FINAL PROGRAM

CVCT WASHINGTON, DC US

16th Global Cardio Vascular Clinical Trialists Forum

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

DECEMBER
2019 THURSDAY 5 - SATURDAY 7

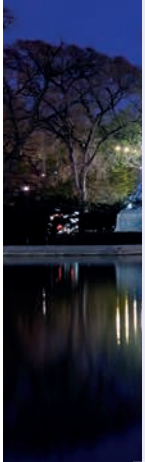
www.globalcvctforum.com

FACULTY – Academy

1. Kirkwood Adams (Chapel Hill, USA)
2. Tariq Ahmad (New Haven, USA)
3. Paul Armstrong (Alberta, CAN)
4. Michel Azizi (Paris, FRA)
5. George Bakris (Chicago, USA)
6. Jeroen Bax (Leiden, NED)
7. Bijal Balasubramanian (Dallas, USA)
8. Pierre Boutouyrie (Paris, FRA)
9. Jeffrey Borer (New York, USA)
10. Martin Borggrefe (Heidelberg, GER)
11. Javed Butler (Jacksonville, USA)
12. John Camm (London, GBR)
13. Kimberly Chapman (Washington, USA)
14. Antoniades Charalambos (Oxford, GBR)
15. Julio Chirinos (Philadelphia, USA)
16. Robert Cody (Flemington, USA)
17. David J Cohen (Kansas City, USA)
18. Lisa Cooper (Baltimore, USA)
19. Kennedy Cruickshank (London, GBR)
20. Nikolaos Dagres (Leipzig, GER)
21. George Dangas (New York, USA)
22. David DeMets (Madison, USA)
23. Thomas Deering (Atlanta, USA)
24. Peter DiBattiste (Raritan, USA)
25. Kenneth Dickstein (Stavanger, NOR)
26. Victor Dzau (Washington, USA)
27. Murray Epstein (Miami, USA)
28. Keith Ferdinand (New Orleans, USA)
29. Dean Fergusson (Ottawa, CAN)
30. João Ferreira (Nancy, FRA)
31. Gerasimos Filippatos (Athens, GRE)
32. Mona Fiuzat (Washington, USA)
33. Darrel Francis (London, GBR)
34. Jane Freedman (Worcester, USA)
35. Bernard Gersh (Rochester, USA)
36. Nadia Giannetti (Montreal, CAN)
37. Michael C. Gibson (Boston, USA)
38. Rachel Gold (Portland, USA)
39. Chris Granger (Durham, USA)
40. John Gregson (London, GBR)
41. Kendra Grubb (Atlanta, USA)
42. Leonardo Guimarães (Quebec City, CAN)
43. Koji Hasegawa (Kyoto, JAP)
44. Adrian Hernandez (Durham, USA)
45. Gerhard Hindricks (Leipzig, GER)
46. Jemma Hopewell (Oxford, GBR)
47. Stefan James (Uppsala, SWE)
48. Jim Januzzi (Boston, USA)
49. Meg Jardine (Sydney, AUS)
50. Thomas Jernberg (Stockholm, SWE)
51. Peter Jüni (Toronto, CAN)
52. David E Kandzari (Atlanta, USA)
53. Mina Karami (Amsterdam, NED)
54. Muhammad Shahzeb Khan (Chicago, USA)
55. Korey Kennelty (Iowa City, USA)
56. David Kent (Boston, USA)
57. Sverre Kjeldsen (Oslo, NOR)
58. Susheel Kodali (New York, USA)
59. Wolfgang Koenig (Munich, GER)
60. Marvin Konstam (Boston, USA)
61. Jim Kremidas (Alexandria, USA)
62. Harlan Krumholz (New Haven, USA)
63. Valentina Kutyifa (Rochester, USA)
64. Reijo Laaksonen (Tempere, FIN)
65. Carolyn Lam (Singapore, SIN)
66. Hiddo Lambers Heerspink (Groningen, NED)
67. Yan Lijing (Kunshan, CHN)
68. Joseph Loscalzo (Boston, USA)
69. Lars Lund (Stockholm, SWE)
70. Thomas Lüscher (Zurich, CHE)
71. Holly Fernandez Lynch (Philadelphia, USA)
72. Finnian McCausland (Boston, USA)
73. Darren McGuire (Dallas, USA)
74. John McMurray (Glasgow, GBR)
75. Louise Marais (Issy les Moulineaux, FRA)
76. David Maron (Stanford, USA)
77. Felipe Martinez (Cordoba, ARG)
78. Manuel Mayr (London, GBR)
79. Roxana Mehran (New York, USA)
80. Robert Mentz (Durham, USA)
81. Erin Michos (Baltimore, USA)
82. Brian Mittman (Pasadena, USA)
83. Christopher O'Connor (Washington, USA)
84. Milton Packer (Dallas, USA)
85. Marc Pfeffer (Boston, USA)
86. Jonathan Piccini (Durham, USA)
87. Ileana Piña (Detroit, USA)
88. Bertram Pitt (Ann Arbor, USA)
89. Geoffrey Pitt (New York, USA)
90. Stuart Pocock (London, GBR)
91. Piotr Ponikowski (Wroclaw, POL)
92. Arshed Quyyumi (Atlanta, USA)
93. Clare Relton (London, GBR)
94. Franck Rockhold (Durham, USA)
95. Matt Roe (Durham, USA)
96. Julio Rosenstock (Dallas, USA)
97. Patrick Rossignol (Nancy, FRA)
98. Hani Sabbah (Detroit, USA)
99. Naveed Sattar (Glasgow, GBR)
100. Heribert Schunkert (Munich, GER)
101. Sanjiv Shah (Chicago, USA)
102. Tabassome Simon (Paris, FRA)
103. Scott Solomon (Boston, USA)
104. Manish Sood (Ottawa, CAN)
105. Francis Spinale (Columbia, USA)
106. Kári Stefánsson (Reykjavik, ICE)
107. Erik Stroes (Amsterdam, NED)
108. Robert Tagalicod (Clarksburg, USA)
109. Wilson Tang (Cleveland, USA)
110. Jean Claude Tardif (Montreal, CAN)
111. Nina Teicholz (New York, USA)
112. Jan Tijssen (Amsterdam, NED)
113. Thomas Thum (Hanover, GER)
114. Peter van der Meer (Groningen, NED)
115. Muthiah Vaduganathan (Boston, USA)
116. Orly Vardeny (Minneapolis, USA)
117. Erkki Vartiainen (Helsinki, FIN)
118. Rajesh Vedanthan (New York, USA)
119. Eric Velasquez (New Haven, USA)
120. Hector Ventura (Jefferson, USA)
121. Subodh Verma (Toronto, CAN)
122. Christoph Wanner (Würzburg, GER)
123. Charles Weijer (London, CAN)
124. Janet Wittes (Washington, USA)
125. Joseph Wu (Stanford, USA)
126. Salim Yusuf (Hamilton, CAN)
127. Faiez Zannad (Nancy, FRA)
128. Michael Zile (Charleston, USA)

FACULTY – Industry

130. Jodi Akin (Hawthorne Effect, USA)
131. Sameer Ather (Xpert Dox, USA)
132. Agim Beshiri (Abbott Diagnostics, USA)
133. Elisabeth Björk (AstraZeneca, SWE)
134. Maria Borentain (BMS, USA)
135. Uli Broedl (Boehringer, CAN)
136. Philippe Brudi (Kinexum, CAN)
137. Alan Cheng (Medtronic, USA)
138. Sidney Cohen (Medtronic, USA)
139. Gadi Cotter (Momentum Research, USA)
140. Björn Dahlöf (Cereno, SWE)
141. Beth Davison (Momentum Research, USA)
142. Lorenzo A. DiCarlo (Livanova, USA)



143. Wilfried Dinh (Bayer, GER)
144. Jay Edelberg (Myokardia, USA)
145. Alexander Fleming (Kinexum, USA)
146. Liz Galle (CVRx, USA)
147. Jyothis George (Boehringer, GER)
148. Stephen Gough (Novo Nordisk, DEN)
149. Andrey Gurevich (Vifor Fresenius, CHE)
150. Marlene Haffner (Haffner Associates, USA)
151. Maxime He (Owkin, FRA)
152. Yoran Hummel (eki.ai, SIN)
153. Helina Kassahun (Amgen, USA)
154. Tamara Krcmar (Servier, FRA)
155. Fouzia Laghrissi-Thode (DalCor, CHE)
156. Anna Maria Langkilde (AstraZeneca, SWE)
157. Jack Lawrence (Janssen, USA)
158. Francesca Lawson (Applied Therapeutics, USA)
159. Marty Lefkowitz (Novartis, USA)
160. Barry Liden (Edwards, USA)
161. Douglas Losordo (Caladrius, USA)
162. Theodore Lystig (Medtronic, USA),
163. Carolyn Magill (Aetion, USA)
164. Fady Malik (Cytokinetics, USA)
165. Laura Mauri (Medtronic, USA)
166. Evan Mills (OLINK, USA)
167. Claudio Mori (Vifor Fresenius, CHE)
168. Manal Morsy (Athersys, USA)
169. Rajat Mukherjee (Cytel, USA)
170. Linda Mundy (American Regent, USA)
171. Pieter Muntendam (G3Pharma, USA)
172. Rachel Ostroff (Somalogic, USA)
173. Magnus Petersson (AstraZeneca, SWE)
174. Jon Plehn (Covance, USA)
175. Cristina Rabadan-Diehl (Westat, USA)
176. Jeremy Rassen (Aetion, USA)
177. Stephanie Reisinger (Veradigm, USA)
178. Jeffrey Riesmeyer (Eli Lilly, USA)
179. Dan Riskin (Verantos, USA)
180. Lothar Roessig (Bayer, GER)
181. Sebastien Roux (Idorsia, CHE)
182. Amy Sehnert (Myokardia, USA)
183. Bobby Stutz (AtCor, USA)
184. Benoît Tyl (Servier, FRA)
185. Kenneth Stein (Boston Scientifc, USA)
186. David Thompson (Syneos Health, USA)
187. Martin Unverdorben (Daiichi-Sankyo, USA)
188. Patrick Verta (Edwards, USA)
189. Fred Yang (KBP Biosciences, USA)

FACULTY – Finance, Technology and Reimbursement Experts

190. Omar Ali (Portsmouth, GBR)
191. Steve Farmer (CMS, USA)
192. Bruno Flamion (Namur, BEL)
193. Joseph Hutter (CMS, USA)

FACULTY – Patients/ Patient Advocacy

194. Jacqueline Alikhaani (Los Angeles, USA)
195. Sadegh Alikhaani (Los Angeles, USA)
196. Brenda Alsemgeest (Amsterdam, NED)
197. Cynthia Chauhan (Wichita, USA)
198. Jillianne Code (Vancouver, CAN)
199. Patrick Gee (Chesterfield, USA)
200. Penilla Gunther (Stockholm, SWE)
201. Nick Hartshorne-Evans (London, GBR)
202. Denis Janssen (Zuid, NED)
203. Robin Martinez (Denver, USA)
204. Greg Merritt (Ann Arbor, USA)
205. Susan Quella (Rochester, USA)
206. Juddson Rupp (Charlotte, USA)
207. Marietta Verbakel (Nijmegen, NED)
208. Patricia Vlasman (Amsterdam, NED)

FACULTY – Journal

209. Joseph Hill (Circulation, USA)
210. John Jarcho (NEJM, USA)
211. Stuart Spencer (The Lancet, GBR)

FACULTY – MEDIA

212. Larry Husten (New York, USA)

FACULTY – Government Funding and Regulatory Agencies

213. Angeles Alonso (EMA, GBR)
214. Jacqueline Corrigan-Curay (FDA, USA)
215. Andrew Farb (FDA, USA)
216. Christian Grimstein (FDA, USA)
217. Kolbeinn Gudmundsson (CHMP, EMA, ICE)
218. Ilan Irony (FDA, USA)
219. Robert Kazmierski (FDA, USA)
220. Scott Kim (NIH,USA)
221. Andrea Laslop (CHMP, EMA, AUT)
222. Adrian Magee (FDA, USA)
223. George Mensah (NIH, USA)
224. Mauro Moscucci (FDA, USA)
225. Theresa Mullin (FDA, USA)
226. Jessica Paulson (FDA, USA)
227. Krishna Prasad (MHRA, EMA, GBR)
228. Yves Rosenberg (NIH, USA)
229. Fred Senatore (FDA, USA)
230. Norman Stockbridge (FDA, USA)
231. Catherine M. Stoney (NIH, USA)
232. Robert Temple (FDA, USA)
233. Aliza Thompson (FDA, USA)
234. Ellis Unger (FDA, USA)
235. Bart Van der Schueren (CVWP, CHMP, BEL)
236. Bernard Vasseur (FDA, USA),
237. George F. Van Hare (FDA, USA)
238. Emmanouil Zouridakis (MHRA, GBR)
239. Bram Zuckerman (FDA, USA)

GENERAL MESSAGE

16th Global Cardio Vascular Clinical Trialists Forum CVCT WASHINGTON, DC US

Welcome to the 16th 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, regulatory and health technology experts, health care professionals and health insurance experts, major media and medical journal experts, patient advocacy group experts, and industry R&D experts. This mix from various backgrounds makes CVCT unique, a place where faculty and participants are more willing to brainstorm together rather than teach future generations. It is an opportunity to work together.

Our 2019 edition brings more new and exciting ways to engage. For the first time we will have sessions for Interventional CardioVascular Clinical Trialists (*i*CVCT). Saturday, December 7th will see a third track just for *i*CVCT led by Dr. Roxana Mehran. A few of our topics include: PCI PHARMACOLOGY TRIALS/DEVICE DRUG INTERACTIONS, TAVR PHARMACOLOGY TRIALS, TAVR AND TMVR AND TRICUSPID REPAIR, HOW TO BRIDGE THE GAPS IN EVIDENCE? and HOW WILL THE CLINICIAN KNOW WHOM TO TREAT?

We are happy to bring back our Focused CVCT Workshop sessions after great success in 2018! These campfire-sessions are a great fit for smaller groups where the experts and participants sit as equals in small U shaped-tables. Experts are allowed brief openings and then it is over to the participants in the hope that the participants feel freer to speak to each other.

