Proposal for a Novel Drug combination of SGLT2 Inhibitor with Torsemide ER for CHF
Christopher Wilcox (Sarfez Inc, USA)

Amyloid Cardiomyopathy Trials
Claudio Rapezzi (Bologna, ITA)

Q & A DISCUSSION

AUDITORIUM

4:30 – 7:00 PM
ONGOING HEART FAILURE TRIALS (II)
LOOKING INTO THE CRYSTAL BALL
CVCT & HFSA Joint Session

Moderators: Michael Felker (Durham, USA); Christopher O'Connor (Washington, USA)

Cell Therapy Trials
Andreas Zeiher (Frankfurt, GER)

Moving from Phase II to Phase III
Sanjiv Shah (Chicago, USA)

Mega Studies in HF – the Good, the Bad and the Unknown: The Serelaxin Case Study
Beth Davison (Momentum Research, USA)
Claudio Gimpelewicz (Novartis, USA)

A Statistical Perspective
Stuart Pocock (London, GBR)

Device Trials
William Abraham (Columbus, USA)

Remote Monitoring and Disease Management Program Trials
Martin Cowie (London, GBR)

Biomarker Guided Trials (ICON RELOADED, STRONG HF)
James Januzzi (Boston, USA)

The Value (or not) of Using Repeat Events in Heart Failure Trials
Brian Claggett (Boston, USA)

Regulatory Viewpoint
Angeles Alonso (EMA, GBR), Ileana Piña (FDA, USA); Norman Stockbridge (FDA; USA)

Patients Viewpoint
Jillianne Code (Vancouver, CAN)

THE FORUM
Moderated Multi-Stakeholder Expert Panel Debate with the Audience
ARE WE PREPARED FOR OPTIMAL IMPLEMENTATION AND MANAGEMENT OF POLYPHARMACY IN HF?

Moderators: James Januzzi (Boston, USA), Jean-Claude Tardif (Montreal, CAN)

Panelists: William Abraham (Columbus, USA); Angeles Alonso (EMA, GBR); Stefan Anker (Berlin, GER); Paul Armstrong (Edmonton, CAN); Javed Butler (Jacksonville, USA); Brian Claggett (Boston, USA); Jillianne Code (Vancouver, CAN); Martin Cowie (London, GBR); Beth Davison (Momentum Research, USA); Justin Ezekowitz (Edmonton, CAN); Michael Felker (Durham, USA); João Ferreira (Nancy, FRA); Claudio Gimpelewicz (Novartis, USA); Nicolas Girerd (Nancy, FRA); James Januzzi (Boston, USA); Lars Lund (Stockholm, SWE); Robert Mentz (Durham, USA); Christopher O'Connor (Washington, USA); Ileana Piña (FDA, USA); Stuart Pocock (London, GBR); Claudio Rapezzi (Bologna, ITA); Jean Rouleau (Montreal, CAN); Sanjiv Shah (Chicago, USA); Scott Solomon (Boston, USA); Norman Stockbridge (FDA, USA); John Teerlink (San Francisco, USA); Christopher Wilcox (Sarfez Inc, USA); Andreas Zeiher (Frankfurt, GER)

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, patient and patient representatives, 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 2018:

Ahmed Albadri
Robert Avram
Kevin Bainey
Archna Bajaj
David Berg
Ankheet Bhatt
Yiorgos Bobetsis
Sergio Buccheri
Alvin Chandra
Christopher Cheung
Julio Chirinos
Bimmer Claessen
Amit Dey
Katie Dodd
Marat Fudim
Michael Garshick
Lucas Godoy
Niels Grote Beverborg
Kemely Guzman
Dagmar Hernandez-Suarez
Alexa Hollinger
Alice Jackson
Xurui Jin
Rekha Kambhampati
Konstantinos Konstantinou
Shuangbo Liu
Guillaume Marquis-Gravel
Pieter Martens
Albulena Mecinaj
Naoki Misumida
Yusuke Miyazaki
Hamed Nazzari
Ayodele Odutayo
Ravi Patel
Pierpaolo Pellicori
Johannes Petutschnigg
Mitchell Psotka
Mehnaz Rahman
Aniket Rali
Pratik Sandesara
Gianluigi Savarese
Nigar Sekercioglu
Martin Serg
Camilla Settergren
Abhinav Sharma
Matthew Shun-Shin
Shashank Sinha
Konstantinos Siontis
Nathaniel Smilowitz
Konstantinos Stathogiannis
Susan Stienen
Edlira Tam
Jozine Ter Maaten
Jasper Tromp
Michael Wilkinson
Joseph Zaccaria
Rosita Zakeri

CVCT LIBRARY AND CVCT PUBLICATIONS

We offer a complete record of previous CVCT Forum presentations, including the webcast programs for 2011 and 2012, which are 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 the latest CVCT publications.

In addition we are pleased to welcome this year's young writer team:
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. Mentz and Dr. Fiuzat alongside Dr. Ferreira and Dr. Vaduganathan as they work with junior faculty and fellows:

David Berg
Ankeet Bhatt
Dario Cani
Marat Fudim
Ravi Patel
Pierpaolo Pellicori
Gianlugi Savarese
Abhinav Sharma
Susan Stienen
Jozine Ter Maaten
Jasper Tromp

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

2018

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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

WITH THE PARTICIPATION OF

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 **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

The **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 Transplantation 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 **French Clinical Research Infrastructure Network**, (F-CRIN), 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

Alexandre Abizaid (Sao Paulo, BRA)

Alexandre Abizaid is the Director of Intervential Cardiology at the institute Dante Pazzanese of Cardiology in Sao Paulo, Brazil. A faculty member at the Cardiovascular Research Foundation and Visiting Professor of Medicine at Columbia University Medical Center, both in New York. Dr. Abizaid is an Interventionalist Cardiologist at Sirio Libanes Hospital and at Hosital do Coracao in Sao Paulo. He received his Medical Degree from the Fedeal University of Juiz de Fora in Brazil as well as his post-doctoral training as a resident in Internal Medicine. Dr. Abizaid is a member of the Sao Paulo State of Brazil Society of Cardiology, the Brazilian Society of Cardiology, the Latin Amrican Society of Interventional Cardiology, the Sao Paulo State of Brazil Socieyt of Interventional Cardiology, a fellow of the American College of Cardiology and a Board Trustee of the Society of Cardiac Interventions.

William Abraham (Columbus, USA)

William Abraham earned his Medical Degree from Harvard Medical School and completed post-graduate training in Internal Medicine, Cardiovascular Medicine, and Advanced Heart Failure/Transplant Cardiology at the University of Colorado. At Ohio State University, Dr. Abraham holds several leadership positions, including Associate Dean for Clinical Research and Director of Cardiovascular Medicine. He has been recognized as one of the “Best Doctors in America” for 16 consecutive years and is ranked among the top 10% of physicians nationally in patient satisfaction. He has participated in all clinical/regulatory phases of new drug and device development. His work has led to the approval/adoption of new heart failure therapies, including beta-blockers, natriuretic peptides, cardiac resynchronization therapy, ultrafiltration, implantable hemodynamic monitoring, and transvenous phrenic nerve stimulation. He has authored more than 1,000 original works and been named a Clarivate Analytics Highly Cited Researcher and one of The World’s Most Influential Scientific Minds. He received the 2017 Distinguished Scientist Award from the American College of Cardiology.

Kirkwood F. Adams Jr. (Chapel Hill)

Kirkwood F. Adams Jr., 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.

Tariq Ahmad (New Haven, USA)

Tariq Ahmad is an Assistant Professor in the Section of Cardiovascular Medicine at the Yale University School of Medicine and an Investigator in the Center for Outcomes Research and Evaluation (CORE). His interest lies in the use of advanced analytics to improve phenotyping of heart failure and to use the EHR and mobile health technologies to perform pragmatic clinical trials across large health care systems. He

completed his clinical training at Brigham and Women's Hospital (Internal Medicine) and Duke University School of Medicine (Cardiology and Advanced Heart Failure). He has an MPH from the Harvard School of Public Health and did a fellowship in cardiovascular research at the Duke Clinical Research Institute. He is actively involved in numerous research studies in heart failure, ranging from translational research involving novel biomarkers, to registries, and clinical trials. His scholarly work has been published in JAMA, Circulation, and the Journal of the American College of Cardiology. He has served in leadership positions at the ACC. He is passionate about the role of physicians in leading the big data revolution in medicine.

Cat Davis Ahmed (Pasadena, USA)

Cat Davis Ahmed is Vice President, Policy and Outreach for the FH Foundation, where she works with individuals with Familial Hypercholesterolemia (FH) and the medical professionals who treat them to raise awareness of FH and improve the understanding, diagnosis, and care of this life-threatening genetic condition that too often leads to early heart disease. As someone who has FH herself, she knows first hand the impact the disorder can have on individuals and families. Cat works on a national level to advocate on behalf of individuals with FH with policy makers and other decision makers to ensure that FH is recognized and understood as a distinct genetic disorder affecting approximately 1.3 million Americans. The FH Foundation is a non-profit, patient-centered, research and advocacy organization dedicated to increasing the rate of early diagnosis and encouraging proactive treatment of FH in order to prevent premature heart disease. Cat holds an MBA from the Yale School of Management.

Jacqueline Deloach Alikhaani (Los Angeles, USA)

Jacqueline Deloach Alikhaani is a Los Angeles based Heart Survivor/Patient/Volunteer. She is a graduate of the University of Southern California and serves as a PCORI-American Heart Association Organizational Ambassador, Citizen Scientist, and WomenHeart Champion.

As a PCOR(Patient-Centered Outcomes Research) Engagement Patient-Partner/ADAPTOR, she serves as a patient representative for several PCORI(Patient-Centered Outcomes Research Institute) Funded CER PCORnet projects.

Her interests include national/global Patient-Centered Outcomes Research engagement to help address disparities in healthcare for traditionally under-served communities, and rare disease patients. To help improve care for all patients living with chronic, disabling and life-threatening medical conditions.

Jacqueline is also a long-time IVCLA-International Citizen Diplomat for the City of Los Angeles.

Her primary objective is to help represent the patient/healthcare-consumer voice by using her personal medical story/healthcare experiences to help determine and voice best-practices that help advance clinical care and daily quality-of-life for healthcare-consumers/patients, family members and caregivers by better use of PROs(Patient-Reported-Outcomes).

Sadegh Alikhaani (Los Angeles, USA)

Sadegh Alikhaani is a Healthcare-Consumer/Heart & Stroke Survivor/Patient/CER Advocate. He is a graduate of the University of Southern California School of Engineering and serves as a PCORI & American Heart Association Ambassador and UCLA(University of California-Los Angeles) Volunteer Patient Advocate.

As a CER (Comparative Effectiveness Research) Advocate, his volunteer interests include national/global Patient-Centered Outcomes Research engagement targeting the areas of prevention, diagnosis, and treatment of heart patients, potential heart patients and traditionally under-served CVD segments such as rare disease patients.

Sadegh is also a long-time IVCLA-International Citizen Diplomat for the City of Los Angeles.

While he is a career Aerospace Mechanical Engineer/Scientist by profession, his latest self-

adopted mission command is to combine his voice, medical experiences and support with his family members and others to help advance the use of PROs(Patient-Reported Outcomes) into research and clinical care to help improve patient-centered care.

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) and PhD at the Medical School (1991). She was a staff member of the Department of Cardiology at the Academic Hospital Puerta de Hierro (Madrid), between 1987 and 2013 with several positions: 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.

Stefan Anker (Berlin, GER)

Stefan Anker is Professor of (Tissue)Homeostasis in Cardiology & Metabolism (W3) at Charité Berlin (June 2017 to present). He studied medicine at Charité Berlin and completed his clinical training in Germany and the UK. He obtained his Medical Degree from Charité Medical School, Berlin, Germany (1993), and his Ph.D. (1998) at National Heart & Lung Institute of Imperial College London. He was Professor of Cardiology & Cachexia Research (W2) at Charité (2002-2014), and Professor of Innovative Clinical Trials (W3) in Göttingen (2014-2017). Dr. Anker has authored more than 800 original papers, reviews, and editorials that are well cited.

Dr. Anker has won several prizes, including the 2018 Copernicus Prize of German DFG & Polish FNP. He was Vice President of the European Society of Cardiology (2016-2018), serving on the ESC board 2012-2018. Dr. Anker serves in the board of the Heart Failure Association of the ESC since 2006; he was HFA President (2012-14). He is founding Editor-in-Chief of the open access journal ESC Heart Failure.

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. 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 of Circulation: Heart Failure, a senior advisory editor for Circulation, guest editor for the American Heart Journal and JACC Heart Failure, and is a member of several editorial boards including those of the American Heart Journal, the European Heart Journal and JAMA Cardiology. 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). He was the founding President of the Canadian Academy of Health Sciences (CAHS) a Fellow of the Royal Society of Canada and an Officer in the Order of Canada.

Alejandro Arrieta (Miami, USA)

Alejandro Arrieta is a health economist in the Department of Health Policy and Management at Florida International University. He is also the director of Healthcare Management Americas, an initiative to build capacity and research to enhance patient safety in Latin America and the Caribbean. Dr. Arrieta has served as principal investigator, co-investigator and consultant in studies assessing the economic evaluation of technological devices to improve self-control of hypertension, cholesterol-lowering drugs, smoking cessation programs, care management programs to improve diabetes control, and retrofitting projects to improve hospital safety. He has more than 20 publications in journals such as Health Economics, Social Science and Medicine, World Development and JAMA cardiology. He holds a PhD in Economics from Rutgers University and a BA in Economics from Universidad Catolica in Peru.

Usman Baber (New York, USA)

Usman Baber is an Assistant Professor of Medicine at the Icahn School of Medicine at Mount Sinai and serves as the Director of Clinical Biometrics in the Office of Interventional Cardiovascular Research and Clinical. Dr. Baber is a graduate of Rice University and earned his Medical Degree at the University of Texas Southwestern Medical Center, where he also completed his Internship and Residency in internal medicine. He moved to New York City where he completed fellowships in Clinical Cardiology and Coronary Vascular Intervention at the Mount Sinai Medical Center. During his fellowship training he also earned a Master's Degree in biostatistics from the Mailman School of Public Health at Columbia University.

Dr. Baber is a practicing Cardiologist with a clinical interest in coronary intervention. He is a lecturer for the Cardiovascular Pathophysiology course for second year medical students at the Icahn School of Medicine and also serves on the faculty for the annual Interventional Cardiology Board Review Course sponsored by the American College of Cardiology and the Society of Coronary Angiography and Interventions.