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

We look forward to another great meeting discussing all we have seen this year.

Pr Faiez Zannad

Dr Bertram Pitt

ICVCT WELCOME

The practice of interventional cardiology has been traditionally based on evidence based medicine and clinical trials. From device and drug approval to post approval programs, clinical trials have been central for generations of evidence to be translated into clinical care of our patients. We are thrilled to bring to you *i*CVCT, a comprehensive program at CVCT, focused on trials in interventional cardiology. This one day program will cover important clinical trial design and execution issues in the field of interventional vascular therapies. We plan to cover topics in coronary, vascular and structural interventions with our expert faculty from around the globe.

Welcome to this inaugural program, we look forward to having you engaged with critical and excellent audience participation.

Dr. Roxana Mehran *Dr. C. Michael Gibson*

16th Global Cardio Vascular Clinical Trialists Forum

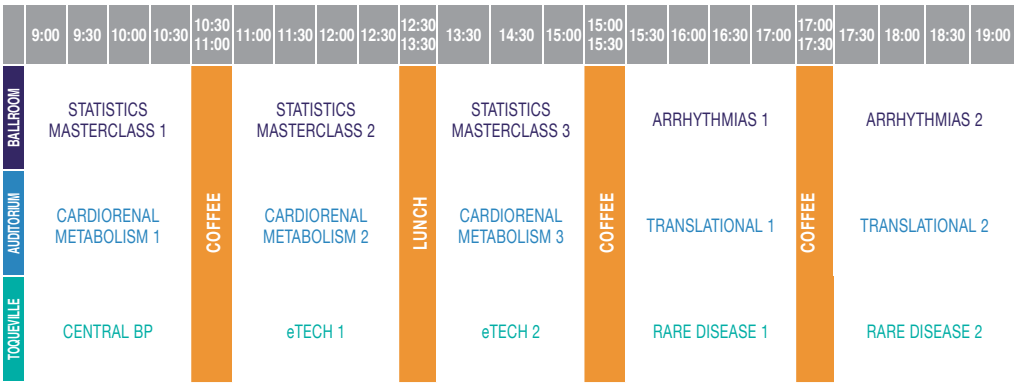
CVCT WASHINGTON, DC US

Summary

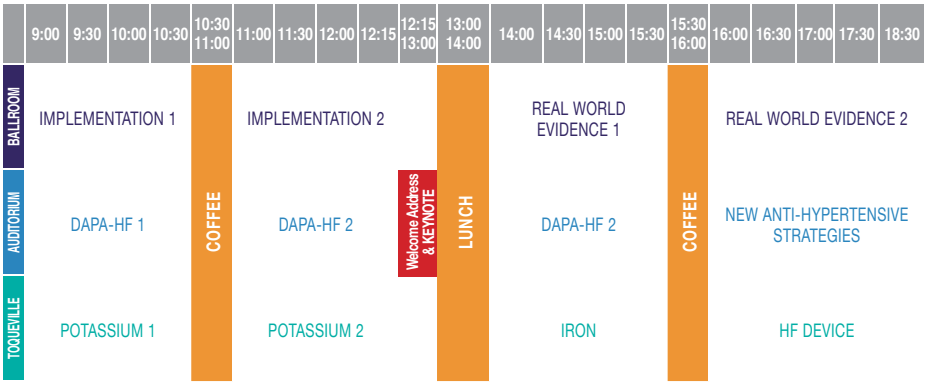
SCIENTIFIC PROGRAM

PROGRAM AT-A-GLANCE

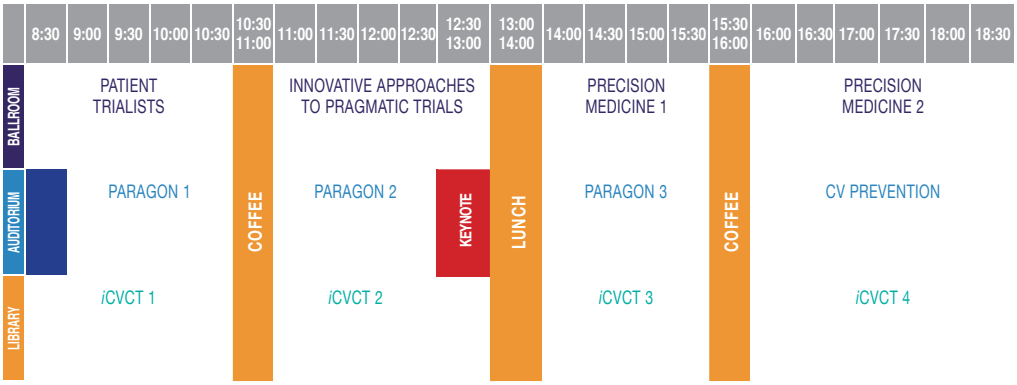
DAY 1 – **THURSDAY, DECEMBER 5th**



DAY 2 – **FRIDAY, DECEMBER 6th**



DAY 3 - **SATURDAY, DECEMBER 7th**



THURSDAY, DECEMBER 5, 2019

BALLROOM

9:00 AM – 3:00 PM
CVCT MASTERCLASS
HOW TO REPORT AND CRITIQUE MAJOR TRIALS IN CARDIOLOGY FROM A STATISTICAL PERSPECTIVE, INCLUDING RECENT STATISTICAL ADVANCES

By: Stuart Pocock (London, GBR); John Gregson (London, GBR)

Learning Objectives

To provide a comprehensive review of major clinical trials in cardiology, as regards to their reporting and critical appraisal, including a "cardiologist friendly" update on recent statistical advances.

Target audience

The content will be aimed at cardiologists, regulators, academic researchers, industry scientists and statisticians: indeed all health professionals wanting to expand their understanding of clinical trial reports and their statistical methods.

Course Description

The course will comprise three 90 minute sessions, covering key aspects of statistical analysis, reporting and critical appraisal of major trials in cardiology. This includes some recent advances in analysis of event outcomes and implications for future trial design. All will be presented in a non-technical manner, comprehensible to non-statisticians.

The two lecturers will actively encourage audience participation in a lively discussion, facilitated by an expert cardiologist as lead discussant.

Topics will be illustrated by real examples of cardiovascular trials. The goal is to structure the whole experience to be of direct practical value. Appropriate references to enhance further knowledge will be provided.

Part 1: 9:00 AM to 10:30 AM

Moderator: Bernard Gersh (Rochester, USA)

A critique of some key recent clinical trials in cardiology from a statistician's perspective:

Bernard Gersh (Rochester, USA)

Part 2: 11:00 AM to 12:30 PM

Moderator: Scott Solomon (Boston, USA)

a) Analysis and interpretation of event outcomes: life beyond the hazard ratio
John Gregson (London, GBR)

b) When to stop (and not stop) a trial early for efficacy, safety, or futility
Stuart Pocock (London, GBR)

c) Patient viewpoint
Jillianne Code (Vancouver, CAN)

Part 3: 1:30 PM to 3:00 PM

Moderator: Jan Tijssen (Amsterdam, NED)

a) The value of using repeat events in cardiology trials and how to allow for the competing risk of death
John Gregson (London, GBR)

b) How to handle the trade-off between efficacy and safety: what's best for the individual patient
John Gregson (London, GBR)

BALLROOM

3:30 PM – 7:00 PM
ARRHYTHMIAS AND ELECTROPHYSIOLOGY TRIALS
A CVCT-HRS-EHRA Joint Session

3:30 PM – 5:00 PM
Part I: Risk stratification for sudden arrhythmic death: Is there a role for machine learning, big data, or other options?

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

- **Imaging (MIBG, MRI) for risk stratification of sudden arrhythmic death**
  Jeroen Bax (Leiden, NED)

- **Trials to prospectively validate risk-guided ICD implantation: Unmet needs, challenges and opportunities**
  Nikolaos Dagres (Leipzig, GER)

- **Case Studies: Slow Trial Enrollment Resulting in Trial Termination: MADIT S-ICD, ADMIRE – ICD, STAR-VT**
  Valentina Kutyifa (Rochester, USA)

- **Industry viewpoint**
  Alan Cheng (Medtronic, USA)

- **FDA viewpoint**
  George Van Hare (CDRH, FDA, USA)

- **Payer viewpoint: What is needed to approve reimbursement?**
  Steve Farmer (CMS, USA)

- **Patient viewpoint**
  Juddson Rupp (Charlotte, USA); Patricia Vlasman (Amsterdam, NED)

The CVCT Forum:
Moderated multi-stakeholder panel discussion
Part I: How to make risk-guided ICD a reality

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

Panelists: Jeroen Bax (Leiden, NED); Alan Cheng (Medtronic, USA); Nikolaos Dagres (Leipzig, GER); Valentina Kutyifa (Rochester, USA); Jessica Paulson (FDA, USA); Jonathan Piccini (Durham, USA); Juddson Rupp (Charlotte, USA); George Van Hare (CDRH, FDA, USA); Patricia Vlasman (Amsterdam, NED); Bram Zuckerman (FDA, USA)

BALLROOM

5:30 PM – 7:00 PM
Part II: Have Rhythm Management randomized clinical trials died: who killed them and where are the alternatives?

Moderators: John Camm (London, GBR); Yves Rosenberg (NIH/NHLBI, USA)

- **AFib ablation trials tribulations– Is CABANA an exception or a warning of the future?**
  Bernard Gersh (Rochester, USA)

- **Have we lost our ability to execute electrophysiology clinical trials? If so, what can we do about it?**
  John Camm (London, GBR)

- **Are there alternatives? Value of registries/real world evidence to supplement or even replace randomized clincial trials**
  Kenneth Dickstein (Stavenger, NOR)

- **NIH Perspective**
  Yves Rosenberg (NIH/NHLBI, USA)
- **FDA viewpoint**
  George Van Hare (CDRH, FDA, USA)
- **Patient viewpoint**
  Juddson Rupp (Charlotte, USA)
- **Industry viewpoint**
  Kenneth Stein (Boston Scientific, USA)

The CVCT Forum:
Moderated multi-stakeholder panel discussion
Part II: How to make EP more evidence-based

Moderators: John Camm (London, GBR); Yves Rosenberg (NIH/NHLBI, USA)

Panelists: Bernard Gersh (Rochester, USA); Kenneth Dickstein (Stavenger, NOR); Jessica Paulson (FDA, USA); Jonathan Piccini (Durham, USA); Juddson Rupp (Charlotte, USA); Kenneth Stein (Boston Scientific, USA); George Van Hare (CDRH, FDA, USA); Bram Zuckerman (FDA, USA)

AUDITORIUM

9:00 AM – 3:00 PM
DIABETES CARDIORENAL OUTCOME TRIALS

9:00 AM – 10:30 AM
DIABETES CARDIORENAL OUTCOME TRIALS
Part I: Claims and approvable indications. How to adapt to the changing landscape?

Moderators: Adrian Hernandez (Durham, USA); Muthiah Vaduganathan (Boston, USA)

GLP1 receptor agonist trials across the CV risk spectrum
Robert Mentz (Durham, USA)

Clinical significance of CREDENCE: A cardiorenal composite outcome trial
Meg Jardine (Sydney, AUS)

Targeting diabetes kidney disease. Insight from FIGARO, FIDELIO and other trials
Georges Bakris (Chicago, USA)

Endothelin receptor antagonists. The SONAR trial
Georges Bakris (Chicago, USA)

How to design outcomes trials when standards of care are changing
Darren McGuire (Dallas, USA)

Statistical viewpoint
David DeMets (Madison, USA)

DIABETES CARDIORENAL OUTCOME TRIALS
The CVCT Forum:
Multi-stakeholders moderated panel discussion
Part I: Claims and approvable indications.
How to adapt to the changing landscape?

Moderators: Adrian Hernandez (Durham, USA); Muthiah Vaduganathan (Boston, USA)

Panelists: Georges Bakris (Chicago, USA); David DeMets (Madison, USA); Meg Jardine (Sydney, AUS); Hiddo Lambers Heerspink (Groningen, NED); Robert Mentz (Durham, USA); Darren McGuire (Dallas, USA)

AUDITORIUM

11:00 AM – 12:30 PM
DIABETES CARDIORENAL OUTCOME TRIALS
Part II: Interpretation and reporting issues

Moderators: Robert Mentz (Durham, USA); Julio Rosenstock (Dallas, USA)

Industry viewpoint
Pete DiBattiste (Raritan, USA); Jyothis George (Boehringer Ingelheim, GER); Stephen Gough (Novo Nordisk, DEN); Jeffrey Riesmeyer (Eli Lilly, USA); Lothar Roessig (Bayer, GER)

Regulatory viewpoint. When can we rely on surrogate renal endpoints in pivotal trials for approval?
Angeles Alonso (MHRA-EMA, GBR)

Journal Editors viewpoint
John Jarcho (NEJM, USA)

CARDIORENAL OUTCOME TRIALS
Part II: Interpretation and reporting issues
The CVCT Forum:
Multi-stakeholders moderated panel discussion

Moderators: Robert Mentz (Durham, USA); Julio Rosenstock (Dallas, USA)

Panelists: Angeles Alonso (MHRA-EMA, GBR); Pete DiBattiste (Raritan, USA); Jyothis George (Boehringer Ingelheim, GER); Stephen Gough (Novo Nordisk, DEN); John Jarcho (NEJM, USA); Jeffrey Riesmeyer (Eli Lilly, USA); Lothar Roessig (Bayer, GER)

AUDITORIUM

1:30 PM – 3:00 PM
CARDIORENAL OUTCOME TRIALS
Part III: Implementation issues. How to facilitate adoption?

Moderators: Darren McGuire (Dallas, USA); Christoph Wanner (Würzburg, GER)

How guidelines are to adapt to the rapidly changing landscape? Who will be at the driving seat?

- **The Diabetologist?**
  Julio Rosenstock (Dallas, USA)
- **The Cardiologist?**
  Muthiah Vaduganathan (Boston, USA)
- **The Nephrologist?**
  Christoph Wanner (Würzburg, GER)

Payer viewpoint
Bruno Flamion (Namur, BEL)

Patient viewpoint
Denis Janssen (Zuid, NED); Susan Quella (Rochester, USA)

CARDIORENAL OUTCOME TRIALS
The CVCT Forum: Multi-stakeholders moderated panel discussion
Part III: Implementation issues. How to facilitate adoption?

Moderators: Darren McGuire (Dallas, USA); Christoph Wanner (Würzburg, GER)

Panelists: Bruno Flamion (Namur, BEL); Denis Janssen (Zuid, NED); Susan Quella (Rochester, USA); Julio Rosenstock (Dallas, USA); Muthiah Vaduganathan (Boston, USA)

AUDITORIUM

3:30 PM – 7:00 PM
HOW CAN WE DO A BETTER JOB MAXIMIZING THE CHANCES OF SUCCESS IN PROGRESSING TO PHASE III TRIALS?

3:30 PM – 5:00 PM
Part I: Early strategies for downstream success

Moderators: Jane Freedman (Worcester, USA); Hani Sabbah (Detroit, USA)

Limitations and advantages of preclinical animal models
Hani Sabbah (Detroit, USA)

Human-induced pluripotent stem cell model
Joseph Wu (Stanford, USA)

Biomarker guided early development
Francis Spinale (Columbia, USA)

Basic science journal editor viewpoint
Jane Freedman (Circulation Research, USA)

Industry viewpoint
Fady Malik (Cytokinetics, USA); Benoît Tyl (Servier, FRA)

Patient viewpoint
Mariette Verbakel (Nijmegen, NED)

The CVCT Forum: Moderated Multi-stakeholders panel discussion
Part I: Reassessing upstream strategies for success

Moderators: Jane Freedman (Worcester, USA); Hani Sabbah (Detroit, USA)

Panelists: Fady Malik (Cytokinetics, USA); Hani Sabbah (Detroit, USA); Francis Spinale (Columbia, USA); Benoît Tyl (Servier, FRA); Mariette Verbakel (Nijmegen, NED); Joseph Wu (Stanford, USA)

AUDITORIUM

5:30 PM – 7:00 PM
Part II: Are ongoing early trials designed to optimally transition to phase III?
RAPID FIRE CASE STUDIES
(5 min presentations)

Moderators: Christopher O'Connor (Washington, USA)

BAY 1753011Dual Vasopressin antagonist
Wilfried Dinh (Bayer, GER)

Valproic Acid repurposing
Björn Dahlöf (Cereno, SWE)

HNO donors
Maria Borentain (BMS, USA)

Cardiac myosin inhibitor
Fady Malik (Cytokinetics, USA)

Aldose reductase inhibitors
Francesca Lawson (Applied Therapeutics, USA)

Cardiac myosin modulators
Amy Sehnert (Myokardia, USA)

Galectin-3 inhibitors for treatment and prevention of cardiovascular disease
Pieter Muntendam (G3Pharma, USA)

Calcium antagonists for valve disease
Geoffrey Pitt (New York, USA)

Noncoding RNA therapeutics
Thomas Thum (Hanover, GER)

Anti IL-6 tocilizumab in myocardial infarction
Ola Kleveland (Oslo, NOR)

New P2Y12 receptor antagonist
Sebastien Roux (Idorsia, CHE)

The CVCT Forum:
Moderated Multi-stakeholders panel discussion
Part II: Are we creative enough in dealing with early STAGE DEVELOPMENTS?

Moderators: Christopher O'Connor (Washington, USA)

Panelists: Maria Borentain (BMS, USA); Björn Dahlöf (Cereno, SWE); Wilfried Dinh (Bayer, GER); Ola Kleveland (Oslo, NOR); Francesca Lawson (Applied Therapeutics, USA); Fady Malik (Cytokinetics, USA); Pieter Muntendam (G3Pharma, USA); Geoff rey Pitt (New York, USA); Sebastien Roux (Idorsia, CHE); Amy Sehnert (Myokardia, USA); Thomas Thum (Hanover, GER)

TOCQUEVILLE

9:00 AM – 10:30 AM
AN ARTERY CVCT FOCUSED WORKSHOP
ARTERIAL STIFFNESS/AORTIC PRESSURE WAVEFORM ANALYSIS.
HOW HELPFUL FOR CV TRIALS?

Moderators: Pierre Boutouyrie (Paris, FRA); Arshed Quyyumi (Atlanta, USA)

FOCUSED WORKSHOP

Focused CVCT Workshops are organized as campfire-sessions, fit for smaller focused groups: the experts and participants brainstorm around a U shape-table, as equals. These are high caliber faculty with a typical mix of stakeholders from academia, regulatory, payers, industry, patients and journal editors. The moderated panel discussion aims at fostering exchanges, potentially shifting the lines and reaching operational conclusions.

State of the art: Arterial stiffness/Aortic pressure waveform analysis in health and disease
Pierre Boutouyrie (Paris, FRA)

Is arterial stiffness a potential target for therapy?
Julio Chirinos (Philadelphia, USA)

Could arterial stiffness become a surrogate for CV protection?
Kennedy Cruickshank (London, GBR)

Regulatory viewpoint: Are subclincial disease endpoints approvable?
Norman Stockbridge (FDA, USA)

Investigator viewpoint
Arshed Quyyumi (Atlanta, USA)

Industry viewpoint
Wilfried Dinh (Bayer, GER); Jon Plehn (Covance, USA); Bobby Stutz (AtCor, USA)

CVCT Multi-stakeholders moderated panel discussion

Moderators: Pierre Boutouyrie (Paris, FRA); Arshed Quyyumi (Atlanta, USA)

Panelists: Julio Chirinos (Philadelphia, USA); Kennedy Cruickshank (London, GBR); Wilfried Dinh (Bayer, GER); Louise Marais (Issy les Moulineaux, FRA); Jon Plehn (Covance, USA); Norman Stockbridge (FDA, USA); Bobby Stutz (AtCor, USA)

TOCQUEVILLE

11:00 AM – 3:00 PM

CVCT FOCUSED WORKSHOP
eTECHNOLOGY AND OTHER CREATIVE SOLUTIONS FOR OPTIMIZING RANDOMIZED CLINICAL TRIAL EXECUTION
A CVCT- ACRP (ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS) Joint Session

FOCUSED WORKSHOP

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- **The cost of conducting CV clinical trials is the rising cost of drug development, and has increased at a much higher rate than inflation during the past 25 years.**
- **The total development costs for a drug have risen nearly 13-fold ($100 million in 1975 to $1.3 billion in 2005 in constant dollars), as a consequence of increases in the size and length of trials.**
- **However, major duration and cost drivers are work required by study personnel, the number of trial visits and procedures, the type and amount of data collected, and site monitoring.**
- **These considerations have resulted in some pharmaceutical companies shifting away from the cardiovascular arena beceause they perceive a relatively greater potential return from investments in non-cardiovascular areas.**
- **Many creative solutions for optimizing randomized clinical trial execution are being offered, tested and implemented.**
- **This multi-stakeholder session will examine the progress so far, successes and failures, expectations and challenges, hype and hope.**

TOCQUEVILLE

11:00 AM – 12:30 PM

Part I: eSolutions for clinical trials

Moderators: Jim Kremidas (Alexandria, USA); Harlan Krumholz (New Haven, USA)

Use of Electronic Medical Records for patient screening, recruitment, and follow up
Stefan James (Stockholm, SWE); Harlan Krumholz (New Haven, USA)

Artificial Intelligence decision tool for echocardiography in clinical trials
Yoran Hummel (eki.ai, SIN)

Machine learning for medical research
Maxime He (Owkin, FRA)

Decentralized follow up with trained healthcare professionals. The HEROs experience
Jodi Akin (Hawthorne Effect, USA)

Deriving Real-World Insights From Real-World Data: Statistician viewpoint
Frank Rockhold (Durham, USA)

The CVCT Forum: Multi-stakeholders moderated panel discussion
Part I: eSolutions for clinical trials

Moderators: Jim Kremidas (Alexandria, USA); Harlan Krumholz (New Haven, USA)

Panelists: Jodi Akin (Hawthorne Effect, USA); Maxime He (Owkin, FRA); Stefan James (Stockholm, SWE); Yoran Hummel (eki.ai, SIN); Frank Rockhold (Durham, USA)

TOCQUEVILLE

1:30 PM – 3:00 PM

Part II: Creative operational solutions for trial execution

Moderators: Gadi Cotter (Momentum Research, USA); Mona Fiuzat (Washington, USA)

What went wrong with phase III "failed" trials?
Gadi Cotter (Momentum Research, USA); Beth Davison (Momentum Research, USA)

The role of collaborative investigator networks. Experience from Heart Failure Collaboratory
Mona Fiuzat (Washington, USA)

Transitioning to single institutional review boards
Orly Vardeny (Minneapolis, USA)

Trials in resource limited settings
Yan Lijing (Kunshan, CHN)

Site clinical research professional view
Jim Kremidas (Alexandria, USA)

Industry viewpoint
Uli Broedl (Boehringer, CAN)

Patient viewpoint
Robin Martinez (Denver, USA); Greg Merritt (Ann Arbor, USA)

The CVCT Forum: Multi-stakeholders moderated panel discussion
Part II: Creative operational solutions for trial execution

Moderators: Gadi Cotter (Momentum Research, USA); Mona Fiuzat (Washington, USA)

Panelists: Uli Broedl (Boehringer, CAN); Beth Davison (Momentum Research, USA); Jim Kremidas (Alexandria, USA); Yan Lijing (Kunshan, CHN); Greg Merritt (Ann Arbor, USA); Orly Vardeny (Minneapolis, USA)

TOCQUEVILLE

3:30 PM – 7:00 PM

A KINEXUM CVCT FOCUSED WORKSHOP
WHAT CAN RARE CV DISEASE TRIALISTS AND COMMON CV DISEASE TRIALISTS LEARN FROM EACH OTHER?

FOCUSED WORKSHOP

Focused CVCT Workshops are organized as campfire-sessions, fit for smaller focused groups: the experts and participants brainstorm around a U shape-table, as equals. These are high caliber faculty with the typical mix of stakeholders from academia, regulatory, payers, industry, patients and journal editors. The moderated panel discussion aims at fostering exchanges, potentially shifting the lines and reaching operational conclusions.

Orphan and rare cardiovascular diseases include rare diseases of systemic or pulmonary circulation, cardiomyopathies, congenital or genetic cardiovascular diseases, arrhythmogenic disorders, cardiac tumors and cardiovascular disease in malignancy, cardiovascular diseases in pregnancy, and subsets of common cardiovascular conditions (e.g. heart failure with preserved ejection fraction).

There are distinctive features of clinical and regulatory development of drugs in such rare diseases, compared to standard common CV diseases. This includes tiny patient pools, challenging recruitment strategies, "creative" adaptive design and biostatistical approaches adapted to "small" samples, more reliance on biomarkers, surrogate endpoints, and patient reports outcomes endpoints and frequent use of post-approval safety and Real-World Evidence data collection. Topics worth discussing are whether i) there are lessons Small Trialists may offer to Large Trialists, and vice-versa, ii) innovations of rare disease trials may or may not be extendable to large trials, iii) common diseases will approach rare diseases with the advent of precision medicine, iv) FDA and EMA may act synergistically and better align in more impactful, respective, or common guidance documents.

Objectives:

- **Discuss issues, opportunities and solutions associated with rare cardiovascular diseases and their small to tiny clinical trials.**
- **Promote exchange of resourceful approaches and best practices in trials and evidence generation for therapies targeting rare cardiovascular diseases.**
- **Case studies and examples from emerging companies working on rare cardiovascular diseases will serve for a robust multi-stakeholder discussion involving small and large pharma (and device) companies, R&D experts, small and large trialists, methodologists, statisticians, NIH, EMA and FDA experts, as well as input from payers, lawyers, and importantly from "patients trialists," a mix unique to CVCT meetings.**

TOCQUEVILLE

3:30 PM – 5:00 PM
Part I: Creative solutions for rare disease trials

Moderators: Kimberly Chapman (Washington, USA); Janet Wittes (Washington, USA)

Clinical and Regulatory challenges/Opportunities in Rare Cardiovascular Diseases
Kimberly Chapman (Washington, USA)

Innovative design and statistical solutions for small clinical trials
Janet Wittes (Washington, USA)

Innovative operational solutions enabling trials in rare/orphan disease
Marlene Haffner (Haffner Associates, USA)

Challenges of matching patients, clinical trials, and practitioners
Sameer Ather (Xpert Dox, USA)

Case Study: Advanced Therapy for Rare CV Disease
Douglas Losordo (Caladrius, USA)

The CVCT Forum: Moderated multi-stakeholder panel discussion
Part I: Creative solutions for rare disease trials

Moderators: Kimberly Chapman (Washington, USA); Janet Wittes (Washington, USA)

Panelists: Sameer Ather (Xpert Dox, USA); Marlene Haffner (Haffner Associates, USA); Douglas Losordo (Caladrius, USA)

TOCQUEVILLE

5:30 PM – 7:00 PM
Part II: The innovations of rare disease trials and how they may or may not be extendable to large trials

Moderators: Alexander Fleming (Kinexum, USA); Marlene Haffner (Haffner Associates, USA)

Are FDA and EMA guidance aligned regarding clinical development of drugs for rare/orphan diseases?
Kolbeinn Gudmundsson (CHMP, EMA, ICE); Ilan Irony (FDA, USA)

Statistical viewpoint
Janet Wittes (Washington, USA)

Industry viewpoint
Jay Edelberg (Myokardia, USA); Alexander Fleming (Kinexum, USA)

Payer viewpoint
Joe Hutter (CMS, USA)

Patient viewpoint
Brenda Alsemgeest (Amsterdam, NED); Robin Martinez (Denver, USA)

The CVCT Forum: Moderated multi-stakeholder panel discussion Part II: The innovations of rare disease trials and how they may or may not be extendable to large trials

Moderators: Alexander Fleming (Kinexum, USA), Marlene Haffner (Haffner Associates, USA)

Panelists: Brenda Alsemgeest (Amsterdam, NED); Philippe Brudi (Kinexum, USA); Jay Edelberg (Myokardia, USA); Alan Fisher (Kinexum, USA); Kolbeinn Gudmundsson (CHMP, EMA, ICE); Joe Hutter (CMS, USA); Ilan Irony (FDA, USA); Robin Martinez (Denver, USA); Manal Morsy (Athersys, USA); Janet Wittes (Washington, USA)

FRIDAY, DECEMBER 6, 2019

BALLROOM

9:00 AM – 12:15 PM
NOVEL IMPLEMENTATION TRIALS: MAXIMIZING RIGOR & PRAGMATISM
A CVCT-NIH Joint Session

The last several decades of clinical research have resulted in clinically important advances in cardiovascular research, yet much remains lost in translation. For example, although high-quality practice guidelines are available, effective strategies for sustained behavior change at multiple levels (patient, provider, community, health system) in diverse populations and conditions are still elusive. To close the research to translation gap, we need innovative implementation trials incorporating multilevel strategies that are designed for rigor, pragmatism, and sustainability. The purpose of this session is to highlight several innovative implementation design strategies that are rigorous and pragmatic and discuss challenges and strategies for moving cardiovascular implementation science forward.