Colin Baigent (Oxford, GBR)

Colin Baigent is Director of the MRC Population Health Research Unit and Deputy Director of the Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU) at the University of Oxford, where he is Professor of Epidemiology. He has led some of the world's largest collaborative meta-analyses of randomized trials, typically with individual participant data, resulting in landmark papers that have helped determine, for example, the effects of statins and aspirin in different types of people. He led the Study of Heart and Renal Protection (SHARP), the largest ever randomized trial in patients with moderate-to-severe chronic kidney disease (CKD), recruiting 9438 patients in nearly 400 hospitals in 18 countries. His group is now coordinating the EMPA KIDNEY trial, a trial comparing empagliflozin versus placebo in 5000 patients with CKD, which is designed to assess the effects of empagliflozin on progression to ESRD or cardiovascular death.

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. 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 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.

Erin Bohula (Boston, USA)

Erin Bohula is an Associate Physician in Cardiovascular Medicine at Brigham and Women's Hospital, an Instructor of Medicine at Harvard Medical School, and an Investigator at the TIMI Study Group. Dr. Bohula earned her Doctor of Philosophy (D.Phil.) in Molecular Biology from Oxford University on a Rhodes Scholarship and her Medical Degree from Harvard Medical School. She completed her internal medicine residency and fellowships in cardiovascular medicine and critical care medicine at Brigham and Women's Hospital. She is board certified in internal medicine, cardiology, and critical care medicine. In her role as a TIMI Study Group Investigator, Dr. Bohula studies pharmacologic interventions for atherosclerotic cardiovascular disease. As a cardiac intensivist and researcher, she is interested in innovative therapies and devices for critically-ill cardiovascular patients. In addition to her scientific and trial responsibilities, Dr. Bohula is an active member of the clinical staff at Brigham and Women's hospital and attends in the Cardiology Critical Care Unit and inpatient General Cardiology Service.

Kelley Branch (Washington, USA)

Kelley Branch is an Associate Professor in cardiology at the University of Washington in Seattle, WA with a research focus in clinical trials and advanced cardiac imaging. His research support included the NIH KL2 Mentored Training Grant and is currently supported by grants from the NIH and clinical trials. He is Associate Director of the Clinical Trials Service Unit, which facilitates international clinical trials, and is Director of Cardiovascular Clinical Trials Unit. He is also on the Board of Directors for the Society of Cardiovascular CT and on the Editorial Board of European Radiology. Other awards include the American College of Cardiology/Merck Fellowship Award, the Cardiology Teaching Excellence Award, the University of Washington School of Medicine Outstanding CME Teacher and the ACC Emerging Faculty award. His most recent research has been dissemination of the completed rivaroxaban/aspirin arm of COMPASS clinical trial that showed significant cardiovascular benefit of the combined therapy.

Javed Butler (Jacksonville, USA)

Javed Butler is the Patrick A. Lehan Professor and Chairman of the Department of Medicine Department at University of Mississippi. Prior to joining the University of Mississippi, he was Charles A. Gargano Professor and Director of the Division of Cardiovascular Medicine and Co-Director of the Heart Institute at Stony Brook University, New York. He had served as the Director for heart failure research at Emory University and Director of the heart and heart-lung transplant programs at Vanderbilt University prior to that.

He received his Medical Degree from the Aga Khan University in Karachi, Pakistan. He then completed residency training at Yale University, cardiology fellowship and advanced heart failure and transplant fellowships at Vanderbilt University, and cardiac imaging fellowship at the Massachusetts General Hospital, Harvard Medical School in Boston, Massachusetts. He has completed Master of Public Health degree from Harvard University and Master in Business Administration from Emory University.

He serves on several national committees for the American College of Cardiology, American Heart Association, and the National Institutes of Health, and serves on the Heart Failure Society of America Board of Directors.

Robert M. Califf (Durham, USA)

Robert M. Califf 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 fi rst fi ve 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.

William Chong (FDA, USA)

William Chong is the Acting Deputy Director of the Division of Metabolism and Endocrinology Products at the Food and Drug Administration (FDA). He earned his Medical Degree from Temple University and completed his Internal Medicine training at Thomas Jefferson University Hospital in Philadelphia, PA. Dr. Chong went on to complete his fellowship in Endocrinology and Metabolism at the National Institutes of Health before joining the FDA in 2012. During his time at the FDA, Dr. Chong has worked primarily with drug products that alter glucose metabolism and has served as a team leader and Acting Director of the Division of Metabolism and Endocrinology Products.

Jennifer Christian (IQVIA, USA)

Jennifer Christian is Vice President of Clinical Evidence & Epidemiology at IQVIA, where she provides scientific oversight to the design and conduct of innovative, real world studies. Her research has focused on strengthening clinical effectiveness and safety evaluations of newly approved treatments through advanced epidemiology methods and conducting patient centered analyses. Christian has published numerous articles, including editor of AHRQ's "21st Century Registries" book and author on the National Academy of Medicines' paper, "Generating Knowledge from Best Care: Advancing the Continuously Learning Health System". She is a National Academy of Medicine Anniversary Fellow and adjunct faculty within the Division of Clinical Epidemiology and Evaluative Sciences Research at Weill Cornell Medical College. She is a Fellow and former board member of the International Society of Pharmacoepidemiology and a graduate of the UNC- Chapel Hill School of Pharmacy & School of Public Health, and Brown University School of Public Health.

Brian Claggett (Boston, USA)

Brian Claggett is an Associate Scientist in the Division of Cardiovascular Medicine at Brigham and Women's Hospital and Instructor in Medicine at Harvard Medical School. He received a PhD in Biostatistics from Harvard University in 2012. He has collaborated with researchers in a variety of disease areas, including HIV/AIDS, diabetes, and heart failure. His methodological research includes topics relevant to the analysis of clinical trials, including survival analysis, multiple patient-level outcomes, meta-analysis, and the identification of patient subpopulations who may or may not respond to a novel treatment. Dr. Claggett has continued to pursue «translational statistics», bringing relevant statistical concepts to a clinical research audience. He has more than 50 peer-reviewed publications and has served as statistician for large, multinational, phase-III clinical trials.

Gad Cotter (Monumentum Research, USA)

Gad Cotter co-founded in 2007 Momentum Research, Inc., a company who through its consulting services aims to ensure the sound evaluation of cardiovascular therapies. Gad received his graduate training in Medicine at the Hebrew University in Jerusalem, Israel and has held positions in the academical and consulting firms. Gad has played a key role in the development of heart failure therapies including rolofylline, serelaxin, and a cardiopoietic stem cell therapy, serving as an Executive Committee member for several trials. Gad's interests include prognostication in acute heart failure, endpoint selection and operational factors in heart failure clinical trials, and the worldwide management of heart failure. He has authored numerous peer-reviewed manuscripts and several editorials and is an in the editorial board of the European Journal of Heart Failure.

Jillian Code (Vancouver, CAN)

Jillian Code is currently an Assistant Professor in the Faculty of Education at the University of British Columbia. Prior to this she completed a Post-Doctoral Research Fellowship at the Harvard Graduate School of Education, and holds a PhD in Educational Psychology, and a Masters of Educational Technology. Dr. Code's most important role, however, is that of a heart failure survivor and two-time heart transplant recipient. Following her first heart transplant, Dr. Code worked hard to advocate for the inclusion of patients as partners in health care research and practice. As such she has served as Co-Chair of the oversight and advisory committee for Patient Voices Network, member of the Steering Committee for Cardiac Services BC, and member on the Medical Services Commission of BC. I am also an active keynote speaker, and in July 2016 Dr. Code co-founded the HeartLife Foundation, Canada's first – and only – national patient-led heart failure organization.

Martin Cowie (London, GBR)

Martin Cowie is Professor of Cardiology at Imperial College, London, UK and Honorary Consultant Cardiologist at the Royal Brompton Hospital, London. A founding member and past-chairman of the British Society for Heart Failure, Professor Cowie has also been a Board Member (and Chair of the Education Committee) of the Heart Failure Association of the European Society of Cardiology (ESC). From November 2016, he has been a Non-Executive Director of the National Institute for Health and Care Excellence (NICE) in England. He has advised that organization on its heart failure guidelines and quality standards. He sits on the Cardiovascular Round Table and the EU Affairs Committee of the ESC, and leads its work in e-health, recently being appointed as Chair of the e-health Unit at the European Heart Health Institute in Brussels. He was shortlisted for the NHS Digital Champion (Leadership) Award in 2017.

Professor Cowie's studies and reviews have been featured in a variety of peer-reviewed journals, including The New England Journal of Medicine, The Lancet, Circulation, JAMA, European Heart Journal, British Medical Journal, and the European Journal of Heart Failure.

Donald Cutlip (Boston, USA)

Donald Cutlip is Vice Chair Department of Medicine at Beth Israel Deaconess medical Center and Professor of Medicine at Harvard Medical School. His research interests are related to clinical outcomes after percutaneous coronary intervention. He is Director of Clinical Operations at Baim Institute for Clinical Research and has been involved in the design and management of a number of pivotal clinical trials in interventional cardiology. He co-founded the Academic Research Consortium (ARC) that has led efforts for standardization of endpoint definitions in coronary stent and other cardiac device clinical trials. He has published a number of original papers related to clinical outcomes after percutaneous coronary intervention and clinical trial methodology and serves as Section Editor of Interventional Cardiology for the electronic textbook of medicine, UpToDate.

Nikolaos Dagres (Leipzig, GER)

Nikolaos Dagres is Consultant Electrophysiologist at the Heart Center Leipzig in Germany. He is Chair of the Scientific Documents Committee and member of the board of the European Heart Rhythm Association. He is also Deputy Editor of the EP Europace journal and chair of the Atrial Fibrillation Ablation Long-Term Registry of the ESC. He has a particular research interest in sudden cardiac death and in international randomized trials in the field of arrhythmias. He is Deputy Chair of the Steering Committee of the RESET-CRT randomized trial in the field of cardiac devices.

Kirsten Dahlgren (Michigan, USA)

Kirsten Dahlgren resides in Michigan with family scattered up and down the east coast. A 1987 graduate of Indiana University with a Degree in Chemistry, she continued her studies at the Henry Ford Hospital School of Nursing and The University of Michigan, receiving a Master's Degree in health services administration. Kirsten began her career at Henry Ford Hospital as pediatric nurse handling complex pediatric illnesses and then took her skills to administration at Henry Ford where she worked in utilization management, maximizing revenues for the hospital and eventually leading the Department handling insurance denials and appeals including both commercial and governmental insurers.

In 2005, Kirsten was diagnosed with severe heart failure (EF 5%). Working with her doctor, adhering to the medication regimen, and with sheer determination, Kirsten was able to survive and even began to play tennis again. During her initial treatment, Kirsten participated in a couple of clinical trials offered through her provider. It was through the lessons learned from these clinical trials, as well as others, that she is now able to lead a somewhat normal "cardiac life".

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.

Beth Davison (Momentum Research, USA)

Beth Davison co-founded in 2007 Momentum Research, Inc., a company who through its consulting services aims to ensure the sound evaluation of cardiovascular therapies. She received her graduate training in epidemiology and biostatistics at UNC School of Public Health, and has held positions in the pharmaceutical and CRO industries, academia, and consulting firms. Beth has played a key role in the development of heart failure therapies including rolofylline, serelaxin, and a cardiopoietic stem cell therapy, serving as an Executive Committee member for several trials. Beth's interests include prognostication in acute heart failure, endpoint selection and operational factors in heart failure clinical trials, and the worldwide management of heart failure. She has authored numerous peer-reviewed manuscripts and several editorials and is an Associate Editor of the European Journal of Heart Failure.

Thomas Deering (Atlanta, USA)

Thomas Deering is Chief of the Arrhythmia Center, Chairman of the Clinical Centers for Excellence and Chief Quality Officer for Piedmont Heart Institute in Atlanta. He has served in a variety of volunteer roles within HRS and presently serves as president. His research interests are focused on defining and implementing quality initiatives in electrophysiology and cardiovascular medicine. He has served as a speaker and moderator at national and international electrophysiology and cardiology meetings. Dr. Deering earned his Medical Degree from Yale University School of Medicine. He completed his residency at the Yale-New Haven Hospital, his cardiology fellowship training at Boston University Medical Center and his cardiac electrophysiology fellowship at Tufts New England Medical Center.

Efthymios "Makis" Deliargyris (PLX Pharma INC, USA)

Efthymios "Makis" Deliargyris is the Chief Medical Officer of PLX Pharma, Inc. Dr. Deliargyris is a triple board-certified physician (internal medicine, cardiology and interventional cardiology). Most recently, Dr. Deliargyris was the founder and managing director of the Science and Strategy Consulting Group providing expert advice on scientific, regulatory, strategic and commercialization challenges to companies engaging in the cardiovascular arena. He served as Global Medical Lead of the Cardiovascular franchise at The Medicines Company where he led global medical strategy, global medical affairs and late stage R&D activities with successful FDA and EMA presentations leading to the approval of Cangrelor in both US and Europe.

He served as Chief, Cardiology and Interventional Cardiology at Athens Medical Center in Athens, Greece from 2004 until 2010 and as Assistant Professor of Cardiology and Director of the Intravascular Laboratory (IVUS) at Wake Forest University in Winston- Salem, NC from 2001 to 2004. He received his Medical Degree from the Kapodistrian University of Athens School of Medicine and completed his residency training in internal medicine at Tufts University School of Medicine and his fellowships in cardiology and interventional cardiology at the University of North Carolina at Chapel Hill.

Alex Denner (Greenwich, USA)

Alex Denner is the founding partner and chief investment officer of Sarissa Capital Management LP, which he founded in 2012. Sarissa Capital focuses on improving the strategies of companies to enhance shareholder value. Sarissa Capital has been involved in lucrative healthcare deals including Idenix Pharmaceuticals, ARIAD Pharmaceuticals and most recently Bioverativ Inc. Dr. Denner played pivotal roles in the sale of ARIAD

Pharmaceuticals to Takeda in 2017 for $5.2 billion and the recent sale of Bioverativ Inc to Sanofi early this year for $11.6 billion. From 2006 to 2011, Dr. Denner served as a Senior Managing Director at Icahn Capital. Prior to that, he served as a portfolio manager at Viking Global Investors, and Morgan Stanley Investment Management. Dr. Denner currently serves as a director of Biogen Inc., and The Medicines Company. He also previously served as a director of ARIAD Pharmaceuticals, Inc., where he also served as Chairman, Amylin Pharmaceuticals, Inc., Bioverativ Inc., Enzon Pharmaceuticals, Inc., ImClone Systems Incorporated where he also served as Chairman of the Executive Committee. Dr. Denner received his S.B. degree from the Massachusetts Institute of Technology and his M.S., M.Phil. and Ph.D. degrees from Yale University.

Pooja Dewan (Glasgow, GBR)

Pooja Dewan is a PhD candidate at the Institute of Cardiovascular and Medical Sciences; University of Glasgow, UK. Her research, under the supervision of Prof. John McMurray and Dr. Pardeep Jhund, focuses on the effects of socio-economic factors and multimorbidity on heart failure. Dr. Dewan received her medical degree from the Sikkim Manipal Institute of Medical Sciences and a MSc in cardiovascular sciences from the University of Glasgow.