9:00 AM – 10:30 AM
Part I: Implementation Strategies in Health Care and Other Settings

Moderators: George A. Mensah (NIH, USA); Catherine M. Stoney (NIH, USA)

Part I includes presentations of rigorous and innovative on-going work from implementation scientists to illustrate novel design and implementation strategies embedded in a variety of settings including urban and metropolitan health care systems, rural settings, worksites, and community health systems. Two use cases of completed studies are presented to underscore the impact of implementation science on clinical outcomes.

Implementation Strategies Embedded in the Health Care Setting

- **Implementation Designs embedded within the health care system**
  Bijal Balasubramanian (Dallas, USA); Deborah J. Cohen (Portland, USA)
- **Implementation Designs embedded within rural health care settings**
  Korey Kennelty (Iowa City, USA)
- **Use case: Implementation Designs embedded within the health care system**
  Rachel Gold (Portland, USA)

Implementation Strategies Embedded in the Other Settings

- **Implementation Designs within Worksites**
  Rajesh Vedanthan (New York, USA)
- **Implementation Designs within Community Settings**
  Lisa Cooper (Baltimore, USA)
- **Use Case: The Barbershop Study**
  Keith Ferdinand (New Orleans, USA)

Patient viewpoint
Penilla Gunther (Stockholm, SWE)

The CVCT Forum: Multi-stakeholder moderated panel discussion
Part I: Implementation Strategies Embedded in Various Settings

Moderators: George A. Mensah (NIH, USA); Catherine M. Stoney (NIH, USA)

Panelists: Bijal Balasubramanian (Dallas, USA); Deborah J. Cohen (Portland, USA); Lisa Cooper (Baltimore, USA); Keith Ferdinand (New Orleans, USA); Korey Kennelty (Iowa City, USA); Rachel Gold (Portland, USA); Rajesh Vedanthan (New York, USA)

BALLROOM

11:00 AM – 12:15 PM
Part II: Communication Challenges and Opportunities

Moderators: Harlan Krumholz (New Haven, USA); Brian Mittman (Pasadena, USA)

Part II includes presentations of the challenges and opportunities in communicating implementation science findings in high impact journals.

Joseph Hill (Circulation, USA)

John Jarcho (NEJM, USA)

The CVCT Forum:
Multi-stakeholder moderated panel discussion and concluding remarks
Part II: Communicating implementation science findings

Moderators: Harlan Krumholz (New Haven, USA); Brian Mittman (Pasadena, USA)

Panelists: Joseph Hill (Circulation, USA); John Jarcho (NEJM, USA)

BALLROOM

2:00 PM – 6:30 PM
LEVERAGING, MANAGING, VALIDATING, AND PROTECTING REAL WORLD DATA TO FACILITATE THE TRANSFORMATION OF CLINICAL EVIDENCE
A CVCT- DCRI Think Tank Joint Session

Moderators: Patrick Gee (Chesterfield, USA); Helina Kassahun (Amgen, USA); Stefan James (Stockholm, SWE); Matthew Roe (Durham, USA)

- **Cardiovascular disease has historically been the subject of a wide variety of study designs falling under the RWE umbrella, including long-term endpoint trials, pragmatic clinical trials, and health-economic evaluations.**
- **Given the increasing interest in real-world evidence (RWE) generation to inform the development of new therapeutics, the underlying data sources, technology approaches, and study solutions for pragmatic trials with regulatory implications are evolving rapidly.**
- **Real-world data (RWD) obtained from electronic health records (EHRs), administrative claims databases, or directly from patients via digital health applications and/or biosensors/wearables are increasingly being utilized to design, plan, and execute clinical trials and observational studies.**
- **However, recent experiences with pragmatic trials and observational studies using RWD sources and technology advances have highlighted several important considerations including how to best access, utilize, and protect RWD during all phases of a clinical trial, opportunities for patients to directly acquire and share their health data from RWD sources to increase opportunities for clinical trial participation, and methodologies for assessing data quality with RWD sources.**
- **The 21st Century Cures Act in the US has increased FDA acceptance of RWE and given rise to the term "regulatory-grade RWE." But how is the regulatory-grade criterion for regulators and payers defined and what does it take for RWE to meet it?**
- **Issues of data validity, data provenance, and data protection related to RWE continue to evolve.**
- **This issue is complicated by variations in real world data RWD quality, rigor of RWD validation, analysis, and evidentiary standards for different regulatory and reimbursement decisions (post-marketing safety assessments, changes to product labeling, comparative effectiveness).**
- **Strong collaborations among all stakeholders will be needed to conduct the clinical trials and observational studies of the future.**

BALLROOM

2:00 PM – 3:30 PM
Part I: Continuous Learnings from Digital Health and RWD-Enabled Trials

Moderators: Patrick Gee (Chesterfield, USA); Helina Kassahun (Amgen, USA); Stefan James (Stockholm, SWE)

Apple Heart Study
Chris Granger (Durham, USA)

ADAPTABLE
Matthew Roe (Durham, USA)

The SWEDEHEART experience
Thomas Jernberg (Stockholm, SWE)

Real-world data, to predict randomized trial results before they're done; The RCT DUPLICATE initiative
Nicolle Gatto (Aetion, USA)

The CVCT Forum: Multi-stakeholder moderated panel discussion
Part I: Continuous Learnings from Digital Health and RWD-Enabled Trials

Moderators: Patrick Gee (Chesterfield, USA); Helina Kassahun (Amgen, USA); Stefan James (Stockholm, SWE)

Panelists: Nadia Giannetti (Montreal, CAN); Chris Granger (Durham, USA); Thomas Jernberg (Stockholm, SWE); Jack Lawrence (Janssen, USA); Nicolle Gatto (Aetion, USA)

BALLROOM

4:00 PM – 5:00 PM
Part II: Data Provenance and Protection with Real World Data,
Practical aspects of implementing credible Real World Evidence

Moderators: Patrick Gee (Chesterfield, USA); Helina Kassahun (Amgen, USA); Matthew Roe (Durham, USA)

Patients to acquire and share their EHR and claims data. The Blue Button initiative.

- **Health and Human Services viewpoint**
  Robert Tagalicod (Clarksburg, USA)
- **Patient viewpoint**
  Patrick Gee (Chesterfi eld, USA); Penilla Gunther (Stockholm, SWE)
- **Investigator viewpoint**
  Harlan Krumholz (New Haven, USA)
- **Industry viewpoint**
  Helina Kassahun (Amgen, USA); Theodore Lystig (Medtronic, USA)
- **Regulatory viewpoint**
  Krishna Prasad (CVWP, EMA, GBR)
- **Media viewpoint:**
  Larry Husten (New York, USA)

The CVCT Forum: Multi-stakeholder moderated panel discussion
Part II: Data Provenance and Protection with Real World Data, Practical aspects of implementing credible Real World Evidence

Moderators: Patrick Gee (Chesterfield, USA); Helina Kassahun (Amgen, USA); Matthew Roe (Durham, USA)

Panelists: Nadia Giannetti (Montréal, CAN); Penilla Gunther (Stockholm, SWE); Helina Kassahun (Amgen, USA); Harlan Krumholz (New Haven, USA); Theodore Lystig (Medtronic, USA); Carolyn Magill (Aetion, USA); Robert Tagalicod (Clarksburg, USA)

BALLROOM

5:00 PM – 6:30 PM
Part III: Data Authenticity and Data Quality. How to meet regulatory requirements for advanced Real World Evidence

Moderators: Stefan James (Stockholm, SWE); Matthew Roe (Durham, USA)

Trial Designs to Leverage Real World Data
Peter Jüni (Toronto, CAN); Tariq Ahmad (New Haven, USA)

AI techniques to enrich and validate RWD
Dan Riskin (Verantos, USA)

Regulatory Perspectives on Assessing RWD Quality
Jacqueline Corrigan-Curay (FDA, USA); Krishna Prasad (MHRA, EMA, GBR)

Industry Perspective
Laura Mauri (Medtronic, USA); David Thompson (Syneos Health, USA)

The CVCT Forum: Multi-stakeholder moderated panel discussion
Part III: Data Authenticity and Data Quality. How to meet regulatory requirements for advanced Real World Evidence

Moderators: Stefan James (Stockholm, SWE); Matthew Roe (Durham, USA)

Panelists: Tariq Ahmad (New Haven, USA); Jacqueline Corrigan-Curay (FDA, USA); Nadia Giannetti (Montreal, CAN); Peter Jüni (Toronto, CAN); Jack Lawrence (Janssen, USA); Laura Mauri (Medtronic, USA); Krishna Prasad (MHRA, EMA, GBR); Dan Riskin (Verantos, USA); David Thompson (Syneos Health, USA)

AUDITORIUM

9:00 AM – 3:30 PM
SGLT2 INHIBITORS HEART FAILURE TRIALS

- **Type 2 diabetes mellitus (T2DM) increases the risk of HF, frequently occurs concomitantly with HF, and worsens the prognosis of HF. Some anti-hyperglycemic medications have been associated with worse HF outcomes. Sodium glucose co-transporter 2 (SGLT2) inhibition reduce CV risk in T2DM.**
- **Across three large SGLT2 inhibitor (SGLT2i) CV outcome trials, EMPA-REG Outcomes, CANVAS) Program and DECLARE -TIMI 58 trials, SGLT2is reduced the risk of the composite of CV death or hospitalization for HF (HHF). CV benefits were more related to a reduction in incident HF events as opposed to ischemic vascular endpoints. HF prevention in T2DM may become a new indication for SGLT2is.**
- **Several mechanisms have been put forward to explain the HF benefits of SGLT2is and these drugs may emerge as therapies in the prevention of HF, but also for the treatment of patients with established heart failure in patients with or without diabetes.**
- **Several large trials are currently exploring this potential treatment opportunity for patients with HF. DAPA-HF is the first such trial with results available short before (3 weeks) the CVCT 2019 Forum.**
- **Beyond and after the main results of the DAPA-HF trial there is an important need for understanding the clinical significance, the practical consequences in terms of change of drug label, new label claims, change in international guidelines, implementation issues, and consequences on ongoing similar trials.**

- **These issues will be discussed from all stakeholders' perspectives which can be assembled only at CVCT meetings, including the principal investigators of DAPA-HF and of all other major trials in this space, clinicians and guideliners with cardiology, diabetology and nephrology respective backgrounds, statisticians, industry R&D experts, key regulatory people from FDA, EMA and Japan PMDA, major journal editors, patients, health technology agencies and payers .**

AUDITORIUM

9:00 AM – 10:30 AM
Part I: Understanding and Interpreting the results of DAPA-HF

Moderators: Naveed Sattar (Glasgow, GBR); Scott Solomon (Boston, USA)

DAPA-HF main results
John McMurray (Glasgow, GBR)

Target population and insight from subgroup analyses
Scott Solomon (Boston, USA)

Renal endpoints. Time to mind the kidney?
Scott Solomon (Boston, USA)

Safety considerations
Piotr Ponikowski (Wroclaw, POL)

Statistical viewpoint
David DeMets (Madison, USA)

Mechanistic insight. What can be learnt from DAPA-HF and other mechanistic studies?
Subodh Verma (Toronto, CAN)

The CVCT Forum. Moderated Multi-stakeholders panel discussion.
Part I: Interpreting the results of DAPA-HF

Moderators: Naveed Sattar (Glasgow, GBR); Scott Solomon (Boston, USA)

Panelists: David DeMets (Madison, USA); Hiddo Lambers Heerspink (Groningen, NED); John McMurray (Glasgow, GBR); Piotr Ponikowski (Wroclaw, POL); Scott Solomon (Boston, USA); Subodh Verma (Toronto, CAN)

AUDITORIUM

11:00 AM – 3:30 PM
Part II: Implementing the results of DAPA-HF

Moderators: Piotr Ponikowski (Wroclaw, POL); Faiez Zannad (Nancy, FRA)

What's next? The consequence of DAPA-HF on the other ongoing SGLT2i HF trials
Milton Packer (Dallas, USA); Bertram Pitt (Ann Arbor, USA)

Implementation issues in HFrEF. How to accommodate novel therapies in an ever-increasing polypharmacy burden
Faiez Zannad (Nancy, FRA)

Globalisation Issues
Felipe Martinez (Cordoba, ARG)

Industry viewpoint
Jyothis George (Boehringer, GER); Anna Maria Langkilde (AstraZeneca, SWE)

Regulatory viewpoint
Bob Temple (FDA, USA); Bart Van der Schueren (CVWP, CHMP, BEL)

Payer viewpoint
Bruno Flamion (Namur, BEL)

Patient viewpoint
Susan Quella (Rochester, USA)

The CVCT Forum. Moderated multi-stakeholder panel discussion.
Part II: Implementing the results of DAPA-HF

Moderators: Piotr Ponikowski (Wroclaw, POL); Faiez Zannad (Nancy, FRA)