Peter DiBattiste (Janssen, USA)

Peter M. DiBattiste 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, Dr. DiBattiste 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 his 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. Dr. DiBattiste is focused on the continued development of Xarelto, and on the continued exploration and development of novel antithrombotics.

Pete obtained his Medical Degree 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.

Jun Dong (FDA, USA)

Jun Dong is a medical officer and senior clinical reviewer at the Center for Devices and Radiological Health (CDRH), US Food and Drug Administration (FDA). He serves as the primary medical officer for the atrial fibrillation program in the CDRH's Division of Cardiovascular Devices. He provides scientific and clinical leadership in the area of cardiac electrophysiological devices and procedures, with particular emphasis on clinical evaluation of ablation devices for the treatment of arrhythmias. A significant part of his work involves collaborating with device manufacturers and clinical investigators to design pivotal studies that are robust, efficient, and tailored to the technology and the medical need being addressed. Dr. Dong is also an Adjunct Assistant Professor of Medicine at the Johns Hopkins Medicine/Cardiology. He earned his Medical Degree from Chongqing Medical University in China. He received further training in clinical cardiac electrophysiology at the German Heart Center Munich and received a doctorate degree from the Technische Universtät München in Germany. He then completed a postdoctoral clinical research fellowship in cardiac electrophysiology under Hugh Calkins, MD.

Kristina Dunder (EMA, SWE)

Kristina Dunder graduated from Uppsala University (School of Medicine) in 1988. She specialized in internal medicine and endocrinology/diabetology and served as a medical doctor at the Uppsala Academic Hospital until 2005.

In 2004 she defended a thesis with the title "Clinical manifestations of coronary heart disease and the metabolic syndrome". Since 2005 Dr. Dunder holds a position as a clinical assessor and senior expert at the Medical Product Agency in Uppsala, Sweden. She is also the Swedish member of the CHMP (Committee of Human Medical Products) at the EMA (European Medicine Agency) in London, UK since 2012 and a member of the Cardiovascular Working Party.

Dr. Dunder was one of the Rapporteurs for the update of the guideline Clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus which became effective November 2012, and is currently coordinating the ongoing update of the Guideline of medical products used in weight control as well as the Reflection paper on assessment of the cardiovascular safety profile of medicinal products for the treatment of cardiovascular and metabolic diseases.

Ashraf El Fiky (Washington, USA)

Ashraf El Fiky has regulatory, translational, and clinical experience from previous positions at the US Food and Drug Administration (FDA), US National Institutes of Health (NIH), US academia, and non-US institutions. Currently, Dr. El Fiky is a full-time Medical Officer at a global regulatory and clinical research consulting firm headquartered in the Washington DC metropolitan region. Dr. El Fiky's regulatory experience at the FDA involved authoring technical reports on comparative clinical effectiveness of investigational biologics in Phase I through III development stages applied for treatment of auto-immune diseases, including allergic disorders. A multi-lingual naturalized US Citizen and a native of Egypt, he received his Medical Degree from Egypt's University of Alexandria and Ph.D. in Experimental Pathology/Immunology from the University of California-Irvine. He was invited as a guest speaker at leading US universities including Stanford and Harvard Medical Schools as well as medical conferences in the United States, Egypt, South Korea, China and Italy.

Michael Engelgau (NHLBI, USA)

Michael Engelgau is the Director for China NCD activities with the US Centers for Disease Control and Prevention (CDC). He is assigned to the US CDC office in Beijing, China, where he manages the portfolios for non-communicable disease research and capacity building. He completed a four year assignment with the World Bank during which he was the lead consultant for the World Bank's non-communicable diseases portfolio and led a number of studies on non-communicable diseases in South Asia. Prior to the World Bank assignment he was with the CDC's Division of Diabetes Translation since 1992, where he held several key positions, including the Division's Directorship during 2006. During his time with the World Bank and CDC his focus has been on research programs and policies that translate science into practice to prevent and control non-communicable diseases. He is extensively published in the peer-reviewed US and international scientific literature. After earning his BA and MS at Oregon State University, he obtained his MD at Oregon Health Science University. He completed residencies in both Internal Medicine and Preventive Medicine and training with CDC's Epidemic Intelligence Service.

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 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.

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. His 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).

Andrew Farb (FDA, USA)

Andrew Farb 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. 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. In 2004 he 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.

Gary Michael Felker (Durham, USA)

Gary Michael Felker is 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.

Brian Ference (Cambridge, GBR)

Brian Ference is a cardiologist and genetic epidemiologist who was educated and trained at Harvard, Yale, Oxford and Cambridge Universities. He is currently Director of Research and Professor in Translational Therapeutics, and Head of the Centre for Naturally Randomized Trials at the University of Cambridge, UK. His research focuses on using Mendelian randomization to design 'naturally randomized trials' to generate naturally randomized evidence that can be used to improve the drug discovery and development process; inform the optimal design of randomized trials; fill evidence gaps when a randomized trial is not possible or practical; and define the practice of precision cardiovascular medicine.

João Ferreira (Nancy, FRA)

João Ferreira is a university and hospital assistant in Nancy, France and invited assistant professor at the department of physiology and cardiothoracic surgery at the Hospital de São João, Portugal. Currently Dr. Ferreirais also collaborating with the University of Glasgow. His main clinical and research interests are: heart failure; hypertension; aldosterone antagonists; biomarkers; and co-morbidities.

Judith Fradkin (NIDDK, USA)

Judith Fradkin became the Director of the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEMD) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) in 2000. Dr. Fradkin graduated magna cum laude from Harvard College, received her Medical Degree from the University of California at San Francisco, completed her internship and residency in internal medicine at Harvard's Beth Israel Hospital in Boston, and her endocrinology fellowship at Yale University and NIDDK. In her 35-year career at NIDDK, Dr. Fradkin has created or directed a diverse array of high-impact clinical and basic research programs, including multi-centered clinical trials to evaluate new approaches to prevent and treat diabetes and its complications, scientific consortia to define the genetic and environmental triggers of diabetes, and diabetes research centers. The recipient of numerous NIH and Public Health Service awards, Dr. Fradkin is also the 2003 recipient of the American Medical Association's Dr. Nathan Davis Award for outstanding public service in the advancement of public health.

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.

Augusto Gallino (ISCP, CHE)

Augusto Gallino is a Cardiologist at CHUV, Lausanne. He is the Chief Cardiovascular Research Unit consultant for Cardiology and Angiology and

attending physician at the University of Zurich. Prof Gallino has been involved in international clinical studies since 1997 as a primary investigator. He received his Medical Degree in 1979 from the University of Basel and was a resident at the University hospital in Berne, Switzerland.

He is the President elect for the Swiss Atherosclerosis Association (2020) and the International Society of Cardiovascular Pharmacotherapy.

He is the current president of CardioVascSuisse.

Philip Galtry (Syneos Health, BEL)

Philip Galtry is Vice President, Clinical Development at Syneos Health, a global CRO, where he has the role of global therapeutic lead for cardiology and endocrinology. Phil has a bachelor degree in biochemistry from Bristol University, UK, and is a member of the Association for Project Management. He has 30 years of experience in the industry, all involving cardiovascular projects at CROs. This includes 17 years as a hands-on project manager/project director; mainly spent leading CV Outcomes Trials in dyslipidaemia, ACS and HF. Since his time in active project management, Phil been responsible for setting strategy for CV trials at 2 CROs and has led their project management teams.

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 advocating for a more comprehensive healthcare, patient engagement, community educational resources and a better quality of live for kidney patients.

Patrick retired from the Virginia Department of Corrections as a Major/Chief of Security. He has a Bachelor's and Master's in Criminal Justice, with an emphasis in Public Administration from the University of Richmond, in Richmond, VA. He also has a Doctorate of Philosophy in Justice, Law and Criminology. Patrick is also a licensed Associate Minister at Mountain Movers Ministry Church, Richmond, VA. His ministry is working with those suffering from kidney disease.

Jyothis George (Boehringer Ingelheim, GER)

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

Bernard Gersh (Rochester, USA)

Bernard Gersh is a Professor of Medicine and Consultant at Mayo Clinic, Honorary Professor of Medicine at UCT, and Adjunct Professor of Medicine at Duke University. He received his MB, ChB, from the University of Cape Town and his PhD from Oxford University as a Rhodes Scholar.

He has published 1131 manuscripts and book chapters, is the editor of 15 books, and is on the editorial board of 25 journals. He has received major awards from the ACC, AHA, and in 2103 was designated at the ESC as one of four "legends of modern cardiology". He has also received the Silver Medal of the ESC, the Gold Medal of the ESC in August of 2016, and the Hatter Award from UCT and UCL. Dr. Gersh is the 2015 recipient of the Mayo Clinic Distinguished Alumnus Award. His clinical interests include acute and chronic coronary artery disease, electrophysiology, hypertrophic cardiomyopathy, and valvular heart disease.

Claudio Gimpelewicz (Novartis, USA)

Claudio Gimpelewicz is Sr Global Program Clinical Head at the CV Franchise in the Novartis Pharma Clinical Development Department. He received his Medical Degree 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 is 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 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.

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.

David C. Goff (NHLBI, USA)

David C. Goff is Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health. In this role, he leads a diverse team of scientists and administrators committed to turning discovery into cardiovascular health. Prior to joining the NHLBI, he served as Dean and Professor of Epidemiology in the Colorado School of Public Health and as Chair of the Department of Epidemiology and Prevention at the Wake Forest School of Medicine. He received an MD from the University

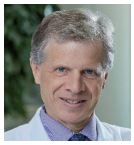
of North Carolina and a PhD in epidemiology from the University of Texas-Houston School of Public Health. He trained in internal medicine at Baylor College of Medicine in Houston. He is an elected member of the American Epidemiological Society, and a Fellow of the American College of Physicians and the American Heart Association. He has published over 300 manuscripts, book chapters, and other scientific reports. The major focus of his research has been on developing, testing, and implementing better strategies for promoting cardiovascular health and preventing CVD.

Shaun Goodman (Toronto, CAN)

Shaun Goodman is a Staff Cardiologist and Associate Head in the Division of Cardiology, Department of Medicine, at St. Michael's Hospital. He is a Professor and Heart & Stroke Foundation of Ontario (Polo) Chair in the Department of Medicine at the University of Toronto. He is an Adjunct Professor in the Department of Medicine at the University of Alberta and a Co-Director of the Canadian VIGOUR Centre (CVC).

Melanie Goth (Bayer, GER)

Melanie Goth is a board-certified pediatrician and a fellow of the American Academy of Pediatrics. She is the lead Study Medical Expert for Bayer's Rivaroxaban pediatric phase III trial. Prior to joining Bayer Pharmaceuticals, she was in private practice and on the faculty of New York Medical College. Dr. Goth received her medical degree from the University of North Carolina, Chapel Hill and her undergraduate degree from the University of Rochester.



Christopher Granger (Durham, GER)

Christopher Granger is a Professor of Medicine in the Division of Cardiology at Duke University and Director of the Cardiac Care Unit for the Duke University Medical Center. Dr. Granger is a Fellow of the American College of Cardiology, the American Heart Association, and of the European Society of Cardiology. He is Associate Editor of the American Heart Journal and serves on the editorial board of the Journal of the American College of Cardiology. He is a cardiology section author for Current Medical Diagnosis and Treatment. He serves on the publication oversight committee of the American Heart Association and he is chairman of the Advisory Working Group of the American Heart Association Mission: Lifeline program. He is a member of the 2011 ACC/AHA STEMI Guidelines Committee. He has served on FDA advisory committees on an ad hoc basis. He is on the Board of External Experts of the National Heart, Lung and Blood Institute (NHLBI).

Jean-Marc Guettier (Sanofi, FRA)

Jean-Marc Guettier is part of the regulatory oversight of all new antidiabetic drug CV-risk Outcomes Trials (2009-2018), new weight management and dyslipidemia drug outcomes trials (2013-2018).

Andrew Hamer (Amgen, USA)

Andrew Hamer is an Executive Medical Director in Global Development at Amgen Inc, and Lead for Repatha. Prior to Joining Amgen, Andrew was VP of Medical Affairs at Capricor Therapeutics, a small biotech company, from November 2013 to August 2015. He had a twenty-year career

as a cardiologist and clinical researcher. These activities led to his stewardship in numerous national healthcare quality improvement roles including chairing the Cardiac Society 2008-2009, National Cardiac Surgery Network 2009-2011 and New Zealand Cardiac Network 2011-2013. Andrew is a clinical researcher having been the principal investigator in clinical trials in acute coronary syndrome, heart failure, hypertension, cholesterol disorders, atrial fibrillation, and diabetes. He received his education at Cathedral Grammar and Christ's College, Christ Church, and his MBChB from the University of Otago Medical School, Dunedin, New Zealand. His pre-fellowship training was at Wellington Hospital, University College & Middlesex Hospitals, and Princess Margaret Hospital. Andrew was Prof. Harvey White's Clinical Research Fellow, Green Lane Hospital, Auckland for two years, prior to a post Fellowship year in Cardiology at The Deaconess Hospital, Harvard Medical School, Boston, MA, 1995-1996.

Ahmed Hasan (NHLBI, USA)

Ahmed A Hasan is a Medical Officer and Program Director with the atherothrombosis and coronary artery disease branch, division of cardiovascular sciences at the NHLBI, NIH since 2002He serves as the project officer for the NHLBI supported large multi-center phase III trial, Cardiovascular Inflammation Reduction Trial (CIRT) and the deputy project officer for TAILOR-PCI and COAG trials. Dr. Hasan also serves as the project officer for six phase II trials studying targeted anti-inflammatory therapies for the management of coronary artery disease and heart failure in non-AIDS and AIDS population: VCU-ART3, D-HART2, RED-HART, Lp-PLA2 and coronary atherosclerosis in humans, inflammation and coronary endothelial function (InCEF trial), and Effect of IL-1B inhibition on inflammation and CV risk in HIV. In addition, Dr. Hasan is the founder and chairman of the scientific steering committee of the MATIG (meta analytical interagency group). The data science research group analyzes patient level data of multiple clinical trials from various database including BioLINCC, dbGap, and other publicly available dataset in cardiovascular and cardiometabolic disorders and product areas to define sex, gender, racial, and age-group differences in hard outcomes, efficacy, and utility.

Koji Hasegawa (Kyoto, JPN)

Koji Hasegawa is a fellow of the American College of Cardiology, American Heart Association, Asian Pacific Society of Cardiology. He obtained his Medical Degree in 1985 and his PhD in 1993 from Kyoto University.

Dr. Hasegawa was a fellow at Albert Einstein College of Medicine (1993-1996) and assistant professor from 1996 to 2003 at Kyoto University. He is currently the Director, Division of Translational Research, Kyoto Medical Center, leader of the Cardiovascular Research Network, visiting professor at the University of Shizuoka and the President of the International Society of Cardiovascular Pharmacotherapy (ISCP).

Robert Hemmings (EMA, GBR)

Robert Hemmings has been with the MHRA for 18 years and heads the group of medical statisticians and pharmacokineticists. Most of Rob's time is dedicated to work on behalf of the scientific committees that are hosted at the European Medicines Agency.

He is a member of the European Medicines Agency Committee for Medicinal Products for Human Use (CHMP), 'co-opted' for expertise in clinical trial methodology. In addition, he is also the chair of the CHMP's Scientific Advice Working Party (SAWP), a multi-disciplinary group providing scientific advice and protocol assistance to drug developers to facilitate access of medicinal products to patients by optimizing research and development and reducing uncertainties in regulatory outcomes. Robert has a broad interest in all aspects of clinical trial design, statistical methodology and drug development.

Adrian Hernandez (Durham, USA)

Adrian Hernandez is a cardiologist with extensive experience in clinical research ranging from clinical trials to health services policy research. Since 2017, he has been the Vice Dean for Clinical Research at the Duke University School of Medicine. Previously, he was a Faculty Associate Director of Duke Clinical Research and Director of Health Services and Outcomes Research at the Duke Clinical Research Institute. 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. He has served as the Steering Committee Chair or Principal Investigator of multiple large studies in the field of cardiovascular medicine and diabetes. Dr. Hernandez has over 450 published articles in high-tier journals including the New England Journal of Medicine, Journal of the American Medical Association, and Lancet. He is an elected member of the American Society of Clinical Investigation and Association of American Physicians.

Charles Herzog (Minneapolis, USA)

Charles Herzog is professor of medicine, University of Minnesota, and cardiologist at Hennepin County Medical Center (HCMC) for 34 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 participated in the development of the National Kidney Foundation's K/DOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients and 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 a 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 Critical Event Committee of the CARSK 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).

Joseph Hill (Dallas, 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. In addition, he serves on several editorial boards, including Circulation, Circulation Research, Journal of Biological Chemistry, and American Journal of Cardiology. 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.

Gerhard Hindricks (Leipzig, GER)

Gerhard Hindricks is a Professor of Cardiology at the University of Leipzig, Leipzig, Germany. His career spans three decades and he was part of the team which carried out the first radiofrequency

catheter ablations in the world in the late 1980s in Münster, Germany. He later helped develop radiofrequency catheter ablation on a clinical basis and establish it as a cornerstone for the treatment of many arrhythmias. He heads one of the largest electrophysiology departments in Europe in the Heart Center Leipzig in Germany, providing services for up to 5000 patients and performing almost 2500 interventions for arrhythmias per year. He is also the Chief Medical Officer of the whole Heart Center Leipzig. He is also General Manager of the Leipzig Heart Institute.

He has been involved with the management of the European Heart Rhythm Association for over a decade. He has served as President of EHRA from June 2015 to June 2017. He previously served as the committee chair for international affairs and also chaired the programme committee for EUROPACE 2011 which produced a highly successful congress in Spain.

Anne-Cecile Huby (Nancy, FRA)

Anne-Cecile Huby is a physiologist specialized in the integrative approach of cardiovascular diseases. During her PhD in Paris, she studied the development of fibrosis in chronic kidney diseases, followed by a post-doc at the Heart Institute (Cincinnati) where she worked on the pathophysiology of genetic cardiac diseases. Her second post-doc aimed at identifying the mechanisms of hypertension in the obese female population. She then moved to a research scientist position in regenerative medicine at the Texas Heart Institute to work on the utilization of stem cells in creating a biological heart. She is currently a European project manager at the Clinical center for investigation in Nancy.

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.

Elaine M. Hylek (Boston, USA)

Elaine M. Hylek is a Professor of Medicine at Boston University School of Medicine. She received her Medical Degree from the University of Pittsburgh School Of Medicine and a Masters in Public Health (quantitative methods) from Harvard University School of Public Health. She completed her residency training in internal medicine at Massachusetts General Hospital and Harvard Medical School in Boston, Massachusetts. Her research areas include arterial (stroke) and venous thrombosis, anticoagulant therapies, and atrial fibrillation. She has served as PI on several NIH R01 grants, served on the Executive Steering Committees for international clinical trials and national registries, Event Adjudication Committees, and Data Safety Monitoring Boards. She has also served as the Late Breaking Clinical Trial Discussant for multiple international trials in the field of thrombosis. Dr. Hylek is a Section Editor for Thrombosis and Haemostasis, a member of the International Society of Thrombosis and Haemostasis Executive Committee for World Thrombosis Day, and the Director of the Thrombosis and Anticoagulation Service at Boston Medical Center. She is extensively published and designated a U.S. News Top Doctor and voted Best Doctors in America for the past decade.

Alar Irs (EMA, EST)

Alar Irs is Chief Medical Officer at the Estonian Medicines Agency where he has worked in different roles in clinical assessment of medicines for 20 years. He is a member of the Committee for Human Medicines (CHMP) at the European Medicines Agency since 2004 and a member of the Cardiovascular Working Party of the CHMP. He is a practicing interventional and acute cardiologist and has been a lecturer in clinical pharmacology at the University of Tartu teaching clinical pharmacology, pharmacotherapy, pharmacoepidemiology and pharmacoeconomics to the students plus post-graduates and in CME.

His current interests in addition to the work of a medicines regulator and teaching cardiologist are supporting academic clinical research and quality in pharmacotherapy.

Stefan James (Upsala, 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 and 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.

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. His research has been published in over 300 peer-reviewed cardiology journals, and he is an associate editor of Circulation and an editorial board member for the European Heart Journal, and American Heart Journal.

Salim Janmohamed (GSK, GBR)

Salim Janmohamed is a practising endocrinologist trained in London and Oxford (UK), has been working in cardiovascular and metabolism medicines development at GSK for 15 years, most recently as lead physician for the Harmony Outcomes trial evaluating the effects of albiglutide in patients with Type 2 Diabetes and cardiovascular disease.

James Januzzi (Boston, USA)

James Januzzi is the Hutter Family Professor of Medicine at Harvard Medical School, a staff cardiologist at Massachusetts General Hospital, and Senior Cardiometabolic Faculty at Baim Institute for Clinical Research.

Dr. Januzzi's research has contributed to the understanding of cardiac biomarker testing, where his studies have set international guideline standards for use in diagnosis, prognosis, and management of patients suffering from acutely decompensated heart failure, chronic heart failure as well as those with acute coronary syndromes. Dr. Januzzi has published more than 500 manuscripts, book chapters and review articles, has edited five text books. He is among the top 1% most cited researchers, according to Clarivate/Web of Science. He has mentored dozens of trainees over the years, and has an international presence as a cardiovascular educator. He is an Associate Editor at both JACC and JACC Heart Failure and is chair of the ACC Task Force on Expert Consensus Decision Pathway Documents.

John Jarcho (NEJM, USA)

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.

Mariell Jessup (Philidelphia, USA)

Mariell Jessup is Chief Science and Medical Officer of the American Heart Association and an Emeritus Professor of Medicine at the University of Pennsylvania School of Medicine.

Dr. Jessup has been a member of the committee to revise ACC/AHA Guidelines for the Management of Congestive Heart Failure, published in 2001 through the present. She was the Chair of the ACC/AHA Guidelines focused update for heart failure; published in March, 2009. She was the Vice-Chair of that same committee with the newest version of the heart failure guidelines published in 2016. She served on the European Society of Cardiology's Heart Failure Guideline writing committee as well. She was a member of the Board of Directors of the national AHA, and was the President from 2013-2014. She was the Chief Scientific Officer of the Leducq Foundation from January 2017 through August of 2018, before moving to the American Heart Association role.

Nichole Jefferson (Iowa, USA)

Nichole Jefferson, a native of Dallas, Texas, currently resides in West Des Moines, Iowa. When diagnosed with end-stage renal disease in 2003, not only was she unaware of what it meant, she had no idea she was at high-risk for developing kidney disease. Though Nichole experienced both forms of dialysis (HD and PD), she preferred the convenience peritoneal dialysis offered. On June 12, 2008, she received the gift of life, a kidney transplant. Due to the many obstacles she faced following her transplant, Nichole realized that a transplant was simply another form of treatment and not a cure. This realization sparked her quest for knowledge, which later initiated her enthusiasm for advocacy.

Peter Jüni (Toronto, CAN)

Peter Jüni is the Director of the Applied Health Research Centre (AHRC) at the Li Ka Shing Knowledge Institute of St. Michael's Hospital and a Professor at the Department of Medicine of the University of Toronto. He graduated from the Faculty of Medicine at the University of Bern, Switzerland, completed his training in Internal Medicine at various hospitals in Switzerland, was a Research Fellow at the Department of Social Medicine at the University of Bristol, UK, and held previous appointments as Director of the Institute of Social and Preventive Medicine and Founding Director of CTU Bern, the University of Bern's clinical trials unit. Dr. Jüni is internationally known for his methodological work and for clinical trials and meta-analyses on the management of cardiovascular and musculoskeletal disorders. A Fellow of the European Society of Cardiology, he has had leading roles in several major cardiovascular trials, including SIRTAX, LEADERS,

FAME 2 and MATRIX. He served as a member of several task forces of the European Society of Cardiology and co-authored the European guidelines on myocardial revascularization and on the management of acute myocardial infarction.

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 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.

Wolfgang Koenig (Munich, GER)

Wolfgang Koenig is a Professor of Medicine/ Cardiology at the University of Ulm Medical School, Germany. A board-certified internist and interventional cardiologist specialised in intensive care medicine and has extensive experience in the molecular epidemiology of cardiovascular diseases. 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 Prof Koenig 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. In 2014 he received the Rudolf Schönheimer Award from the German Atherosclerosis Society.

Csaba P. Kovesdy (Nashville, USA)

Csaba P. Kovesdy is the Fred Hatch Professor of Medicine in Nephrology and Director of the Clinical Outcomes and Clinical Trials Program at the University of Tennessee Health Science Center in Memphis, Tennessee and Chief of Nephrology at the Memphis VA Medical Center in Memphis, Tennessee. Dr. Kovesdy earned his Medical Degree Summa cum Laude from

the University of Pecs Medical School in Pecs, Hungary. He completed his residency in Internal Medicine at the Henry Ford Hospital in Detroit, MI, and a clinical fellowship in Nephrology at the Johns Hopkins Bayview Medical Center in Baltimore, MD.

Dr. Kovesdy's main research interests are centered on the epidemiology and outcomes of patients with pre-dialysis chronic kidney disease and ESRD. He has published his research in over 400 peer-reviewed articles, as well as numerous abstracts and book chapters. He is a Fellow of the American Society of Nephrology, and a member of the European Renal Association – European Dialysis and Transplant Association, the International Society of Nephrology and the International Society of Renal Nutrition and Metabolism.

Carolyn Lam (Singapore, SIN)

Carolyn Lam is a Senior Consultant of the National Heart Centre, Singapore, Professor of Duke-NUS Cardiovascular Academic Clinical Program, and Chairperson of the Asia Pacific Association of Women's Cardiovascular Disease. She graduated from the Faculty of Medicine, National University of Singapore, completed advanced specialty training in Cardiology in Singapore, and pursued her Research Fellowship at the Cardiorenal Laboratory, Heart Failure Fellowship at the Division of Cardiovascular Diseases, and Advanced Cardiology and Master of Biomedical Sciences at Mayo Clinic, Rochester, MN. She further obtained training in clinical and genetic epidemiology at the Framingham Heart Study in Boston, MA before returning to Singapore in 2010 on the National Medical Research Council's Clinician Scientist Award.

Dr Lam started the first Heart Failure with Preserved Ejection Fraction Programme and Women's Heart Health Clinic in Singapore, was awarded the L'Oreal Women In Science Award (2012) for her work in women's cardiovascular disease. She is the Programme Lead of the Asian network for Translational Research and Cardiovascular Trials and principal investigator of an ongoing nation-wide heart failure study in Singapore (SHOP study), a multinational Asian study of heart failure across 11 Asian countries (ASIAN-HF study).

Anna Maria Langkilde (AstraZeneca, SWE)

Anna Maria Langkilde is Global Clinical and Scientific Lead for Oral Diabetes including dapagliflozin (FORXIGA) at AstraZeneca. Since joining AstraZeneca in 2003 Dr. Langkilde has had leading roles in development projects in the Cardiovascular, Metabolic and Chronic Kidney Diseases Therapeutic Area, in both early and late phase projects, as well as line management roles.

Dr. Langkilde earned her Medical Degree from Gothenburg University and Sahlgrenska University Hospital in Gothenburg, Sweden and has a broad clinical and scientific background in the field of Internal Medicine, with focus on diabetes, obesity and metabolism. Her academic work ranges from metabolic ward studies to large clinical studies, and international research collaborations.

Patrick Lawler (Toronto, CAN)

Patrick Lawler is an Assistant Professor of Medicine at the University of Toronto, and a cardiac intensivist at the Peter Munk Cardiac Centre at Toronto General Hospital in Toronto, Canada. He attended medical school and completed internal medicine residency at McGill University in Montreal. He completed training in cardiovascular disease and cardiac critical care at Brigham and Women's Hospital/Harvard Medical School in Boston. He completed research training initially in vascular biology as a Fulbright Scholar at the Karolinska Institute in Stockholm, and subsequently in molecular epidemiology at Brigham and Women's Hospital, where he was the 2016 Eugene Braunwald Scholar. He holds a Masters in Public Health from Harvard School of Public Health in Boston. His research interests are in using biomarkers to facilitate precision medicine approaches within clinical trials.

Francesca Lawson (Sanofi, FRA)

Francesca Lawson received her Medical Degree from the University of Rome in 1981 and an advanced degree in Clinical Pharmacology from Catholic University in Rome. She is the Associate Vice President and head of Cardiovascular outcome trials for diabetes development with Sanofi.

Dr. Lawson has devoted most of my professional career to the clinical development of cardiovascular drugs and the evaluation of the cardiovascular effects of investigational drugs. While working at the University of Pennsylvania as Associate Director of the Clinical Research Center she conducted the first clinical trials indicating the potential pro-thrombotic effects of selective Cox-2 inhibitors, such as Vioxx.

Most recently she has focused on the development of the CV outcomes trial strategy for glucose lowering medications. In particular, has been responsible for the design and implementation of various CVOTs, including ELIXA with lixisenatide, SCORED and SOLOIST with sotagliflozin and AMPLITUDE-O with efpeglenatide.

Kerry Lee (Durham, USA)

Kerry Lee is Professor Emeritus, Department of Biostatistics and Bioinformatics, Duke University School of Medicine, and Duke Clinical Research Institute. He received his PhD from the University of North Carolina at Chapel Hill. He has over 30 years of experience as Director of the Statistical and Data Coordinating Center at the Duke Clinical Research Institute for more than 25 multi-center international clinical trials in cardiovascular disease, including the large GUSTO series of mega-trials and several major studies funded by the NHLBI, including MUSTT, MOST, SCD-HeFT, HAT, STICH, TACT, PROMISE, CABANA, and the Heart Failure Network. He is a fellow for the Society for Clinical Trials and for the American Statistical Association. A member of numerous Data and Safety Monitoring Boards; a member of Clinical Trials Review Committee for NHLBI and Chair of the Biometrics Section of American Statistical Association.