Panelists: Bruno Flamion (Namur, BEL); Robert Cody (Flemington, USA); Jyothis George (Boehringer, GER); Anna Maria Langkilde (AstraZeneca, SWE); Felipe Martinez (Cordoba, ARG); Milton Packer (Dallas, USA); Bertram Pitt (Ann Arbor, USA); Susan Quella (Rochester, USA); Bob Temple (FDA, USA); Bart Van der Schueren (CVWP, CHMP, BEL)

AUDITORIUM

4:00 PM – 6:30 PM
NEW ANTIHYPERTENSIVE STRATEGIES

Moderators: George Bakris (Chicago, USA); Patrick Rossignol (Nancy; FRA)

- **Several polypill formulations have been developed and trials results have proven the feasibility, safety and efficacy in reducing risk factor levels of the polypill in individuals at moderate risk. Many challenges remain relative to the content and the formulation of polypills, the long-term safety and tolerability, the efficacy in reducing risk factor levels and cardiovascular events, physician, patient and societal acceptability, adherence, regulatory requirements, cost, and impact on lifestyle habits.**

- **Hypertension HT remains poorly controlled worldwide, and its prevalence is growing. Not all HT pathophysiological mechanisms are mitigated by the current classes of antihypertensive treatment currently available.**

- **This session will focus on the unmet needs and the development of new antihypertensive drugs acting on new targets, and the challenges related to the market pressure of cheap generic drugs.**

- **The results of early uncontrolled and unblinded trials reported large reductions in blood pressure following renal denervation in patients with uncontrolled hypertension were negated by the results of the randomized, sham-controlled SYMPLICITY HTN-3 trial. Non-adherence to antihypertensive medications, patient selection, renal denervation technologies, and center effect might have influenced these results. New trials using modern technologies and different target populations are reviving interest in renal denervation.**

- **The rigor of developing device-based treatments as well as technological modifications of existing devices is a matter of debate.**

Low cost polypill approach towards hypertension control and lowering CVD risk
Salim Yusuf (Hamilton, CAN)

Resistant hypertension
Patrick Rossignol (Nancy, FRA); Hector Ventura (Jefferson, USA)

Non steroidal mineralocorticoid receptor antagonists
Bertram Pitt (Ann Arbor, USA)

Renal denervation revival: Ongoing and recent trials

- **Hypertension specialist viewpoint**
  Michel Azizi (Paris, FRA)
- **Interventional cardiologist viewpoint**
  David E Kandzari (Atlanta, USA)

Carotid barostimulation: internal or external stimulation?
George Bakris (Chicago, USA)

Industry perspective
Sidney Cohen (Medtronic, USA); Fred Yang (KBP Biosciences, USA)

The CVCT Forum: Multi-stakeholder moderated panel discussion

Moderators: George Bakris (Chicago, USA); Patrick Rossignol (Nancy, FRA)

Panelists: Michel Azizi (Paris, FRA); Sidney Cohen (Medtronic, USA); David E Kandzari (Atlanta, USA); Bertram Pitt (Ann Arbor, USA); Hector Ventura (Jeff erson, USA); Fred Yang (KBP Biosciences, USA); Salim Yusuf (Hamilton, CAN)

TOCQUEVILLE

9:00 AM – 12:15 PM

FOCUSED CVCT WORKSHOP

WHAT ARE THE DATA NEEDS OF REGULATORS, PAYERS, GUIDELINES TO ESTABLISH POTASSIUM BINDERS AS RAASI ENABLERS?

Moderators: Bertram Pitt (Ann Arbor, USA); Patrick Rossignol (Nancy, FRA)

FOCUSED WORKSHOP

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- **Development of hyperkalemia is associated with higher risk of mortality.**
- **The concern about inducing or worsening hyperkalemia in patients eligible to or receiving RAS inhibitors and MRAs is the main driver of poor optimization of these therapies.**
- **The availability of new safe and well tolerated potassium-lowering agents may reduce the risk of hyperkalemia associated with RAASi and MRA use and could potentially enable better long-term use of these life saving medications.**
- **How best to assess the long-term risks and benefits of strategies using potassium-lowering agents is the focus of this session.**

Reassessing the risk associated with dyskalemia
Ileana Piña (Detroit, USA)

Strategies for mitigating the risk of hyperkalemia, and where potassium binders may fit?
Patrick Rossignol (Nancy, FRA)

Initiating clinical trials in patients with heart failure with reduced ejection fraction undergoing chronic hemodialysis to ascertain whether treatment with a K+ binder can ENABLE sustained RAASi therapy
Murray Epstein (Miami, USA)

RAASi enabling and cardiovascular/kidney disease outcome trials for new potassium binders. Why and when are they needed?
Javed Butler (Jackson, USA)

What efficacy endpoints, other than CV outcomes? The importance of Patient Reported Outcomes, quality of life measures and dietary modification
Jean-Claude Tardif (Montreal, CAN)

What safety endpoints and what should new potassium binders be compared to?
Manish Sood (Ottawa, CAN)

End stage renal disease trials
George Bakris (Chicago, USA)

Industry viewpoint
Elisabeth Björk (AstraZeneca, SWE); Andrey Gurevich (Vifor Fresenius, CHE)

Payer viewpoint
Omar Ali (Portsmouth, GBR)

Regulatory viewpoint
Aliza Thompson (FDA, USA)

Patient viewpoint
Patrick Gee (Chesterfield, USA); Nick Hartshorne-Evans (London, GBR); Greg Merritt (Ann Arbor, USA)

The CVCT Forum: Multi-stakeholder moderated panel discussion

Moderators: Bertram Pitt (Ann Arbor, USA); Patrick Rossignol (Nancy, FRA)

Panelists: Omar Ali (Portsmouth, GBR); George Bakris (Chicago, USA); Elisabeth Björk (AstraZeneca, SWE); Javed Butler (Jackson, USA); Murray Epstein (Miami, USA); Patrick Gee (Chesterfield, USA); Nick Hartshorne-Evans (London, GBR); Andrey Gurevich (Vifor Fresenius, CHE); Greg Merritt (Ann Arbor, USA); Ileana Piña (Detroit, USA); Manish Sood (Ottawa, CAN); Jean-Claude Tardif (Montreal, CAN); Aliza Thompson (FDA, USA)

TOCQUEVILLE

2:00 PM – 3:30 PM

FOCUSED CVCT WORKSHOP IRON IN HEART FAILURE – PATIENT REPORTED OUTCOMES TO MORTALITY MORBIDITY TRIALS

Moderators: Gerasimos Filippatos (Athens, GRE); Robert Mentz (Durham, USA)

FOCUSED WORKSHOP

Focused CVCT Workshops are organized as campfire-sessions, fit for smaller focused groups: the experts and participants brainstorm around a U shape-table, as equals. These are high caliber faculty with the typical mix of stakeholders from academia, regulatory, payers, industry, patients and journal editors. The moderated panel discussion aims at fostering exchanges, potentially shifting the lines and reaching operational conclusions.

Iron therapy for heart failure: What is the rationale and mechanistic background?
Pieter van der Meer (Groningen, NED)

Iron therapy for heart failure: the evidence so far

- **Is oral iron out?**
  Javed Butler (Jackson, USA)
- **Is intravenous iron in?**
  Gerasimos Filippatos (Athens, GRE)

Iron therapy for heart failure: navigating from patient reported outcomes to morbidity-mortality trials
Robert Mentz (Durham, USA)

Industry viewpoint
Claudio Mori (Vifor, CHE); Linda Mundy (American Regent, USA)

Regulatory viewpoint
Andrea Laslop (CHMP, EMA, AUT); Noman Stockbridge (FDA, USA)

Patient viewpoint
Nick Hartshorne-Evans (London, GBR); Patricia Vlasman (Amsterdam, NED)

The CVCT Forum: Moderated multi-stakeholder panel discussion
Moving from patient reported outcome trials to cardiovascular outcome trials

Moderators: Gerasimos Filippatos (Athens, GRE); Robert Mentz (Durham, USA)

Panelists: Javed Butler (Jackson, USA); Nick Hartshorne-Evans (London, GBR); Claudio Mori (Vifor, CHE); Linda Mundy (American Regent, USA); Andrea Laslop (CHMP, EMA, AUT); Noman Stockbridge (FDA, USA); Patricia Vlasman (Amsterdam, NED); Pieter van der Meer (Groningen, NED)

TOCQUEVILLE

4:00 PM – 6:30 PM

HEART FAILURE DEVICE THERAPY. CASE STUDIES OF RECENT THE NEW FDA BREAKTHROUGH APPROVALS

Moderators: Ileana Piña (Detroit, USA); Michael Zile (Charlestone, USA)

- **On April 13, 2015, the Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions document was issued as guidance for industry and FDA Center for Devices and Radiological Health staff.**
- **The Expedited Access Pathway (EAP) was designed as a new program for medical devices to address unmet medical needs for life-threatening or irreversibly debilitating conditions.**
- **The FDA Center for Devices and Radiological Health intended the EAP program to "help patients have more timely access to medical devices by expediting their development, assessment, and review, while preserving the FDA's statutory standard for premarket approval." This guidance document also described the types of clinical evidence that might be used to support approval of a device under the EAP and, in particular, discussed the use of intermediate and surrogate endpoints.**
- **Bayesian adaptive trial designs are particularly well suited to studies with a primary clinical endpoint and related intermediate endpoints. During trial updates, interim data are analyzed using a statistical model that estimates the treatment effect(s), as well as the strength of the relationship between the primary and intermediate endpoints. Provided that early trial data confirm that the intermediate endpoints are closely related to primary outcomes, the intermediate endpoints can assist in predicting the outcome of the eventual primary analysis, potentially reducing the number of patients enrolled and improving the study conclusions.**
- **A number of HF devices have recently been approved for premarket access using this new FDA breakthrough devices program, based on beneficial effects in intermediate endpoints trials embedded in still ongoing hard outcome trials.**
- **The objectives of this session are:**
  - **to understand and discuss the value of the evidence generated using the EAP, by clinicians and HF drug trialists/statisticians more familiar with frequentist statistics, regulators behind the EAP new guidance and the recent approvals, editors of journals to report related trials, payers, HTA experts, and patients**
  - **to discuss opportunities and challenges for implementation in clinical practice**

The FDA CV device breakthrough program. Rationale and guidance
Bram Zuckerman (FDA, USA)

Design and methodology of expedited access pathway HF trials

- **Intermediate endpoints used for pre-market access**
  Faiez Zannad (Nancy, FRA)
- **Adaptive design and the use of Bayesian methodology**
  Rajat Mukherjee (Cytel, USA)

Question and Answers

Case Studies

- **Cardiac Contractility Modulation. Optimizer Smart System. The FIX-HF-5 trial**
  Martin Borggrefe (Heidelberg, GER)
- **Baroreflex stimulation. Barostim. The BEAT-HF trial**
  Michael Zile (Charlestone, USA)
- **Vagal nerve stimulation. Vitaria. ANTHEM-HFrEF Pivotal Study**
  Marvin Konstam (Boston, USA)

Question and Answers

Multi-stakeholders viewpoints

- **Industry viewpoints**
  Lorenzo A. DiCarlo (Livanova, USA); Liz Galle (CVRx,USA)
- **Regulatory viewpoint**
  Andrew Farb (FDA, USA)
- **Payer viewpoint**
  Joseph Hutter (CMS, USA)
- **Patient viewpoints**
  Sadegh Alikhaani (Los Angeles, USA); Mariette Verbakel (Nijmegen, NED)

The CVCT Forum. Moderated Multi-stakeholders panel discussion. HF BREAKTHROUGH DEVICES. POST APPROVAL AND IMPLEMENTATION ROADMAP

Moderators: Ileana Piña (Detroit, USA); Michael Zile (Charlestone, USA)

Panelists: Sadehgh Alikhaani (Los Angeles, USA); Martin Borggrefe (Heidelberg, GER); Lorenzo A. DiCarlo (Livanova, USA); Andrew Farb (FDA, USA); Joseph Hutter (CMS, USA); Rajat Mukherjee (Cytel, USA); Liz Galle (CVRx,USA); Leonardo Guimarães (Quebec City, CAN); Marvin Konstam (Boston, USA); Mariette Verbakel (Nijmegen, NED); Faiez Zannad (Nancy, FRA); Michael Zile (Charlestone, USA); Bram Zuckerman (FDA, USA)

SATURDAY, DECEMBER 7th

BALLROOM

8:30 AM – 10:30 AM
PATIENT – TRIALIST FORUM
EMPOWERING PATIENTS TO BE ACTIVE PARTICIPANTS IN CLINICAL TRIALS

Moderators: Cynthia Chauhan (Wichita, USA); Denis Janssen (Zuid, NED)

The aim of this session is to continue the discussion of contributions, concerns, and viewpoints of patients through meaningful dialogue on the issue of patient engagement in the development of and participation in clinical trials. The outcome of this session would include deeper understanding by researchers of the issues patients consider important and better understanding by patients of the hurdles researchers see in engaging patients in research development and participation. The eventual goal is improved patient engagement and better accrual with less early withdrawal from trials.

Introduction:
Cynthia Chauhan (Wichita, USA)

FDA Perspective on Meaningful Patient Engagement: Successes and Failures
Theresa Mullin (FDA, USA)

The role of societies in clinical trials. The patient engagement initiative at HFSA.