Annemieke Lenselink (The Hague Area, NED)

Annemieke Lenselink has an international work experience as HR(D) manager and director in the fields of Telecommunications, Banking and Biotechnology. When she was 47 she had a stroke. During her recovery she participated already in a number of studies. It became clear she could not return to her former job so she decided to make lemons out of lemonade, and is now part of the Clinical Research commission of the RRC rehab center, and she is a patient member of several studies. She enjoys presenting the patient perspective at the CVCT. As a member of the “Harteraad” (heart council) she advises on proposals for research from the patient perspective. Her daughter, Bieneke Nommensen, created a video of last year’s conference and will participate in the blog of this year.

Chris Leptak (FDA, USA)

Chris Leptak completed his Medical Degree and PhD in microbiology/immunology at UCSF. After residency in Emergency Medicine at Harvard’s combined Mass General and Brigham program, he joined FDA in 2007 as a primary reviewer in OND’s division of gastroenterology products, focusing on immunomodulators for inflammatory bowel diseases. In 2010, he joined OND’s Guidance and Policy Team and became OND’s Biomarker and Companion Diagnostics Lead. His focus is on biomarker and diagnostic device utility in clinical trials and drug development, both for drug-specific programs. Chris is the Director of CDER’s Biomarker Qualification Program and also Director of OND’s Regulatory Science Program which aims to improve regulatory consistency and policy development in areas of emerging science and technology.

Daniel Levy (Boston, USA)

Daniel Levy is Director of the Framingham Heart Study, Chief of the Population Sciences Branch of the National Heart, Lung, and Blood Institute, and Professor of Medicine, Boston University School of Medicine. His main areas of research include the epidemiology and genetics of hypertension, heart disease, and heart failure. As one of the founders of an international genetics consortium, he has led genome-wide association studies that have identified many of the known genes associated with hypertension. He leads the Systems Approach to Biomarker Research in Cardiovascular Disease (SABRe CVD) initiative, which seeks to integrate big data resources from thousands of Framingham Heart Study participants using genetic variation in their DNA, gene expression, microRNA expression, proteomics, metabolomics, and DNA methylation to identify casual genes, proteins, and pathways contributing to cardiovascular disease. Dr. Levy has twice received the National Institutes of Health Director's Award for his research accomplishments. In November 2009 he was the recipient of the American Heart Association's highest recognition for research achievements in epidemiology, the Population Research Prize.

Peter Libby (Boston, USA)

Peter Libby 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 received numerous awards and recognitions for his research accomplishments, including a number of lifetime achievement awards. 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 served a 5-year term on the Board of Scientific Councilors of National Heart, Lung, and Blood Institute (NHLBI).

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.

Barbara Linder (NIDDK, USA)

Barbara Linder is Senior Advisor for Childhood Diabetes Research at the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health. Dr. Linder administers a portfolio of research grants related to the care of individuals with type 1 diabetes and youth with type 2 diabetes. She oversees many of NIDDK's large clinical consortia, including the TODAY, DPPOS, GRADE and RISE studies, and the SEARCH study which is co-led by the CDC and NIDDK. She also works at the NIH Pediatric Endocrine Clinic. Prior to coming to the NIH, Dr. Linder was on the faculty at the Albert Einstein College of Medicine, where she directed the Pediatric Endocrinology Fellowship. She received her M.D., Ph.D. from Columbia University's College of Physicians and Surgeons.

Tom Lumbers (London, GBR)

Tom Lumbers is a HDR UK Rutherford Fellow in Cardiology at the UCL Institute of Health Informatics. He graduated in Medicine from Cambridge University with double distinction and trained in Cardiology at the Barts Heart Centre. He completed doctoral training molecular biology

at Imperial college. His current research seeks to define the genetic architecture of heart failure to investigate the molecular determinants of ventricular dysfunction. He co-founded and leads the HERMES Consortium, a large-scale GWAS consortium for heart failure (hermesconsortium.org).

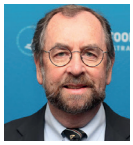
Lars H Lund (Stockholm, SWE)

Lars H Lund is Professor of Medicine at Karolinska Institutet, and Senior Consultant at Karolinska University Hospital where he leads the heart failure research program. He trained in medicine, cardiology and heart failure at Duke University and Columbia University. His expertise is HF clinical and registry-based phenotyping and comparative outcomes studies as well as pragmatic registry-based trials primarily in heart failure with preserved ejection fraction. He has developed a series of prognostic and risk stratification tools that are used to characterize patients and select appropriate therapy. He is active in programs to improve utilization of existing evidence based interventions in heart failure with reduced ejection fraction and advanced heart failure, such as devices and transplantation, as well as in novel interventions and pragmatic trials of new use applications of existing drugs in heart failure with preserved ejection fraction. He has leadership positions in heart failure registries and organizations: such as the Swedish Heart Failure Registry (SwedeHF) and ESC Heart Failure Registry, the Heart Failure Association (HFA) of the ESC, was previously Associate Director the International Society for Heart & Lung Transplantation (ISHLT) Registry and on the Steering Committee of the ISHLT International Registry for Mechanical Circulatory Support (IMACS).

Steven Macari (Poitiers, FRA)

Steven Macari is a Scots-Italian living & working in the Poitiers area of France since 1995 and has been living with chronic heart failure (HFrEF – EF 26%) since June 2010. His first ICD was implanted in 2013, which was subsequently "upgraded" to a CRT-D in 2016.

Steven is a founding member & President of Association Vie Et Cœur (AVEC), a heart failure patient support & advocacy association. He holds a national certificate in Educational Therapy for Patients and co-hosts ETP workshops at the university teaching hospital in Poitiers. Enrolled in the certificate course "Coordinating an Educational Therapy Program" he hopes to undertake a university diploma course in ETP in 2019. Steering Group Committee & Project Advisory Group Member at Heart Failure Policy Network; iHHub member and contributor; Member of Novartis Pharma's European Heart Failure Council; Advisory Board Member - Bayer HF Patient Advocacy Group; Editorial Board Member for the website "SuisTonCoeur".



Adrian Magee (FDA, USA)

Adrian Magee is a regulatory reviewer of clinical trial data in support of the safety and effectiveness of cardiovascular devices at FDA/CDRH/ODE.

Veronique Mahaux (Syneos Health, BEL)

Veronique Mahaux is a certified Cardiologist with 27 years of clinical research experience. After nine years of clinical practice and medical research, heading the pacemaker clinic of the University Hospital of Liège, Belgium, Dr. Mahaux joined the medical device industry as Clinical Research Manager Heart Failure within Medtronic.

In 2005, she joined Quintiles (now IQVIA) - Contract Research Organization - where she was appointed as Sr Director, Global Head Cardiovascular & Metabolic, Therapeutic Strategy & Medical Delivery. Dr. Mahaux then moved to INC Research/Inventiv Health (now Syneos Health) as Executive Medical Director where her main responsibilities involve therapeutic area

consulting and medical input to clinical programs, clinical development and regulatory consulting for the Cardiovascular/General Medicine Business Unit.

First author or co-author of 3 chapters in books and 25 full papers, her specific expertise sits in Arrhythmias, Heart Failure and Medical Devices.

Daniel B. Mark (Durham, USA)

Daniel B. Mark is a Professor of Medicine in the Division of Cardiology, a clinician, researcher, educator and an academic leader. Dr. Mark has been the principal investigator on major R01 grants from the NHLBI and the AHRQ with funding from these organizations continuously since 1987. He is currently PI on 3 R01 grants from NHLBI that are measuring patient reported outcomes and assessing cost effectiveness in major cardiovascular clinical trials. In 2009, Dr. Mark received the American College of Cardiology's Distinguished Scientist Award for his work in outcomes research. He is Editor-in-Chief of the American Heart Journal, the oldest peer-review journal in cardiovascular medicine. Dr. Mark received his Medical Degree from Tufts in Boston and an MPH from Harvard. He completed a residency in Internal Medicine at the University of Virginia before coming to Duke in 1982 for a cardiology fellowship. He joined the Duke faculty in 1985.

Nassir Marrouche (Salt Lake City, USA)

Nassir Marrouche received his Medical Degree from the Medical School at the University of Heidelberg in Germany, and has completed internships in infectious disease, pulmonary medicine and vascular surgery. Dr. Marrouche is a Professor of Medicine at the University of Utah, where he established and is the Executive Director of the Comprehensive Arrhythmia Research Center (CARMA) in addition to directing the Electrophysiology Laboratories and the Atrial Fibrillation Program. Dr. Marrouche's research interests include the pathophysiology and new imaging modalities for treatment of atrial and ventricular arrhythmias.

David Martin (FDA, USA)

David Martin is the Associate Director for Real World Evidence Analytics in the Office of Medical Policy at the FDA Center for Drug Evaluation and Research. He oversees demonstration projects supporting the agency's evaluation of real world evidence, evaluates real world evidence submissions, and contributes to medical policy development mandated by the 21st Century Cures Act. Key focus areas include PCORI/FDA-Catalyst pragmatic trials, the FDA My Studies mobile app, and replication of clinical trial results with non-interventional study designs. As a former Division Director and Acting Deputy Office Director in the Center for Biologics Evaluation and Research, Dr. Martin led analyses of spontaneous reports, formalized risk management planning, and helped develop the Sentinel system. Before joining the FDA, he practiced flight and occupational medicine in the U.S. Air Force. He earned his undergraduate degree at the Citadel and his M.D. and M.P.H. at the Johns Hopkins University.

Felipe Martinez (Cordoba, ARG)

Felipe Martinez is currently distinguished as Emeritus Professor of Medicine. He attended post graduate training at Brussels University, Belgium and Toronto University, Canada. He is also 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. 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.

Robin Martinez (Denver, USA)

Robin Martinez is a patient advocate, like many, has become one by necessity. When her husband was diagnosed with renal cell carcinoma, he was told he would live two to four months. Instead he had good quality of life for almost 10 years. Her role as his advocate, internet researcher, and information gatherer played a part.

By the time he died she was co-administering a large online group of patients and caregivers dealing with kidney cancer. She persisted; this experience is too expensive to waste.

She has provided information and guidance to thousands of patients facing major medical problems and chronic diseases. Clinical trial education is a major element. Today at Smart Patients she also fosters the development of cohesive, highly informed, supportive communities of patients and caregivers. We encourage people to become leaders in their own science-based, research-oriented medical care coupled with persistence, advocacy, and hope.

Simon Matskeplishvili (Moscow, RUS)

Simon Matskeplishvili is a Professor of cardiology, Professor of life sciences and a Member of the Russian academy of sciences.

He is a Director for science and research of the Lomonosov Moscow state university clinic. He graduated with honors from the Sechenov Moscow medical academy in 1994; in 1998 he became the International master in cardiology at the Institute of Clinical Physiology of the National Research Council of Italy and the University of Pisa. For the development of new non-invasive method of intracardiac blood flow evaluation he was awarded a State prize of the Russian Federation in science and technology.

His interests include basic research in cardiology, angiogenesis and regenerative therapy, acute coronary syndrome, advanced heart failure, cardiovascular imaging, antithrombotic treatment, interventional cardiology. Of particular interest are cardiovascular complications of cancer therapy – prevention, early diagnosis and treatment, risk stratification before oncological surgery.

Alexandre Mebazaa (Paris, FRA)

Alexandre Mebazaa 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.

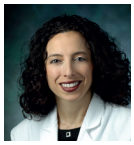
Roxana Mehran (New York, USA)

Roxana Mehran, is a Professor of Medicine, Cardiology and Professor of Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai. 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, the 2017 Bernadine Healy Leadership in Women's CV Disease Award, and this May, the 2018 Wenger Award for Excellence in Medical Leadership. She co-founded the Academic Research Consortium (ARC) and SCAI Women in Innovation (SCAI-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.

Robert Mentz (Durham, USA)

Robert Mentz is an Assistant Professor of Medicine at Duke University and is the Director of the Duke University Cooperative Cardiovascular Society. He completed Internal Medicine training at Brigham and Women's Hospital and Cardiology Fellowship at Duke University Hospital and the Duke Clinical Research Institute with advanced training in heart failure and clinical research methods. He received formal training in clinical pharmacology as part of the DCRI's Clinical Pharmacology training program. Robert spends his clinical time at Duke University Hospital assisting with the care of heart failure, cardiac transplant and ventricular assist device patients. He is the clinical lead for the international EXSCEL trial (exenatide in diabetic patients with cardiovascular disease) and the HEART-FID trial (ferric carboxymaltose for iron deficiency in heart failure). He is the lead co-investigator on the NHLBI-funded TRANSFORM-HF trial – a pragmatic trial of diuretic strategies in HF. He is involved with the NHLBI's Heart Failure Research Network as a site Principal Investigator. He is an active member of the Heart Failure Society of America's Advocacy Committee and the American Heart Association's Heart Failure Committee.



Erin D. Michos (Baltimore, USA)

Erin D. Michos is an Associate Professor of Medicine within the Division of Cardiology and Associate Director of Preventive Cardiology at the Johns Hopkins School of Medicine, with joint appointment in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. Her research focuses on (1) risk prediction for cardiovascular disease including use of coronary artery calcium scores and inflammatory biomarkers, (2) lipids, (3) women's cardiovascular health, and (4) vitamin D. Dr. Michos is the recipient of independent NIH R01 funding. She is a co-investigator in the Multi-Ethnic Study of Atherosclerosis (MESA), the Atherosclerosis Risk in Communities (ARIC) study, and the Study to Understand Vitamin D and Fall Reduction in You (STURDY) clinical trial. She is the Fellowship Training Director for the AHA's Go Red for Women Research Network at Johns Hopkins. She has authored/co-authored over 220 manuscripts in peer reviewed journals.

Manal Milhem (Atlanta, USA)

Manal Milhem, an American Palestinian health care professional, an entrepreneur, and a humanitarian. She obtained her Doctor of Pharmacy degree and training in the United States. In addition to a lifelong passion for development work and compassion for helping the vulnerable, Dr. Milhem has over 20 years' experience in Pharmaceutical research and clinical operations.

Dr. Milhem has global experience in the US and overseas and has broad expertise in the set-up, management and supervision of global clinical trials as well as an in depth experience in training and management of clinical research personnel on a local and international basis.

Dr. Milhem has assumed strategic roles in the assessment of conducting clinical trials in emerging markets. She worked closely with executive management of a large global CRO in

the feasibility project for expansion opportunities in the Middle East and North Africa region (MENA) and developed company's local partner network. As consultant, Dr. Milhem worked with regional CROs and has been involved in process improvement initiatives to establish an optimal process for the integration, training, and management of teams, projects and programs.

Brian S. Mittman (Kaiser Permanente, USA)

Brian S. Mittman is a Senior Scientist at Kaiser Permanente's Department of Research and Evaluation with additional affiliations at the US Department of Veterans Affairs, University of Southern California, and University of California at Los Angeles (UCLA), where he co-leads the UCLA Clinical and Translational Science Institute (CTSI) Implementation and Improvement Science Initiative. Dr. Mittman led the planning committee that launched the journal Implementation Science and served as co-editor in chief from 2005-2012. He was a founding member of the U.S. Institute of Medicine (IoM) Forum on the Science of Quality Improvement and Implementation and chaired the NIH Special Emphasis Panel (grant review committee) on Dissemination and Implementation Research in Health in 2007 and 2010. He directed VA's Quality Enhancement Research Initiative (QUERI) from 2002-2004. He serves on the Methodology Committee for the Patient-Centered Outcomes Research Institute (PCORI), the NIH NHLBI Board of External Experts, and advisory boards for numerous US and non-US research programs.

David J. Moliterno (Lexington, USA)

David J. Moliterno is the Jack M. Gill Chair and Professor of the Department of Internal Medicine at the University of Kentucky. Dr. Moliterno completed a fellowship in Cardiovascular Medicine at The University of Texas-Southwestern Medical Center, and he completed an additional interventional cardiology fellowship at The Cleveland Clinic Foundation, where he remained as an attending cardiologist for 10 years before joining the University of Kentucky in 2004.

He is a fellow of the American College of Cardiology, European Society of Cardiology, Society of Coronary Angiography and Interventions, and the American Heart Association. He is on the editorial board of several leading journals and is the Editor-in-Chief for the Journal of the American College of Cardiology—Cardiovascular Interventions. He has been the primary author of publications in Annals of Internal Medicine, Circulation, JACC, JAMA, Lancet, BMJ, and the New England Journal of Medicine.

As a clinical researcher, Dr. Moliterno has been involved with numerous multinational investigational studies in cardiovascular medicine as principal investigator or international steering committee member.

Wanda Moore (Arizona, USA)

Wanda Moore, a patient who as an American woman is in one of the highest risk groups dying from heart disease. Heart disease, diabetes, obesity and inactivity are risk factors that prevalent in her family. Therefore, she has made every effort to change her lifestyle to offset those risk factors.

A member of the University of Arizona Sarver Heart Center Women's Heart Health Education Committee for many years, she was blessed to be able to say with a humble heart that, "I do not have heart disease and I have not had a heart attack." Well, in spite of her efforts to live a healthy lifestyle, she too became a victim of heart disease (coronary artery disease). In 2015, she had coronary artery bypass graft surgery. Drafted into the ranks of those living with CV disease she is more committed and passionate about research and outreach heart health education.

Carol Moreno (AstraZeneca, SWE)

Carol Moreno is a Senior Global Medical Affairs Lead for Lokelma (AstraZeneca). She obtained her MD and PhD from the University of Murcia (Spain), after which she held a faculty position in the Department of Physiology at the Medical College of Wisconsin (US) until 2013. She them moved to MedImmune in 2014 to lead the development of drugs for Chronic Kidney Disease and joined AstraZeneca Medical Affairs in early 2018. Carol has an extensive record of successful research in renal, cardiovascular, metabolic and genetic research, leading to over 60 published manuscripts. Her expertise is focused on cardiovascular and renal therapeutic areas, with an emphasis in rare diseases and translational medicine. She currently leads several medical activities on education on Hyperkalemia burden and evidence generation.

Claudio Mori (Vifor Fresenius, CHE)

Claudio Mori is a Scientific Advisor Cardiovascular, Director, at Vifor Pharma Ltd, Zurich, Switzerland. He graduated from the University of Zurich Medical School, Switzerland. He then joined the pharmaceutical industry as Medical Advisor Cardiovascular at Bristol Myers Squibb GmbH, Baar, Switzerland. Before moving to Vifor Pharma he worked as Regional Medical Liaison CV&Rheumatology in Spain/Portugal for Centocor B.V., Leiden, Netherlands. He was appointed Medical Affairs Director Cardiology and Nephrology to launch ferric carboxymaltose (Ferinject®). Claudio Mori is interested in the role and treatment of the comorbidities, such as hyperkalaemia and iron deficiency (anaemia), particularly in chronic heart failure and chronic kidney disease and the link to the Cardio-Renal Iron Deficiency (Anaemia) Syndrome (CRIDS) and other for iron deficiency relevant diseases. He is member of the European Society of Cardiology (ESC), Heart Failure Association (HFA), the European Renal Association - European Dialysis Transplant Association (ERA-EDTA), the American Heart Association (AHA) and the American Society of Nephrology (ASN) and a reviewer for different international journals on topic of iron deficiency and anaemia.

Theresa Mullin (FDA, USA)

Theresa Mullin is a principal advisor on strategy and leads international negotiation, regulatory harmonization, and other initiatives. She Leads FDA Patient Focused Drug Development, and heads FDA delegation to ICH. Previously led FDA negotiations for 2002, 2007, 2012 and 2017 cycles of reauthorization of the Prescription Drug User Fee Act, now providing $1B in annual funding. Before joining CDER in 2007, Dr. Mullin was FDA Associate Commissioner for Planning. Since joining FDA she has received awards including Senior Executive Service Presidential Rank Award for Distinguished Service in 2011, and Presidential Rank Award for Meritorious Service in 2006, and was named a recipient of the 2017 FDLI Distinguished Service and Leadership Award. Before joining FDA, Dr. Mullin was Senior Manager with The Lewin Group, and Principal Scientist at Decision Science Consortium. Dr. Mullin received a B.A., magna cum laude, in Economics from Boston College, and Ph.D. in Public Policy Analysis from Carnegie-Mellon University.

Gillian Murtagh (Abbott Diagnostics, 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 Medical Degree 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.

Christopher M. O'Connor (Washington, USA)

Christopher M. O'Connor is the 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. 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. 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 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 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. He currently serves as Editor-in-Chief of JACC: Heart Failure.

Michelle O'Donoghue (Boston, USA)

Michelle O'Donoghue is an Associate Professor of Medicine at Harvard Medical School and a member of the Cardiovascular Division at Brigham and Women's Hospital. She is a Senior Investigator in the Thrombolysis in Myocardial Infarction (TIMI) Study Group, founded by Dr. Eugene Braunwald.

Dr. O'Donoghue's primary research focus is the design and conduct of multicenter clinical trials for patients with stable and unstable heart disease. Additional clinical research interests include the evaluation of novel antiplatelet drugs, established and novel biomarkers, the study of women and heart disease and the development of novel therapeutics in the management of atherosclerosis and diabetes mellitus.

Dr. O'Donoghue earned her Medical Degree from Columbia University College of Physicians and Surgeons in New York. She completed her residency in internal medicine and fellowship in cardiovascular medicine at Massachusetts General Hospital in Boston. She subsequently completed a Masters in Public Health degree at the Harvard School of Public Health.

Jonas Oldgren (Uppsala, SWE)

Jonas Oldgren is Professor of Coagulation Research, Senior Consultant in Cardiology, and the Executive director of Uppsala Clinical Research Center (UCR), within Uppsala University and Uppsala University Hospital.

Dr. Oldgren has been investigator, national coordinator, and more recently executive steering committee member and/or coordinating investigator in several large-scale randomized clinical trials in cardiovascular medicine, e.g. RE-LY, RE-DEEM, EMANATE, RE-DUAL PCI, SPIRRIT-HFpEF, SCOREd, TIMING, and ABC AF. He was the co-chairman of the global RELY AF registry, and serves in data safety monitoring boards of on-going multinational clinical trials. Dr. Oldgren was a member of the task force for the 2016 European Society of Cardiology Atrial Fibrillation Guidelines, participated in the writing committee for European Heart Rhythm Association NOAC Practical guide 2013, 2015 and 2018, and has published more than 100 papers in peer-reviewed journals.

Torbjørn Omland (Lørenskog, NOR)

Torbjørn Omland received his Medical Degree and PhD degrees from the University of Bergen, Norway. Dr. Omland has worked as a postdoctoral fellow at the Cardiovascular Division, Brigham and Women's Hospital in Boston, and has also received a MPH degree from the Harvard School of Public Health. He is a Professor of Medicine at the University of Oslo and a consultant cardiologist at Akershus University Hospital. His research interests include cardiovascular biomarkers of subclinical myocardial injury and dysfunction, risk stratification of patients with heart failure and coronary artery disease, and prevention of cardiac injury and dysfunction in patients receiving cancer therapy. Dr. Omland was the P.I. of the PRADA trial. He is the author of numerous scientific papers in Circulation, JAMA, The Lancet, and NEJM. He is co-editor of "Chronic Coronary Artery Disease. A Companion to Braunwald's Heart Disease" and is currently serving as an Associate Editor of Circulation.

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.

Gail D. 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.

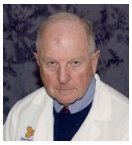
In her role as Director of NHLBI's Office of Clinical Research, Dr. Pearson is responsible for ensuring the appropriate stewardship of NHLBI-funded clinical research. Her research interests focus on clinical trials and clinical research in congenital and acquired pediatric cardiovascular disease.

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.

Ieana L. Piña (New York, USA)

Ieana L. Piña 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.



Bertram Pitt (Ann Arbor, USA)

Bertram Pitt is a professor of medicine emeritus at the University of Michigan, School of Medicine.

He obtained his Medical 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 such as 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.

Stuart Pocock (London, GBR)

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

His primary research interest concerns clinical trials, both as regards methodological developments and applied collaboration in major trials. His particular methodologic interests include: standards for the statistical reporting of trials and epidemiological studies, the statistical ethical and organisational principles for data monitoring including early stopping guidelines, the presentation of time-to-event (survival) data, the pros and cons of equivalence trials, and problems of multiplicity in trial reporting eg subgroup analyses, multiple outcomes and covariate adjustment.

Professor Pocock runs a statistical centre for the design, conduct, analysis and reporting of major clinical trials, especially in cardiovascular diseases. He is also a consultant statistician for a wider range of clinical trials in which expert statistical advice is needed, and serves as a statistical member of many trial data monitoring and steering committees. He collaborates internationally especially with the Cardiovascular Research Foundation in New York and the New England Research Institutes in Boston. He is a frequent lecturer on a variety of clinical trial issues.

Josh Porter (Olink, USA)

Josh Porter is a Business Development Manager for Olink Proteomics, a Swedish biotech company, dedicated to innovation, quality, rigor

and transparency, which provides outstanding products and services for human protein biomarker discovery.

Kristin Pothier (EY-Parthenon, Ernst & Young LLP, Boston, USA)

Kristin Pothier has over 20 years of experience in the life sciences and medical industries. She built and leads Parthenon-EY Life Sciences, the global strategy business of EY, serving corporate, investor, and institutional clients in pharma, device, diagnostics, and life science research tools and services, with focus on commercial strategy and M&A support for corporate and PE clients, and operational and implementation strategy for medical institutions worldwide.

She is also the creator and leader of EY Precision Medicine™, and is a diagnostics clinical laboratory expert, developing platform and reference lab strategies worldwide for corporates and institutions with on the ground experience in North America, South America, EU, Asia, India, MENA, and the Caribbean.

Prior to EY, Kristin was a Partner and owner of Health Advances where she built and managed the firm with 4 other partners, and developed and led the Diagnostics and Life Sciences practice, a global practice focused on product and service strategy, corporate strategy, health economics and deal diligence.

Susan Quella (Rochester, USA)

Susan Quella 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 British Journal 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.

Arshed Quyyumi (Atlanta, USA)

Arshed Quyyumi is currently a tenured Professor of Medicine in the Division of Cardiology at Emory University School of Medicine and Co-Director at Emory Clinical Cardiovascular Research Institute.

He graduated from Guy's Hospital medical school in London, and after accomplishing part of his medicine and cardiology training in London, he completed his fellowship training at Massachusetts general Hospital, Harvard University in Boston and at the National Institutes of Health (NIH), Bethesda, Maryland. He was a Senior Investigator and director of the cardiac catheterization laboratory at the Cardiology Branch of the National Institutes of Health for several years before arriving at Emory.

His research focus over the last quarter century has been on clinical and translational research in vascular biology, progenitor cells and angiogenesis, biomarkers and cardiovascular omics. He has performed seminal studies investigating mechanisms of myocardial ischemia including silent ischemia in the past. His current studies include comprehensive assessment of vascular endothelial function and arterial stiffness and thickness in patients with arteriosclerosis and its risk factors.

Gary Raskob (Oklahoma, USA)

Gary Raskob is Dean of the OU Hudson College of Public Health, and Regents Professor of Epidemiology and Medicine, at the University of Oklahoma Health Sciences Center, Oklahoma

City, Oklahoma. His research and scholarly interests are in the prevention, diagnosis and treatment of deep-vein thrombosis and pulmonary embolism; clinical trials; prevention research; evidence-based medicine and public health; and the translation of research evidence into practice and health policy.

Dr. Raskob serves as Chair of the Steering Committee for World Thrombosis Day, on behalf of the International Society of Thrombosis and Haemostasis (ISTH). Dr. Raskob also serves as a member of the external advisory panel on thrombosis and hemostasis for the National Heart, Lung and Blood Institute (NHLBI), and as an advisor on blood disorders to the Centers for Disease Control and Prevention (CDC).

Dr. Raskob received his PhD in pharmaceutical sciences from the University of Oklahoma, a Master of Science (MSc) degree in clinical epidemiology and health research methodology from McMaster University in Hamilton, Canada, and a Bachelor of Science degree in pharmacology from the University of Toronto, Canada.

Jeff Riesmeyer (Lilly, USA)

Jeff Riesmeyer is the Senior Medical Director for Cardiovascular Development at Eli Lilly and Company. His responsibilities span early to late phase cardiovascular projects including design and execution of cardiovascular outcomes studies (CVOT). Previous development projects include prasugrel (TRITON, TRILOGY, ACCOAST), and evacetrapib (ACCELERATE). Ongoing efforts include REWIND, the CVOT for dulaglutide, and planning for the cardiovascular development of tirzepatide.

He received his Medical Degree from Baylor College of Medicine in Houston, Texas. His postgraduate training included an internship and a residency in Internal Medicine at the University of Michigan in Ann Arbor, and a fellowship in Cardiology at the University of Texas Health Science Center at San Antonio.

Dan Riskin (Verantos, USA)

Dan Riskin is Founder and Chief Executive Officer of Verantos and previously held positions as Founder and CEO of Health Fidelity and Special Projects Consultant at Apple. He is Adjunct Professor of Surgery and Adjunct Professor of Biomedical Informatics Research at Stanford University.

Dr. Riskin is an expert in healthcare artificial intelligence and successful serial entrepreneur. Products he has developed and commercialized influence the care of millions of patients annually. His contributions in data-driven healthcare have been featured in Forbes, The Wall Street Journal, and other leading media. He served on the Obama Healthcare Policy Committee for the 2008 Presidential Campaign and testified before Congress on the 21st Century Cures Initiative. Dr. Riskin is board-certified in four specialties, including surgery, critical care, palliative care, and clinical informatics. He holds degrees and fellowships from MIT, Stanford, and University of California.