Mitchell Psotka (Washington, USA)

The Patient Perspective

- **Empowering Patients as Active Participants in Clinical Trials**
  Denis Janssen (Zuid, NED); Robin Martinez (Denver, USA)
- **Patients with Comorbidities and Trials**
  Cynthia Chauhan (Wichita, USA)
- **Inclusion of Minorities in Trials**
  Patrick Gee (Chesterfi eld, USA)
- **Why Patient Reported Outcomes Matter**
  Susan Quella (Rochester, USA); Greg Merritt (Ann Arbor, USA)
- **The Role of Mental Health Studies in Cardiovascular Trials**
  Jillianne Code (Vancouver, CAN); Penilla Gunther (Stockholm, SWE)
- **Patient Representation in Industry**
  Barry Liden (Edwards, USA); Tamara Krcmar (Servier, FRA)

The CVCT Forum: Moderated multi-stakeholder panel discussion

Moderators: Cynthia Chauhan (Wichita, USA); Denis Janssen (Zuid, NED)

Panelists: Jillianne Code (Vancouver, CAN); Patrick Gee (Chesterfi eld, USA); Penilla Gunther (Stockholm, SWE); Denis Janssen (Zuid, NED); Tamara Krcmar (Servier, FRA); Barry Liden (Edwards, USA); Robin Martinez (Denver, USA); Greg Merritt (Ann Arbor, USA); Theresa Mullin (FDA, USA) Susan Quella (Rochester, USA)

BALLROOM

11:00 AM – 12:30 PM
INNOVATIVE APPROACHES TO INFORMED CONSENT IN PRAGMATIC TRIALS
SOCIETY OF CLINICAL TRIALS (SCT)-CVCT Joint Session

Moderators: Yves Rosenberg (NIH, USA)

- **Pragmatic trials seek to evaluate health interventions in real world conditions to inform decision making by patients, health providers, and health system managers. Pragmatic trials commonly involve comparisons of usual care interventions, take place in primary care settings, and use routinely collected health data.**
- **While informed consent remains a central protection for research participants, trialists and ethicists have questioned whether standard approaches to written informed consent are desirable or required for pragmatic trials.**

- **In this session, we critically assess several innovative approaches to informed consent.**
- **Integrated consent was first proposed by Kim and Miller (2014) and it allows the health provider to obtain verbal consent to research participation guided by a script and documenting consent in the electronic health record.**
- **Trials within cohorts were first described by Relton and colleagues (2010). This novel pragmatic trial design uses a cohort of patients with a chronic disease as a platform for multiple randomized trials. Broad consent is obtained from participants for data collection and future trials while specific informed consent is obtained from participants selected for the experimental condition in trials.**
- **Electronic consent, while standard for the growing number of health apps, is new to pragmatic trials. E-consent offers the opportunity to change the way that participants enroll in research and permits flexibility in information delivered.**
- **The opportunities and limitations of each of these innovative approaches to informed consent in pragmatic trials will be discussed.**

Integrated consent in pragmatic trials
Scott Kim (NIH, USA)

The role of broad consent in trials within cohorts
Clare Relton (London, GBR)

E-consent: regulatory, ethical and practical issues
Holly Fernandez Lynch (Philadelphia, USA)

A trialist's perspective on innovative approaches to consent
Dean Fergusson (Ottawa, CAN)

Industry viewpoint
Helina Kassahun (Amgen, USA)

Regulatory viewpoint
Kolbeinn Gudmundsson (CHMP, EMA, ICE); Ellis Unger (FDA, USA)

Patients viewpoint
Jacqueline Alikhaani (Los Angeles, USA)

The CVCT Forum: Multi-stakeholder moderated panel discussion
Making innovative approaches to consent actionable

Moderators: Yves Rosenberg (NIH, USA)

Panelists: Jacqueline Alikhaani (Los Angeles, USA); Dean Fergusson (Ottawa, CAN); Kolbeinn Gudmundsson (CHMP, EMA, ICE); Helina Kassahun (Amgen, USA); Scott Kim (NIH, USA); Holly Fernandez Lynch (Philadelphia, USA); Clare Relton (London, GBR); Ellis Unger (FDA, USA)

BALLROOM

2:00 PM – 6:30 PM
PRECISION MEDICINE FOR FUTURE CARDIOVASCULAR CLINICAL TRIALS

Heterogeneity of treatment effects is one of the most critical problems in study interpretation today, and may be leading to very erroneous decision making when applying study results to individual patients by clinicians. This is true across all disciplines, not just cardiology, but may be most visible in cardiac, stroke, and diabetes research because of the large volume of trials in these areas, and the influence of these trial results on clinicians.

According to the National Institute of Health (NIH), Precision Medicine is "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle for each person."

Thus far in most cardiovascular trials all comers have been included but increasing evidence over the last couple of years has suggested that this is no longer the appropriate strategy to reduce residual risk, mainly because background therapy in cardiovascular patients nowadays has become very strong and powerful. Thus, it will become more and more difficult to improve risk of recurrent events in this group of patients if one does not focus on specific high risk subgroups. It is fairly evident that patients after myocardial infarction with stable CHD represent a heterogenous group regarding their future risk for recurrent events. For example, in the large SMART cohort study a score has been developed based on clinical and laboratory variables and has shown a wide distribution of risk, e.g. 18% over 5 years had a risk < 10% for recurrent events while on the other side 22% had a > 30% risk over 5 years.

In heart failure, especially HFpEF, the all comers approach has failed so far. Also, future trials of prevention of heart failure can only be affordable if targeting selected patients, stratified according bioprofiles most likely to respond to targeted therapies.
Today, precision medicine is far more advanced in haematology and oncology than in cardiovascular disease. One reason is most likely being related to the underlying multifactorial causes of cardiovascular disease with many different pathways being involved compared to oncology. So basic questions to ask are: Is precision medicine feasible at all in cardiovascular diseases? Are deep phenotyping and pharmacophenomics helpful?

2:00 PM – 3:30 PM
Part I: THE ROADMAP FOR PRECISION MEDICINE

Moderators: Wolfgang Koenig (Munich, GER); Sanjiv Shah (Chicago, USA)

Precision Medicine in Cardiovascular Disease. Do we have a roadmap?
Joseph Loscalzo (Boston, USA)

Lumpers and Splitters: The Bumby Road to Precision Medicine
Thomas Lüscher (Zurich, CH)

Heterogeneity of treatment effect and risk-stratified approach for reporting/ implementing clinical trial results
Speaker: David Kent (Boston, USA)
Discussant: John Gregson (London, GBR)

Genomics and precision medicine: Are polygenic scores the breakthrough?

- **Geneticist viewpoint**
  Heribert Schunkert (Munich, GER)
- **Basic scientist viewpoint**
  Geoffrey Pitt (New York, USA)

CVCT Multi-stakeholders moderated panel discussion
Part I: THE ROADMAP FOR PRECISION MEDICINE

Moderators: Wolfgang Koenig (Munich, GER); Sanjiv Shah (Chicago, USA)

Panelists: John Gregson (London, GBR); David Kent (Boston, USA); Joseph Loscalzo (Boston, USA); Thomas Lüscher (Zurich, CHE); Geoff rey Pitt (New York, USA); Heribert Schunkert (Munich, GER

BALLROOM

4:00 PM – 6:30 PM
Part II: BIOMARKER BIOPROFILING TO ENABLE PRECISION CARDIOLOGY TRIALS

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

Precision post-ACS: Interaction between ADCY9 and CETP genes, from ACCELERATE and REVEAL to DalGenE trial

Speaker: Jean-Claude Tardif (Montreal, CAN)

Discussant: Jemma Hopewell (Oxford, GBR)

Biomarker bioprofiling to enable precision cardiology trials

- **Proteomics approach in CAD**
  Martin Magnusson (Lund, SWE); Erik Stroes (Amsterdam, NED)
- **Metabolomics and risk profiling**
  Manuel Mayr (London, GBR)
- **Multi-omics in heart failure**
  Joao Ferreira (Nancy, FRA)

Currently available "usual suspect" biomarkers. How useful to guide therapy?
Jim Januzzi (Boston, USA)

Radiomics bioprofiling to enable precision cardiology trials
Charalambos Antoniades (Oxford, GBR)

Regulatory viewpoint
Christian Grimstein (FDA, USA); Andrea Laslop (CHMP, EMA, AUT)

Industry viewpoint
Agim Beshiri (Abbott Diagnostics, USA); Reijo Laaksonen (Zora Biosciences, FIN); Fouzia Laghrissi-Thode (DalCor, CHE); Evan Mills (OLINK, USA); Rachel Ostroff (Somalogic, USA)

Payer viewpoint
Omar Ali (Portsmouth, GBR)

Patient viewpoint
Penilla Gunther (Stockholm, SWE); Robin Martinez (Denver, USA)

CVCT Multi-stakeholders moderated panel discussion
Part II: BIOMARKER PROFILING TO ENABLE PRECISION CARDIOLOGY TRIALS

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

Panelists: Omar Ali (Portsmouth, GBR); Kirkwood Adams (Chapel Hill, USA); Charalambos Antoniades (Oxford, GBR); Agim Beshiri (Abbott Diagnostics, USA); Joao Ferreira (Nancy, FRA); Christian Grimstein (FDA, USA); Penilla Gunther (Stockholm, SWE); Jemma Hopewell (Oxford, GBR); Jim Januzzi (Boston, USA); Fouzia Laghrissi-Thode (DalCor, CHE); Reijo Laaksonen (Zora Biosciences, FIN); Andrea Laslop (CHMP, EMA, AUT); Martin Magnusson (Lund, SWE); Robin Martinez (Denver, USA); Manuel Mayr (London, GBR); Evan Mills (OLINK, USA); Rachel Ostroff (Somalogic, USA); Erik Stroes (Amsterdam, NED)

AUDITORIUM

9:00 AM – 3:30 PM
HEART FAILURE WITH PRESERVED EJECTION FRACTION
LIGHT AT THE END OF THE TUNNEL?

- Often, when a clinical trial does not meet its primary end point, we learn more from the secondary analyses than with a successful intervention.

- "The totality of evidence must be carefully considered when evaluating the results of a trial. In this trial, the investigators set a high bar for success and identified some signals suggestive of benefit, despite a neutral result for the primary end point."

Chris O'Connor NEJM editorial of October 24th 2019

AUDITORIUM

9:00 AM – 10:30 AM
Part I: Understanding and Interpreting the results of PARAGON

Moderators: Lars Lund (Stockholm, SWE); Marc Pfeffer (Boston, USA)

PARAGON main results
Scott Solomon (Boston, USA)

Target population and insight from subgroup analyses
Carolyn Lam (Singapore, SIN); Faiez Zannad (Nancy, FRA)

Renal Outcomes
Finnian McCausland (Boston, USA)

Biomarker results and mechanistic insight?
Faiez Zannad (Nancy, FRA)

Statistical viewpoint
Frank Rockhold (Durham, USA)

CVCT Multi-stakeholders moderated panel discussion
Part I: Interpreting the results of PARAGON

Moderators: Lars Lund (Stockholm, SWE); Marc Pfeffer (Boston, USA)

Panelists: Paul Armstrong (Alberta, CAN); Carolyn Lam (Singapore, SIN); Finnian McCausland (Boston, USA); Milton Packer (Dallas, USA); Frank Rockhold (Durham, USA); Scott Solomon (Boston, USA); Faiez Zannad (Nancy, FRA)

What's next? The consequence of PARAGON on the ongoing HFpEF trials
Milton Packer (Dallas, USA); Paul Armstrong (Alberta, CAN); Lars Lund (Stockholm, SWE)

AUDITORIUM

11:00 AM – 12:30 PM
Part II: Implementing the results of PARAGON

Moderators: Carolyn Lam (Singapore, SIN); Lars Lund (Stockholm, SWE)

Sacubutril Valsartan across the spectrum of LV ejection fractions
Marc Pfeffer (Boston, USA)

PARAGON in context; Revisiting the evidence so far with RAAS inhibitiors
Sverre Kjeldsen (Oslo, NOR)

Sacubutril Valsartan across the spectrum of HF disease
Eric Velasquez (New Haven, USA)

What implementation strategies are needed for a prompt adoption? Updating guidelines and beyond
Carolyn Lam (Singapore, SIN); Felipe Martinez (Cordoba, ARG)

MRA therapy in HFpEF, insight from PARAGON, and expectations from SPIRIT, SPIRRIT and FINE-ARTS-HF
Faiez Zannad (Nancy, FRA)

The CVCT Forum. Moderated Multi-stakeholders panel discussion.
Part II: Implementing the results of PARAGON

Moderators: Carolyn Lam (Singapore, SIN); Lars Lund (Stockholm, SWE)

Panelists: Sverre Kjeldsen (Oslo, NOR); Carolyn Lam (Singapore, SIN); Felipe Martinez (Cordoba, ARG); Marc Pfeffer (Boston, USA); Cristina Rabadan-Diehl (Washington, USA); Eric Velasquez (New Haven, USA); Faiez Zannad (Nancy, FRA)

AUDITORIUM

2:00 PM – 3:30 PM
Part III: Stakeholders Viewpoint

Moderators: Kenneth Dickstein (Stavanger, NOR); Scott Solomon (Boston, USA)

Regulatory viewpoint
Krishna Prasad (MHRA-EMA, GBR); Bob Temple (FDA, USA)

Industry viewpoint
Marty Lefkowitz (Novartis, USA)

Patient viewpoint
Cynthia Chauhan (Wichita, USA); Nick Harshorne-Evans (London, GBR)

Epilogue
Marc Pfeffer (Boston, USA)

The CVCT Forum. Moderated Multi-stakeholders panel discussion.
Part III: Stakeholders Viewpoint

Moderators: Kenneth Dickstein (Stavanger, NOR); Scott Solomon (Boston, USA)

Panelists: Cynthia Chauhan (Wichita, USA); Nick Harshorne-Evans (London, GBR); Marty Lefkowitz (Novartis, USA); Marc Pfeffer (Boston, USA); Krishna Prasad (MHRA-EMA, GBR); Bob Temple (FDA, USA)

AUDITORIUM

4:00 PM – 6:30 PM
International Society of Cardiovascular Pharmacology
DIET AND CV PREVENTION TRIALS
CVCT-ISCP Joint Session

Moderators: Bertram Pitt (Ann Arbor, USA); Hector Ventura (Miami, USA)

The New Prevention Guidelines. How was evidence graded?

- **ACC/AHA**
  Erin Michos (Baltimore, USA)
- **ESC**
  Naveed Sattar (Glasgow, GBR)

Are dietary guidelines for cardiovascular prevention evidence-based?
Salim Yusuf (Hamilton, CAN)

Medical misinformation as a barrier to evidence based preventive medicine
Joseph Hill (Circulation, USA)

Media viewpoint. "The Big Fat Surprise About Diet and Nutrition"
Nina Teicholz (New York, USA)

How powerful is population-based prevention through changes in lifestyle and environment? The Finnish experience
Erkki Vartiainen (Helsinki, FIN)

Weight gain after smoking cessation
Koji Hasegawa (Kyoto, JAP)

Is decrease in CV risk score an approvable indication?