Adel Rizkala (Novartis, USA)

Adel Rizkala is a Senior Clinical Development Director at Novartis, which he joined in 2009. He has 16-year experience in drug development in the pharmaceutical industry. Adel led the execution of the PARADIGM-HF megatrial, which demonstrated the benefits of sacubitril/valsartan in reducing morbidity and mortality in HFrEF. Currently, Adel is in charge of PARAGON-HF, the megatrial investigating the safety/efficacy of sacubitril/valsartan in reducing outcomes in HFpEF. As a member of the sacubitril/valsartan team, Adel is heavily involved in all aspects of trial design and execution, patient recruitment, and data analysis and interpretation.

Prior to joining Novartis, Adel designed and managed clinical trials in respiratory disease and in chronic and end stage kidney disease anemia

at Watson Labs and Forrest Labs, respectively. He holds a bachelor's degree in pharmacy from St. John's University in NY, a doctor of pharmacy degree from Rutgers University in NJ, and a master's degree in biostatistics from Columbia University in NY.

Matthew T. Roe (Durham, USA)

Matthew T. Roe is a cardiologist with extensive experience as principal investigator in numerous phase II-IV cardiovascular clinical trials. He has also served in leadership roles for observational registries focusing on patients with acute myocardial infarction, patients undergoing percutaneous coronary intervention, and patients with familial hyperlipidemia.

Dr. Roe is the DCRI Fellowship Program Director and served as faculty director of the Global Megatrials group at the DCRI from 2013-2017. He is the co-principal investigator of the ADAPTABLE trial (the first, large-scale pragmatic trial being conducted in the PCORnet network). He has published over 400 articles in high-tier journals.

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 Medical Degree 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.

Robert S. Rosenson (New York, USA)

Robert S. Rosenson is Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and Director of Cardiometabolic Disorders at Mount Sinai Heart, New York, New York. He is the recipient of numerous awards and honors, including the Ground-Breaking Doctors Award from Chicago magazine, and named New York Top Doc from 2015-2018. Dr. Rosenson was named recipient of the Simon Dack Award for outstanding scholarship by the Journal of the American College of Cardiology in 2015, 2016 and 2017; and received the Jan J. Kellerman Memorial Award by the International Academy of Cardiology in 2016 for distinguished contributions in the field of cardiovascular disease prevention.

Dr. Rosenson served as principal investigator (PI) on a number of studies funded by the National Institutes of Health, and Global PI for pharmaceutical-funded, multicenter drug trials including PLASMA I, PLASMA II, FRANCIS, BANTING and METCHNIKOFF. He has authored more than 300 journal articles published in peer-reviewed journals, and 600 electronic publications for UpToDate Medicine. Dr Rosenson is co-Editor in Chief for Cardiovascular Drugs and Therapy, Section Editor on Metabolic Disorders for the Journal of the American College of Cardiology, and Section Editor on Lipid Disorders for UpToDate.

Patrick Rossignol (Nancy, FRA)

Patrick Rossignol 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.

Jean Lucien Rouleau (Montreal, CAN)

Jean Lucien Rouleau obtained his Medical Degree in 1974 and has held numerous senior administrative positions such as director of the Cardiac Program/Cardiology Divisions at UHN and Mount Sinai Hospital, Toronto, Dean of Université de Montréal, Faculty of Medicine and Scientific Director of the Institute of Circulatory and Respiratory Health of CIHR (2010-2015). In 2011, he directed the development of what has become the largest strategic program of CIHR, the Strategy for Patient Oriented Research (SPOR). He is presently director of the cardiac research axis at the Montreal Heart Institute.

His H index is over 100, and he published over 440 scientific articles in journals such as Circulation, JAMA, Lancet and NEJM. He presently chairs the NHLBI STICH trial, and is an executive committee member of several large clinical trials.

Prabir Roy-Chaudhury (Tucson, USA)

Prabir Roy-Chaudhury 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 which is a comprehensive, integrated, multi-disciplinary translational research program that includes basic science, clinical science and patient care components. 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 received national and international awards, has published over 150 peer reviewed manuscripts and has delivered over 200 invited lectures across the globe.

Juddson Rupp (Charlotte, USA)

Juddson Rupp is a lifelong patient who has a lot of passion behind what we are doing at Milestone. This is true partly from the amazing patient survivor journey he has been on.

From a young athlete having heart murmurs to Hypertrophic Cardiomyopathy in his mid 20's, and miraculously surviving 'Sudden Death' while exercising, thanks to a Good Samaritan using an AED and CPR…to A-Fib, and to eventually having an EF as low as 10%, and Heart Failure to ultimately having a successful Heart Transplant, 3 years ago at Duke University Medical Center. He is truly lucky and blessed to be here today, and to be

working as the Patient Advocacy Manager for an up and coming biopharmaceutical startup. A long time sales and marketing executive, and graduate of the University of Virginia, he yearned to turn something Bad (my health story) into something Good(helping patients live longer, healthier lives) through the biopharma industry.

Donna H. Ryan (Baton Rouge, USA)

Donna H. Ryan is Professor Emerita at Pennington Biomedical in Baton Rouge, LA, and current President of World Obesity Federation. She is Associate Editor-in-Chief of the journal Obesity and has authored more than 200 publications, primarily on obesity. She is co-chair of the SELECT Steering Committee. Dr. Ryan's research focuses on nutrition, obesity and obesity comorbidities. She has been an investigator for various US National Institutes of Health-sponsored studies, including Pounds Lost, DASH (Dietary Approaches to Stop Hypertension), DPP (Diabetes Prevention Program) and the Look AHEAD study. Dr. Ryan's continuing interests focus on translation of effective weight management into primary care practices. Dr. Ryan also served as Co-Chair on the expert panel for the ACC/AHA/TOS evidence-based Guidelines on the Evaluation and Management of Overweight and Obesity in Adults and was a panel member of the 2015 Endocrine Society Systematic Evidence Review and Guidelines for Medications that Affect Body Weight.

Marc S. Sabatine (Boston, USA)

Marc S. Sabatine 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, he leads an Academic Research Organization whose mission has been to advance the knowledge and care of patients suffering from cardiovascular disease and its risk factors. 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, he 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.

Arun Sanyal (Richmond, USA)

Arun Sanyal has developed, mediated and encouraged liver research globally as a physician scientist for over 25 years. His research has focused on nonalcoholic fatty liver disease and the complications of end-stage liver disease with a particular focus on the translation of scientific discovery towards development of better diagnostics and therapeutics for patients with liver disease. He has published 398 scholarly papers with a Hirsch index of 100 and has been continuously funded by the National Institutes of Health for 24 years. Dr. Sanyal has chaired the hepatobiliary study section of the NIH and leads the NIDDK NASH Clinical Research Network and the FNIH NIMBLE consortium. He has served as past President of the AASLD and led the development of the core curriculum for training in hepatology that served as the foundation for establishment of national standards in training. By creation of the Liver Forum, he has also accelerated development of therapeutics for NASH globally. His work and leadership has been recognized by several awards and earlier this year received the Virginia Outstanding Scientist Award for his deep commitment to the betterment of human health globally via science, education and policy.

Jennifer Schumi (AstraZeneca, SWE)

Jennifer Schumi is a Director of Statistical Standards in AstraZeneca's Biometrics and Information Sciences, Advanced Analytics Centre. She develops and maintains cross-therapeutic area standards and guidance documents on statistical methodology. Prior to joining AZ, she spent ten years at Statistics Collaborative, Inc., providing guidance on statistical issues to pharmaceutical and biotechnology clients. She has a special interest in using data visualization tools to simplify monitoring, both internally for risk-based quality monitoring and externally to support independent data monitoring committees. She holds an MS in Statistics (Iowa State University) and a PhD in Biostatistics (Harvard University).

Rob Scott (Abbvie, USA)

Rob Scott is Zimbabwean born and a graduate of University of Cape Town. He has held leadership positions in global Pharma for over thirty years. At Pfizer he developed Lipitor and Norvasc, including personal involvement in many large scale CV trials. At AtheroGenics, he designed and implemented the first large cardiovascular outcomes study to be wholly performed by a small biotech. At Amgen, he conducted the first outcome study for a PCSK9i, FOURIER. Dr. Scott was a member of the FDA Cardiac and Renal Drug Advisory Committee from 2012 to 2016. Dr. Scott is currently the Chief Medical Officer at Abbvie with responsibility for around 40 new molecular entities, three thousand people and a budget of close to two billion dollars. He also created the Development Design Center, a Center of Excellence focused on using predictive analytics and big data to design and implementing clinical trials. He is a board member of Transcelerate and a member of the PhRMA Biomedical Advisory Committee.

Dr. Scott is a leader in digital transformation of clinical research.

Monica Shah (IQVIA, USA)

Monica Shah is Vice President of Cardiovascular Medical Strategy at IQVIA. In this role, Dr. Shah works collaboratively with sponsors, the scientific community, and other stakeholders to develop and implement strategic approaches to cardiovascular clinical trials. She is also responsible for providing executive medical oversight to cardiovascular clinical trials.

Dr. Shah's areas of expertise include clinical trials, clinical research, cardiovascular disease, heart failure, cardiac transplantation, mechanical circulatory support, pulmonary hypertension, and HIV-related cardiovascular disease. She was the Director of the Trial Innovation Network in the Division of Clinical Innovation, the National Center for Advancing Translational Sciences (NCATS). Dr. Shah was also the Deputy Chief of the Heart Failure and Arrhythmias Branch at the National Heart, Lung, and Blood Institute (NHLBI).

Dr. Shah is a board-certified heart failure and transplant cardiologist. She completed her undergraduate education at Brown University and her medical education at the Brown University Medical School. She then completed a residency in internal medicine at the Johns Hopkins Hospital, and a fellowship in cardiology at Duke University Medical Center.

Sanjiv Shah (Chicago, USA)

Sanjiv Shah is the Stone Endowed Professor of Medicine, Director of the T1 Center for Cardiovascular Therapeutics, and Director of the HFpEF Program at Northwestern University Feinberg School of Medicine. Dr. Shah's research interests include understanding the pathophysiology, mechanisms, epidemiology, and treatment of HFpEF. Dr. Shah started the first dedicated HFpEF clinical program at Northwestern University in 2007, and has been a leading enroller in HFpEF clinical trials since that

time. Dr. Shah's research interests also include the study of acquired and genetic risk factors for abnormal cardiac mechanics, and novel machine learning techniques for improved classification and therapeutic targeting for HF syndromes. Dr. Shah is currently the PI of 3 active NIH R01 grants and an AHA Strategically Focused Research Network project grant, and he is also the PI or on the executive/steering committee member for several ongoing international HF clinical trials. Dr. Shah has published over 250 peer-reviewed research publications, and he is an Associate Editor for JAMA Cardiology.

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.

Kimberly A. Smith (FDA, USA)

Kimberly A. Smith is a nephrologist in the Division of Cardiovascular and Renal Products within the Office of New Drugs, Center for Drug Evaluation and Research (CDER), at the FDA. Prior to joining the FDA, she was with the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services (CMS). Dr. Smith is a graduate of the University of Michigan Medical School, and she completed her residency and chief residency in Internal Medicine and fellowship in Nephrology at Vanderbilt University Medical Center. She then returned to the University of Michigan as faculty and obtained a master's degree in Health and Healthcare Research through the Robert Wood Johnson Foundation Clinical Scholars Program.

Scott D. Solomon (Boston, USA)

Scott D. Solomon 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.

Stuart Spencer (The Lancer, GBR)

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

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. 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. 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.

Laurence S. Sperling (Atlanta, USA)

Laurence S. Sperling is the Founder and Director of The Heart Disease Prevention Center at Emory. He is currently the Katz Professor in Preventive Cardiology at the Emory University School of Medicine, and Professor of Global Health in the Rollins School of Public Health. Dr. Sperling served as the President of the American Society for Preventive Cardiology from 2014-2016, and currently serves on the writing committee of the ACC/ AHA Guideline on the Management on Blood Cholesterol.

Dr. Sperling received his Medical Degree in 1989, and completed 8 additional years of training at Emory including a residency in internal medicine, chief resident year at Emory University Hospital, an NIH-supported research fellowship in molecular and vascular medicine, and a clinical fellowship in cardiovascular diseases.

Dr. Sperling has been an investigator in a number of important clinical trials including JUPITER, COURAGE, and BARI-2D. He was co-editor of the ACC's Diabetes Self Assessment Program, a member of the ACC Prevention Committee, and currently serves as Co-Chairman of the ACC's Diabetes and Cardiometabolic Working group. He serves on the Research and Publications committee of the National Diabetes Collaborative Registry, and as Co-Chair of the World Heart Federation Roadmap for Prevention of CVD among people with diabetes.

Kenneth Stein (Boston Scientific, USA)

Kenneth Stein is Senior Vice President and Chief Medical Officer for Rhythm Management and Global Health Policy at Boston Scientific. Ken is a Phi Beta Kappa graduate of Harvard College (in Economics), and earned his Medical Degree 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.

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. He currently 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 also 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 was involved in basic science research prior to joining FDA in 1991. He has served as Director, Division of Cardiovascular and Renal Products in CDER since 2004.

Catherine Stoney (NHLBI, USA)

Catherine Stoney has wide-ranging expertise in the area of stress, psychopathology, and cardiovascular disease with a special interest in studying the pathways by which these psychosocial factors and diseases of the heart and cardiovascular system are linked and modified. She is Deputy Branch Chief and Program Director in the Clinical Applications and Prevention Branch in the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute, where she is involved in a number of clinical trials as well as a program in implementation science. Prior to joining NIH, Dr. Stoney was Professor of Psychology at the Ohio State University, where she conducted clinical investigations of phenotypes associated with patterns of coping with stress, examinations of how psychological factors impact metabolic and inflammatory processes, clinical trials to reduce physiological stress responses, and the biologic mechanisms by which negative affect, depression, and psychopathology affect the progression of cardiovascular disease.

Wai Hong Wilson Tang (Cleveland, USA)

Wai Hong Wilson Tang is Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University, and Research Director of the Section of Heart Failure and Transplantation Medicine at Cleveland Clinic. He is the Director of the Center for Clinical Genetics at the Cleveland Clinic. He serves as Associate Director for Cleveland Clinic Coordinating Center for Clinical Research (C5Research), and the director for Hub Research Capacity (Clinical Research Unit) for Case Western Reserve University's Clinical and Translational Sciences Collaborative. As a clinician-scientist and practicing heart failure/transplant cardiologist, Dr. Tang's translational research focuses on understanding the cellular and molecular mechanisms that contribute to disease progression in heart failure and cardiomyopathies, cardio-renal disease, and cancer-related heart diseases. He has been elected as member of the American Society of Clinical Investigation in 2013 and the Association of American Physicians in 2018 for studying the contributing role of microbiome in cardiovascular diseases.

Jean-Claude Tardif (Montreal, CAN)

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 and is the Chairman of the steering committees of the CIHR funded Canadian Atherosclerosis Imaging Network and Medical Imaging Trials NEtwork of Canad. 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. 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 R. Teerlink (San Francisco, USA)

John R. Teerlink 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.

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.

Pamela Tenaerts (Durham, USA)

Pamela Tenaerts is the Executive Director at the Clinical Trials Transformation Initiative (CTTI) where she works closely with the Executive Committee to develop and implement strategies to accomplish CTTI's mission. She provides senior level oversight of CTTI and orchestrates efforts to effectively engage all stakeholders to improve the conduct of clinical trials. She is on the Board of Directors for the Society of Clinical Trials and a member of the Advisory Council North America, DIA; PCORI's CTAP Expert Post-award Subcommittee; and MIT's Collaborative Initiatives Clinical Trials Process Expert Advisory Board.

With more than 20 years' experience, Dr. Tenaerts practiced medicine in both the emergency department and private practice setting before embarking into research. Prior to CTTI, she oversaw European operations for CoAxia, a medical device company focused on cerebral ischemia. Dr. Tenaerts received her Medical Degree from Catholic University of Leuven, Belgium, and a MBA from the University of South Florida.

Stefan Teunis (Oldenzaal, NED)

Stefan Teunis was born with a VSD and has had two open heart surgeries to date. The first was at two months old and the second was seven years

ago. He knows he will need another surgery in the future but is unsure of when and what type.

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.

Jacob Udell (Toronto, CAN)

Jacob Udell is Cardiologist and Assistant Professor of Medicine at Women's College Hospital and the Peter Munk Cardiac Center of Toronto General Hospital, teaching hospitals of the University of Toronto. Utilizing the administrative health care databases, registries, and clinical trial populations at their disposal, his team studies the cardiovascular benefits and risks of diabetes and antiplatelet therapies and other novel therapies, including influenza vaccination. His work on innovative cardiovascular risk factor identification and therapies has led to: clinical trial and outcomes publications in the NEJM, JAMA, Circulation, JACC, and Lancet Diabetes; alterations in international cardiovascular practice guidelines; and changes by the FDA and EMA in the label of DPP4 and SGLT2 inhibitors.

Ellis F. 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), U.S. 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 is 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.

Muthiah Vaduganathan (Boston, USA)

Muthiah Vaduganathan is a Fellow in Cardiovascular Medicine at Brigham and Women's Hospital and Harvard Medical School (Boston, MA).

He is interested in drug development and clinical trials in HF. He has authored or co-authored over 200 peer-reviewed publications and serves on the editorial boards of the European Journal of Heart Failure and JACC Heart Failure (Social Media/ CME Editor). He is an institutional representative on the NHLBI-supported Heart Failure Apprentice Network, serves on the ACCF/AHA Task Force on Performance Measures, and is involved in an FDA Think Tank on improving future clinical trials in HF. He participates as a Clinical Endpoints Committee member for ongoing advanced-phase trials in HF / post-MI LV dysfunction and as a site investigator for DELIVER (dapagliflozin in HFpEF) and SELECT (semaglutide in obese/overweight) at Brigham and Women's Hospital.

Peter van der Meer (Groningen, NED)

Peter van der Meer received both his MD and PhD cum laude from the University of Groningen in the Netherlands and worked as a visiting scientist at Harvard Medical School, Boston. He is registered as a cardiologist and director of the coronary care unit of the University Medical Center Groningen in the Netherlands. He is a member of the ESC 2016 Heart Failure guidelines committee, member of the cardio-oncology nucleus of the ESC and associate editor of the European Journal of Heart Failure. He is a member of several steering committees to investigate new and old drugs in heart failure, including intravenous iron and digoxin.

His research-group consists of PhD students and post docs with various backgrounds (biologists, physician-scientists, and biomedical-engineers) working on (translational) research topics. His group focuses on exploring novel treatment targets working from bench to bedside. He has an international network consisting of (stem cell) biologists, bioengineers and clinicians, which he established during his years of research abroad. This was in 2016 awarded with an ERC Grant by the European Union.

Natascha van der Post (Nijmegen Area, NED)

Natascha van der Post is 37 years old and mother of two boys, living together with them and her 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 and suggests improvements focusing on the importance of patients, hoping to improve research.

Marion Van Sinttruije (Zwolle, NED)

Marion Van Sinttruije has a degree in Business Economics (Master) and English (Bachelor). Both degrees obtained during working life at ages 37 and 30 respectively. She has worked in civil engineering and professional publishing

and broadcasting. She was born in 1955 and is married. She was diagnosed with hypertrophic cardiomyopathy (hereditary) and has turned out progressive, heart failure. She is active in HCM patient advocacy and research.

Bernard Vasseur (FDA, USA)

Bernard Vasseur 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.

Jeffrey I. Weitz (Hamilton, CAN)

Jeffrey I. Weitz is Professor of Medicine and Biochemistry and Biomedical Sciences at McMaster University and Executive Director of the Thrombosis and Atherosclerosis Research Institute. Board Certified in Internal Medicine, Hematology and Medical Oncology, Dr. Weitz focuses his clinical practice on patients with thrombotic disorders. His research spans the spectrum from basic studies in the biochemistry of blood coagulation and fibrinolysis to animal models of thrombosis and on to clinical trials of antithrombotic therapy. The breadth of his work is highlighted by his over 500 publications in journals as diverse as the Journal of Clinical Investigation, Journal of Biological Chemistry, Biochemistry, Circulation, Blood, Annals of Internal Medicine, New England Journal of Medicine and Lancet, and 60 book chapters. The recipient of numerous awards, Dr. Weitz is a Fellow of the American Heart Association, the Royal Society of Canada and the Canadian Academy of Health Sciences.

Christopher Wilcox (Sarfez, USA)

Christopher Wilcox received his Medical Degree from Oxford University, Ph.D. from London University and specialist training in medicine, neurology, nephrology and hypertension at St. Mary's Hospital, London (U.K.). He has held faculty appointments at London and Cambridge Universities in the U.K., Yale, Harvard and Florida Universities in the U.S.A. For the last 24 years, he has been a Professor of Nephrology, Chief of the Division and Director of the Hypertension Center at Georgetown University. He is a Fellow of the Royal College of Physicians (U.K.), a Fellow of the Royal Society of Medicine (U.K.) and a Master of the American College of Physicians. He has published two books (in their third and sixth editions) and 300 papers. His work is supported by three grants from the National Institutes of Health. He holds two patents as inventor for new drugs. He directs a clinical faculty of five physicians, a research faculty of eight scientists, and ten post-doctoral scientists or clinical nephrology fellows. His research interests include developing new drugs for hypertension or edema and the renal mechanisms of hypertension. He directs a basic science laboratory and a clinical research program.

Jayna Williams (New Hampshire, USA)

Jayna Williams was diagnosed with Cardiomyopathy in April of 2016 after being admitted to Stony Brook University Hospital for Congestive Heart Failure. Her ejection fraction was 14%. With medication therapy, she has increased

to 25% - 30%. A subcutaneous defibrillator was implanted in May of 2017. She has qualified and participated in one trial through Stony Brook University Hospital. Its purpose was to study the effects of sodium in cardiac patients. She was the subject in an educational video regarding potassium and diet for WebMD and Medscape. She is looking forward to becoming involved in others trials.

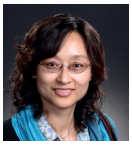
Jayna works full time as an Optician in an Optometry practice. She has 2 sons who are being regularly monitored for her condition. Her father, grandfather and cousin passed in their 60's from this heart disease. Her sister was recently diagnosed.

Stephen Williams (Somalogic, USA)

Stephen Williams is currently Chief Medical Officer, SomaLogic Inc. in Boulder CO. Our mission is to scan the living data stream of human proteins with great precision, sensitivity and scale and translate it into actionable insights for every seeker and enabler of human health. This mission capitalizes on the proprietary SOMAscan 5000-plex protein assay.

Since joining SomaLogic in 2009, Stephen has been responsible for the Clinical R&D that enables discovery and qualification of machine-learning derived protein patterns – "health insights", derived from blood samples that mimic the best objective measures of current and future state of health. Additionally, Steve is responsible for studies that prospectively measure products' impact and utility.

Stephen has been involved in a number of notable biomarker initiatives throughout his career from authorship of PhRMA position papers on "proof of concept", surrogate endpoints and evidentiary standards for biomarkers and diagnostics, through helping to initiate the biomarkers consortium and the Alzheimer's Disease NeuroImaging (ADNI) study, teaching drug and regulatory science at UCSF, and continues today with involvement in the FNIH-FDA-Industry working group on biomarker evidentiary standards.



Lijing L. Yan (Kushan, CHN)

Lijing L. Yan is the Head of Non-communicable Chronic Diseases (NCDs) Research at the Global Health Research Center since July 2014 and Director of Graduate Studies for the Master of Science in Global Health Program at Duke Kunshan University in China. She has a bachelor's degree in Sociology from Peking University, a Master of Public Health degree in Epidemiology and a doctoral degree in Demography from the University of California, Berkeley. Her main areas of research are primary care and community-based cardiometabolic disease prevention and control, healthy aging, health innovation and implementation science. She has led multiple Chinese and international projects and published over 80 peer-reviewed scientific papers some of which in leading medical journals such as JAMA, the Lancet, and Circulation. She is the former secretary general of the China Consortium of Universities for Global Health.

Fred Yang (KBP Biosciences, USA)

Fred Yang has 20+ years of experience in clinical research and drug development, with expertise focusing on statistics and quantitative science. He assumed increasing responsibilities in both Big Pharma (Abbott, Pharmacia, GSK etc.) and small biotech (Discovery Labs), overseeing biostatistics as well as trial conduct and strategic planning. He had successful end-to-end development and worldwide regulatory experiences. His therapeutic experiences range from diabetes, cardiorenal, arthritis, oncology and neonatal care, with many publications.

Dr. Y. Fred Yang leads development of medical strategies of KBP Biosciences. In this capacity Fred provides leadership and insights of medical development of the company's clinical stage compounds.

Fred is currently adjunct associate professor at Drexel University Medical School.

Fred received his B.S. degree of Mathematics from Peking University and his Ph.D. degree on Biostatistics from University of Wisconsin.

Lisa Yanoff (FDA, USA)

Lisa Yanoff is Acting Director of the Division of Metabolism and Endocrinology Products in the Office of New Drugs at the U.S. Food and Drug Administration. She obtained her MD from the University of Maryland School of Medicine, after which she completed post-graduate training in Internal Medicine and in Diabetes, Endocrinology, and Metabolism at the National Institutes of Health Inter-Institute Endocrine Training Program. At FDA since 2008, she has extensive experience with cardiovascular outcomes trials conducted as per the FDA's guidance for industry: Diabetes Mellitus, Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes.

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.

Andreas Zeiher (Frankfurt, GER)

Andreas Zeiher is Professor of Medicine and board-certified in internal medicine and cardiology. He served on the faculties of the Albert-Ludwig-University of Freiburg from 1990 – 1995 as director of interventional cardiology and - since 5/1995- Dr. Zeiher is the Chairman of Medicine III (Cardiology / Angiology / Nephrology) at the J. W. Goethe-University of Frankfurt/ Germany. Dr. Zeiher is currently President-elect of the German Cardiac Society (DGK) and will be acting President from 2019-2021.

His current h-index is 146 according to Google Scholar. According to Thomson Reuters analysis, Dr. Zeiher belongs to the Highly Cited Researchers, ranking among the top 1% most cited for the field of Clinical Medicine. He has served on the Editorial Boards of several Journals, including Circulation, Circulation Research, European Heart Journal and others, and he is an active reviewer for The New England Journal of Medicine, JAMA, The Lancet, Nature, Nature

Medicine, Circulation, Circulation Research, European Heart Journal and others.

Dr. Zeiher's research has been continuously supported by grants from all major institutions in Germany (DFG, BMBF) as well as by the European Union.

Emmanouil Zouridakis (EMA, GBR)

Emmanouil Zouridakis is Senior Medical Assessor at the UK Medicines & Healthcare Products Regulatory Agency (MHRA), working in the Assessment Unit of the Licensing Division that is responsible for cardiovascular, diabetes and renal products.

Dr. Zouridakis is a cardiologist and worked at different teaching hospitals before joining the MHRA in 2004. During his time at MHRA he has been the lead clinical assessor in a wide range of European and National regulatory procedures involving cardiovascular and diabetes medicines, drug/device combinations, class-wide benefit-risk reviews and scientific advices to companies. He is a principal assessor at the Cardiovascular Expert Advisory Group of the UK Commission on Human Medicines and is participating in the European Medicines Agency Cardiovascular Working Party.

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.

Notes

Notes

SAVE the DATE

CVCT FORUM 2019

DECEMBER 5 - 7, 2019

GENERAL INFORMATION

CONGRESS VENUE

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REGISTRATION FEE

CVCT 2018 - Registration rates	ONSITE
CVCT Academia	$500,00
Only for doctors, physicians, clinicians or statisticians. This discount cannot be applied to industy	
CVCT Junior	$150,00
Trainee, assistant, junior.	
CVCT R&D partners	$1 100,00
Only R&D official partner companies of the event are permitted to register to the preferential rate mentioned above.	
CVCT Industry	$5 500,00
Staff of pharmaceutical and device companies who wish to participate in the CVCT and debate about the latest clinical trials are most welcome.	

REGISTRATION FEE

CVCT 2018 - Registration rates ONSITE
Participant registration fee includes

- Access to all scientific sessions
- Access to the Clinical Gathering Space
- Congress materials
- Lunches during the Forum
- Daily coffee breaks
- Networking Reception on Friday, November 30th

Opening hours of the welcome desk

- Thursday, November 29th: 8:00AM - 6:30PM
- Friday, November 30th 7:30AM - 7:00PM
- Saturday, December 1st 7:30AM - 4:30PM

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.

TRANSPORT

Event: 15TH GLOBAL CARDIOVASCULAR CLINICAL TRIALISTS FORUM
Event ID: 33669AF - Valid for travel from November 24 to December 8 December, 2018

Event location: Washington, DC, USA

Attractive discounts on a wide range of airfares on all Air France and KLM flights worldwide**.

Use the website of this event or visit *www.airfranceklm-globalmeetings.com* to:

- access the preferential fares granted for this event*,
- make your booking,
- issue your electronic ticket*,
- and select your seat**.

If you buy your ticket via AIR FRANCE & KLM Global Meetings website, your electronic ticket will carry a special mention which justifies the application of the preferential fares.
Should you prefer to process your reservations and ticket-purchase directly with an Air France and KLM sales outlet, you must keep this current document which serves to justify the application of the preferential airfares. Keep the document to justify the special fares with you as you may be asked for it at any pointof your journey.
Frequent flyer / loyalty programs of Air France and KLM partner airlines are credited with "miles" when Air France or KLM flights are used.

* not available in certain countries
** subject to conditions


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