- **Regulatory viewpoint**
  Fred Senatore (FDA, USA); Emmanouil Zouridakis (MHRA, GBR)
- **Patient viewpoint**
  Jillianne Code (Vancouver, CAN); Marietta Verbakel (Nijmegen, NED)

CVCT Multi-stakeholder panel moderated discussion

Moderators: Bertram Pitt (Ann Arbor, USA); Hector Ventura (Miami, USA)

Panelists: Jillianne Code (Vancouver, CAN); Koji Hasegawa (Kyoto, JAP); Joseph Hill (Circulation, USA); Larry Husten (New York, USA); Muhammad Shahzeb Khan (Chicago, USA); Erin Michos (Baltimore, USA); Naveed Sattar (Glasgow, GBR); Fred Senatore (FDA, USA); Nina Teicholz (New York, USA); Erkki Vartiainen (Helsinki, FIN); Marietta Verbakel (Nijmegen, NED); Salim Yusuf (Hamilton, CAN); Emmanouil Zouridakis (MHRA, GBR)

KEYNOTE SPEECHES

AUDITORIUM

Friday, December 6th

12:15 – 12:30 PM

WELCOME ADDRESS

Philippe Etienne

Ambassador of France to USA

AUDITORIUM

Friday, December 6th

12:30 PM – 1:00 PM

KEYNOTE LECTURE

Cardiovascular Continuum 2020: Implications in Clinical Research

Victor J. Dzau, MD

President, National Academy of Medicine

AUDITORIUM

Saturday, December 7th

12:30 – 1:00 PM

***i*CVCT KEYNOTE LECTURE**

The Democratization of Medicine:
Open Access, Social Media, AI, Apps
& Empowering the Patient as the Future of Clinical Research

C. Michael Gibson (Boston, USA)

INTERVENTIONAL CARDIOVASCULAR CLINICAL TRIALISTS (ICVCT) FORUM
Program Directors: C. Michael Gibson (Boston, USA); Roxana Mehran (New York, USA)
8:30 AM – 6:30 PM

Inaugural Event
Welcome to *i*CVCT
Bertram Pitt and Faiez Zannad
CVCT Chairpersons

LIBRARY

8:30 AM – 10:30 AM
***i*CVCT Session 1**
PCI PHARMACOLOGY TRIALS/DEVICE DRUG INTERACTIONS

Moderators: C. Michael Gibson (Boston, USA); Roxana Mehran (New York, USA)

DAPT duration Trials: Short DAPT in High Bleeding Risk Patients who receive Stents: Strengths and Weaknesses
David J. Cohen (Kansas City, USA)

ASA Withdrawal Studies: When Bleeding becomes an effectiveness endpoint
Chris Granger (Durham, USA)

Drug v. Drug Studies in ACS and PCI: ISAR REACT trial, Role of ISS studies and future needs
C. Michael Gibson (Boston, USA)

Inflammation in ACS: Highlights of the COLCOT trial
Jean-Claude Tardif (Montreal, CAN)

Regulatory viewpoint
Adrian Magee (FDA, USA)

Industry viewpoint
Sidney Cohen (Medtronic, USA)

The *i*CVCT Forum: Multi-stakeholder moderated panel discussion
PCI PHARMACOLOGY TRIALS/DEVICE DRUG INTERACTIONS
ANTITHROMBOTIC DILEMMAS IN PCI: AFIB, HBR, AND DAPT DURATION

Moderators: C. Michael Gibson (Boston, USA); Roxana Mehran (New York, USA)

Panelists: Jeff Borer (New York,USA); David J Cohen (Kansas City, USA); Sidney Cohen (Medtronic, USA); Darrel Francis (London, GBR); Natasha Giordano (PLx Pharma, USA); Chris Granger (Durham, USA); Susheel Kodali (New York, USA); Adrian Magee (FDA, USA); David Maron (Stanford, USA); Ileana Piña (Detroit, USA); Yves Rosenberg (NIH, USA); Tabassome Simon (Paris, FRA); Jean-Claude Tardif (Montreal, CAN); Ellis Unger (FDA, USA); Martin Unverdorben (Daiichi-Sankyo, USA); Emmanouil Zouridakis (MHRA, GBR)

LIBRARY

11:00 AM – 12:30 PM
***i*CVCT Session 2: TAVR PHARMACOLOGY TRIALS**

Moderators: George Dangas (New York, USA); Ileana Piña (Detroit, USA)

TAVR in Patients at Low Risk for Surgery: Public Health Significance and Implications for Antithrombotic Therapies
George Dangas (New York, USA)

Regulatory viewpoint
Emmanouil Zouridakis (MHRA, GBR)

Industry viewpoint
Martin Unverdorben (Daiichi-Sankyo, USA)

The *i*CVCT Forum: Multi-stakeholder moderated panel discussion
ANTITHROMBOTIC STRATEGIES IN THE TAVR ENVIRONMENT

Moderators: George Dangas (New York, USA); Ileana Piña (Detroit,USA)

Panelists: Panelists: Jeffrey Borer (New York,USA); Sidney Cohen (Medtronic, USA); George Dangas (New York, USA); Darrel Francis (London, GBR); Chris Granger (Durham, USA); C. Michael Gibson (Boston, USA); Susheel Kodali (New York, USA); Adrian Magee (FDA, USA); David Maron (Stanford, USA); Roxana Mehran (New York, USA); Mauro Moscucci (FDA, USA); Dragica Paunovic (Terumo, USA); Tabassome Simon (Paris, FRA); Ellis Unger (FDA, USA); Martin Unverdorben (Daiichi-Sankyo, USA); Bernard Vasseur (FDA, USA); Patrick Verta (Edwards, USA); Emmanouil Zouridakis (MHRA, GBR); Bram Zuckerman (FDA, USA)

LIBRARY

2:00 – 3:30 PM
***i*CVCT Session 3:**
STRUCTURAL HEART INTERVENTIONS: DISSECTING THE TRIALS

Moderators: Jeff Borer (New York, USA); Susheel Kodali (New York, USA)

"Proportionate" vs "Disproportionate" mitral regurgitation. Reconciling COAPT and Mitral FR
Milton Packer (Dallas, USA)

Tricuspid Valve: Not so Forgotten-Trial designs and future Directions

Susheel Kodali (New York, USA)

Non Interventional Clinician viewpoint
Jeff Borer (New York, USA)

Regulatory viewpoint
Bernard Vasseur (FDA, USA)

Industry viewpoint
Patrick Verta (Edwards, USA)

Payer viewpoint
Joseph Hutter (CMS, USA)

*i*CVCT Session 3
The CVCT Forum: Moderated Multi-stakeholder panel discussion
TAVR AND TMVR AND TRICUSPID REPAIR. HOW TO BRIDGE THE GAPS IN EVIDENCE?

Moderators: Jeff Borer (New York, USA); Susheel Kodali (New York, USA)

Panelists: Alaide Chieffo (Milano, ITA); Sidney Cohen (Medtronic, USA); George Dangas (New York, USA); Darrel Francis (London, GBR); C. Michael Gibson (Boston, USA); Chris Granger (Durham, USA); David Maron (Stanford, USA); Roxana Mehran (New York, USA); Mauro Moscucci (FDA, USA); Milton Packer (Dallas, USA); Ileana Piña (Detroit, USA); Yves Rosenberg (NIH, USA); Tabassome Simon (Paris, FRA); Ellis Unger (FDA, USA); Martin Unverdorben (Daiichi-Sankyo, USA); Bernard Vasseur (FDA, USA); Patrick Verta (Edwards, USA); Emmanouil Zouridakis (MHRA, GBR); Bram Zuckerman (FDA, USA)

4:00 PM – 6:30 PM
***i*CVCT Session 4**
REVASCULARIZATION STRATEGIES PCI V. CABG V. MEDICAL THERAPY

Moderators: C. Michael Gibson (Boston, USA); Chris Granger (Durham, USA)

ISCHEMIA and COURAGE: Where do we stand for Chronic Coronary Syndromes?
Darrel Francis (London, GBR); Bernard Gersh (Rochester, USA); David Maron (Stanford, USA)

PCI v. CABG: EXCEL, NOBLE, SYNTAXES
Roxana Mehran (New York, USA)

Multi-Vessel Disease in STEMI and Shock: COMPLETE or Culprit only PCI?
David J. Cohen (Kansas City, USA)

Mechanical Support Devices in Complex PCI- Hope or Hype?
Kendra Grubb (Atlanta, USA)

Evidence for Support Devices in STEMI and Shock- What have we learned?
Mina Karami (Amsterdam, NED)

The NHLBI viewpoint
Yves Rosenberg (NIH, USA)

Regulatory viewpoint
Mauro Moscucci (FDA, USA)

Industry viewpoint
Kenneth Stein (Boston Scientific, USA)

Patient viewpoint
Brenda Alsemgeest (Amsterdam, NED)

*i*CVCT Session 4
The CVCT Forum: Moderated Multi-stakeholder panel discussion
HOW WILL THE CLINICIAN KNOW WHOM TO TREAT?

Moderators: C. Michael Gibson (Boston, USA); Chris Granger (Durham, USA)

Panelists: Brenda Alsemgeest (Amsterdam, NED); Jeffrey Borer (New York, USA); David J. Cohen (Kansas City, USA); Sidney Cohen (Medtronic, USA); George Dangas (New York, USA); Andrew Farb (FDA, USA); Darrel Francis (London, GBR); Kendra Grubb (Atlanta, USA); David Holmes (Rochester, USA); Mina Karami (Amsterdam, NED); Susheel Kodali (New York, USA); David Maron (Stanford, USA); Roxana Mehran (New York, USA); Mauro Moscucci (FDA, USA); Ileana Piña (Detroit, USA); Yves Rosenberg (NIH, USA); Tabassome Simon (Paris, FRA); Kenneth Stein (Boston Scientific, USA); Ellis Unger (FDA, USA); Martin Unverdorben (Daiichi-Sankyo, USA); Bernard Vasseur (FDA, USA); Bram Zuckerman (FDA, USA)

Adjourn
C. Michael Gibson

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 cardiovasculardisease. At the CVCT they learn from and network with key opinion leaders, principal investigators, patient and patient representatives, and regulatory and R&D industry experts to shape their future practice toward CV clinical trial related activities.

Our scientific committee learns about candidates in the following ways:

• **Grant applications submitted via the CVCT website** - www.globalcvctforum.com

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

We are pleased to welcome the following young investigators to CVCT Forum 2019:

Khalil Anchouche (McGill University, CAN)
Ankheet Bhatt (Brigham and Women's Hospital, USA)
Allan Böhm (The National Institute of Cardiovascular Diseases, SVK)
Jacinthe Boulet (Université de Montréal, CAN)
Simon Correa Gaviria (Brigham and Women's Hospital, USA)
Annunziata Cotugno (Inova Heart and Vascular Institute, USA)
Jonathan Cunningham (Brigham and Women's Hospital, USA)
Kieran Docherty (University of Glasgow, GBR)
Marat Fudim (Duke University, USA)
Ridhima Goel (Icahn School of Medicine at Mount Sinai, USA)
Camilla Hage (Karolinska University Hospital, SWE)
Yukihiro Harada (Ritsumeikan University, JPN)
Nicholas Hendren (UT Southwestern, USA)
Nasrien Ibrahim(Massachusetts General Hospital / Harvard Medical School, USA)
Nino Isakadze (Johns Hopkins, USA)
Kalliopi Keramida (Attikon University Hospital, GRC)
Shuangbo Liu (St. Michael's Hospital, CAN)
Marion Mafham (University of Oxford, UK)
Guillaume Marquis-Gravel (Duke Clinical Research Institute, USA)
Rina Mauricio (UT Southwestern, USA)
Syed Yaseen Naqvi (University of Rochester, USA)
Victor Nauffal (Brigham and Women's Hospital, USA)
Adam Nelson (Duke Clinical Research Institute, USA)
Brendon Neuen (The George Institute for Global Health, AUS)
Johny Nicolas (Icahn School of Medicine at Mount Sinai, USA)
Ayodele Odutayo (University of Toronto, CAN)
Ravi Patel (Northwestern University Feinberg School of Medicine, USA)
Adam Phillips (Beth Israel Deaconess Medical Center / Harvard Medical School, USA)
Yogesh Reddy (Mayo Clinic, USA)
Brahim Redouane (McGill University, CAN)
Xavier Rossello (Centro Nacional de Investigaciones Cardiovasculares (CNIC), ESP)
Marc Samsky (Duke University, USA)
Gianluigi Savarese (Karolinska University Hospital, SWE)
Benedikt Schrage (Karolinska University Hospital, SWE)
Abhinav Sharma (McGill University, CAN)
Shashank Sinha (Inova Fairfax Medical Center, USA)
Susan Stienen (Amsterdam University Medical Center, NLD)
Inge Van Den Hoogen (Dalio Institute of Cardiovascular Imaging, Weill Cornell Medicine, (USA)
Mahesh Vidula (University of Pennsylvania, USA)
Kimberly Walters (Statistics Collaboratory, Inc., USA)
Nelson Wang (The George Institute for Global Health, AUS)
Duan Zhao (Duke Kunshan University, CHN)

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. Ferreira and Dr. Vaduganathan as they work with junior faculty and fellows.

CVCT PUBLICATIONS REFERENCE LIST
Visit www.globalcvctforum.com to read the articles in full

2018

Antihyperglycemic Therapies to Treat Patients With Heart Failure and Diabetes Mellitus
Sharma A, Cooper LB, Fiuzat M, Mentz RJ, Ferreira JP, Butler J, Fitchett D, Moses AC, O'Connor C, Zannad F. JACC Heart Fail. 2018 Oct;6(10):813-822.

Reassessing the Role of Surrogate End Points in Drug Development for Heart Failure
Greene SJ, Mentz RJ, Fiuzat M, Butler J, Solomon SD, Ambrosy AP, Mehta C, Teerlink JR, Zannad F, O'Connor CM.Circulation. 2018 Sep 4;138(10):1039-1053.

The role of angiotensin receptor-neprilysin inhibitors in cardiovascular disease-existing evidence, knowledge gaps, and future directions
Ambrosy AP, Mentz RJ, Fiuzat M, Cleland JGF, Greene SJ, O'Connor CM, Teerlink JR, Zannad F, Solomon SD. Eur J Heart Fail. 2018 Jun;20(6):963-972.

Evolution of natriuretic peptide biomarkers in heart failure: Implications for clinical care and clinical trials
Vodovar N, Mebazaa A, Januzzi JL Jr, Murtagh G, Stough WG, Adams KF Jr, Zannad F.
Int J Cardiol. 2018 Mar 1;254:215-221

2017

ERole of Payers in the Development of Cardiovascular Therapeutics: Misalignment Between Approval and Reimbursement
Zannad F, Alonso Garcia MLA, Borer JS, Stough WG, Clutton-Brock T, Rosenberg Y, Packer M., J Am Coll Cardiol. 2017 Dec 5;70(22):2822-2830.

Tailoring mineralocorticoid receptor antagonist therapy in heart failure patients: are we moving towards a personalized approach?
Ferreira JP, Mentz RJ, Pizard A, Pitt B, Zannad F. Eur J Heart Fail. 2017 Aug;19(8):974-986.

Declining Risk of Sudden Death in Heart Failure
Shen L, Jhund PS, Petrie MC, Claggett BL, Barlera S, Cleland JGF, Dargie HJ, Granger CB, Kjekshus J, Køber L, Latini R, Maggioni AP, Packer M, Pitt B, Solomon SD, Swedberg K, Tavazzi L, Wikstrand J, Zannad F, Zile MR, McMurray JJV. N Engl J Med. 2017 Jul 6;377(1):41-51

The burden of proof: The current state of atrial fibrillation prevention and treatment trials
Zakeri R, Van Wagoner DR, Calkins H, Wong T, Ross HM, Heist EK, Meyer TE, Kowey PR, Mentz RJ, Cleland JG, Pitt B, Zannad F, Linde C. Heart Rhythm. 2017 May;14(5):763-782.

Evolution of natriuretic peptide biomarkers in heart failure: implications for clinical care and clinical trials
Vodovar N, Mebazaa A, Januzzi JL, Murtagh G, Stough WG, Adams KF, Zannad F. Int J Cardiol (2017); in press.

Streamlining cardiovascular clinical trials to improve efficiency and generalisability
Zannad F, Pfeffer MA, Bhatt DL, Bonds DE, Borer JS, Calvo-Rojas G, Fiore L, Lund LH, Madigan D, Maggioni AP, Meyers CM, Rosenberg Y, Simon T, Stough WG, Zalewski A, Zariffa N, Temple R. Heart 2017;103(15):1156-1162.

Cardiovascular Outcome Trials in Patients with Advanced Kidney Disease: Time for Action
Zannad F, Rossignol P. Circulation 2017;135(19):1769-1771.

Role of payers in the development of cardiovascular therapeutics. Misalignment between approval and reimbursement.
Zannad F, Alonso Garcia M, Borer JS, Stough WG, Clutton-Brock T, Rosenberg Y, Packer M. J Am Coll Cardiol 2017;doi: 10.1016/j.jacc.2017.10.027.

2016

New approaches to hyperkalemia in patients with indications for renin angiotensin aldosterone inhibitors: Considerations for trial design and regulatory approval
Zannad F, Rossignol P, Stough WG, Epstein M, Alonso Garcia Mde L, Bakris GL, Butler J, Kosiborod M, Berman L, Mebazaa A, Rasmussen HS, Ruilope LM, Stockbridge N, Thompson A, Wittes J, Pitt B. Int J Cardiol (2016) 216:46-51.

Assessment of cardiovascular risk of new drugs for the treatment of diabetes mellitus: risk assessment vs. risk aversion
Zannad F, Stough WG, Lipicky RJ, Tamargo J, Bakris GL, Borer JS, Alonso Garcia Mde L, Hadjadj S, Koenig W, Kupfer S, McCullough PA, Mosenzon O, Pocock S, Scheen AJ, Sourij H, Van der Schueren B, Stahre C, White WB, Calvo G. Eur Heart J Cardiovasc Pharmacother (2016) 2(3):200-205.

2015

Design considerations for clinical trials of autonomic modulation therapies targeting hypertension and heart failure
Zannad F, Stough WG, Mahfoud F, Bakris GL, Kjeldsen SE, Kieval RS, Haller H, Yared N, De Ferrari GM, Pina IL, Stein K, Azizi M. Hypertension (2015) 65(1):5-15.

Agents with vasodilator properties in acute heart failure: how to design successful trials
Mebazaa A, Longrois D, Metra M, Mueller C, Richards AM, Roessig L, Seronde MF, Sato N, Stockbridge N, Gattis Stough W, Alonso A, Cody R, Cook Bruns N, Gheorghiade M, Holzmeister J, Laribi S, Zannad F European Journal of Heart Failure (2015) 17, 652–664 doi:10.1002/ejhf.294. Review.

Cardiac resynchronization therapy in heart failure patients with less severe left ventricular dysfunction
Hai OY, Mentz RJ, Zannad F, Gasparini M, De Ferrari GM, Daubert JC, Holzmeister J, Lam CS, Pochet T, Vincent A, Linde C Eur J Heart Fail. 2015 Feb;17(2):135-43. doi: 10.1002/ejhf.208. Epub 2014 Dec 3.

Patient selection in heart failure with preserved ejection fraction clinical trials
Kelly JP, Mentz RJ, Mebazaa A, Voors AA, Butler J, Roessig L, Fiuzat M, Zannad F, Pitt B, O'Connor CM, Lam CS J Am Coll Cardiol. 2015 Apr 28;65(16):1668-82. doi: 10.1016/j.jacc.2015.03.043.

Atherosclerosis: recent trials, new targets and future directions
Ladeiras-Lopes R, Agewall S, Tawakol A, Staels B, Stein E, Mentz RJ, Leite-Moreira A, Zannad F, Koenig W Int J Cardiol. 2015 Aug 1;192:72-81. doi: 10.1016/j.ijcard.2015.05.013. Epub 2015 May 8. Review.

2014

Heart rate: a prognostic factor and therapeutic target in chronic heart failure. The distinct roles of drugs with heart rate-lowering properties.
Dobre D, Borer JS, Fox K, Swedberg K, Adams KF, Cleland JG, Cohen-Solal A, Gheorghiade M, Gueyffier F, O'Connor CM, Fiuzat M, Patak A, Piña IL, Rosano G, Sabbah HN, Tavazzi L, Zannad F. Eur J Heart Fail. 2014 Jan;16(1):76-85.

Decongestion in acute heart failure
Mentz RJ, Kjeldsen K, Rossi GP, Voors AA, Cleland JG, Anker SD, Gheorghiade M, Fiuzat M, Rossignol P, Zannad, F, Pitt B, O'Connor C, Felker GM. Eur J Heart Fail. 2014 May;16(5):471-82.

Current challenges for clinical trials of cardiovascular medical devices
Zannad F, Stough WG, Piña IL, Mehran R, Abraham WT, Anker SD, De Ferrari GM, Farb A, Geller NL, Kieval RS, Linde C, Redberg RF, Stein K, Vincent A, Woehrle H, Pocock SJ. Int J Cardiol. 2014 Jul 15;175(1):30-7. http://dx.doi.org/10.1016/j.ijcard.2014.05.021

Trials of implantable monitoring devices in heart failure: which design is optimal?
Nat Rev Cardiol. 2014 Oct;11(10):576-85. Abraham WT, Stough WG, Piña IL, Linde C, Borer JS, De Ferrari GM, Mehran R, Stein KM, Vincent A, Yadav JS, Anker SD, Zannad F. Nature Reviews Cardiology 2014 doi:10.1038/nrcardio.2014.114

Charting a roadmap for heart failure biomarker studies
Ahmad T, Fiuzat M, Pencina MJ, Geller NL, Zannad F, Cleland JG, Snider JV, Blankenberg S, Adams KF, Redberg RF, Kim JB, Mascette A, Mentz RJ, O'Connor CM, Felker GM, Januzzi JL. JACC Heart **Fail. 2014 Oct;2(5):477-488.**

Design considerations for clinical trials of autonomic modulation therapies targeting hypertensionand heart failure
Zannad F, Stough WG, Mahfoud F, Bakris GL, Kjeldsen SE, Kieval RS, Haller H, Yared N, De Ferrari GM, Piña IL, Stein K, Azizi M. Hypertension. 2014 Oct 27.

Noncardiac comorbidities in heart failure with reduced versus preserved ejection fraction
Mentz RJ, Kelly JP, von Lueder TG, Voors AA, Lam CS, Cowie MR, Kjeldsen K, Jankowska EA, Atar D, Butler J, Fiuzat M, Zannad F, Pitt B, O'Connor CM J Am Coll Cardiol. 2014 Dec 2;64(21):2281-93. doi: 10.1016/j.jacc.2014.08.036. Epub 2014 Nov 24. Review.

2013

Antithrombotic outcome trials in acute coronary syndromes: seeking the optimal balance between safety and efficacy
Verheugt FW, Clemmensen P, Mehran R, Agewall S, Pocock SJ, Goldstein S, Torp-Pedersen C, Simoons ML, Borer JS, Khder YM, Burton P, Deliargyris E, McMurray JJ, Berkowitz SD, Stough WG, Zannad F. Eur Heart J. 2013 Jun;34(22):1621-9.

Biomarker-guided therapies in heart failure: a forum for unified strategies
Fiuzat M, O'Connor CM, Gueyffier F, Mascette AM, Geller NL, Mebazaa A, Voors AA, Adams KF, Piña IL, Neyses L, Muntendam P, Felker GM, Pitt B, Zannad F, Bristow MR. J Card Fail. 2013 Aug;19(8):592-9.

The past, present and future of renin-angiotensin aldosterone system inhibition
Mentz RJ, Bakris GL, Waeber B, McMurray JJ, Gheorghiade M, Ruilope LM, Maggioni AP, Swedberg K, Piña IL, Fiuzat M, O'Connor CM, Zannad F, Pitt B. Int J Cardiol. 2013 Sep 1;167(5):1677-87.

Is thrombosis a contributor to heart failure pathophysiology? Possible mechanisms, therapeutic opportunities, and clinical investigation challenges
Zannad F, Stough WG, Regnault V, Gheorghiade M, Deliargyris E, Gibson CM, Agewall S, Berkowitz SD, Burton P, Calvo G, Goldstein S, Verheugt FW, Koglin J, O'Connor CM. International Journal of Cardiology 167 (2013) 1772-1782 Int J Cardiol. 2013 Sep 1;167(5):1772-82.

Learning from recent trials and shaping the future of acute heart failure trials
Mentz RJ, Felker GM, Ahmad T, Peacock WF, Pitt B, Fiuzat M, Maggioni AP, Gheorghiade M, Ando Y, Pocock SJ, Zannad F, O'Connor CM. Am Heart J. 2013 Oct;166(4):629-35.

Publication of trials funded by the National Heart, Lung, and Blood Institute
Gordon D, Taddei-Peters W, Mascette A, Antman M, Kaufmann PG, Lauer MS. The New England Journal of Medicine 2012, November 14, 369;20.

2012
Targeting the aldosterone pathway in cardiovascular disease
Gustafsson F, Azizi M, Bauersachs J, Jaisser F, Rossignol P. Fundam Clin Pharmacol. 2012 Feb;26(1):135-45.

When to stop a clinical trial early for benefit: lessons learned and future approaches 2012
Zannad F1, Gattis Stough W, McMurray JJ, Remme WJ, Pitt B, Borer JS, Geller NL, Pocock SJ. Circ Heart Fail. 2012 Mar 1;5(2):294-302.

Implications of geographical variation on clinical outcomes of cardiovascular trials
Mentz RJ, Kaski JC, Dan GA, Goldstein S, Stockbridge N, Alonso-Garcia A, Ruilope LM, Martinez FA, Zannad F, Pitt B, Fiuzat M, O'Connor CM. Am Heart J. 2012 Sep;164(3):303-12.

Mineralocorticoid receptor antagonists for heart failure with reduced ejection fraction: integrating evidence into clinical practice
Zannad F, Gattis Stough W, Rossignol P, Bauersachs J, McMurray JJ, Swedberg K, Struthers AD, Voors AA, Ruilope LM, Bakris GL, O'Connor CM, Gheorghiade M, Mentz RJ, Cohen-Solal A, Maggioni AP, Beygui F, Filippatos GS, Massy ZA, Pathak A, Piña IL, Sabbah HN, Sica DA, Tavazzi L, Pitt B. Eur Heart J. 2012 Nov;33(22):2782-95.

2010
Maximizing scientific knowledge from randomized clinical trials
Gustafsson F, Atar D, Pitt B, Zannad F, Pfeffer MA; participants in 10th Cardiovascular Clinical Trialists Workshop. Am Heart J. 2010 Jun;159(6):937-43.

2009
Unconventional end points in cardiovascular clinical trials: should we be moving away from morbidity and mortality?
Journal of Cardiac Failure 2009;15:199-205.
Cohn J1, Cleland JG, Lubsen J, Borer JS, Steg PG, Perelman M, Zannad F. J Card Fail. 2009 Apr;15(3):199-205.

2008
Heart failure as an endpoint in heart failure and non-heart failure cardiovascular clinical trials: the need for a consensus definition
Zannad F, Stough WG, Pitt B, Cleland JG, Adams KF, Geller NL, Torp-Pedersen C, Kirwan BA, Follath F. Eur Heart J. 2008 Feb;29(3):413-21

When should data and safety monitoring committees share interim results in cardiovascular trials?
Borer JS, Gordon DJ, Geller NL. JAMA. 2008 Apr 9;299(14):1710-2.

Similarities and differences in design considerations for cell therapy and pharmacologic cardiovascular clinical trials
Lewis RM, Gordon DJ, Poole-Wilson PA, Borer JS, Zannad F. Cardiology. 2008;110(2):73-80.

2007
Cardiovascular safety of drugs not intended for cardiovascular use: need for a new conceptual basis for assessment and approval
European Heart Journal 2007;28:1904-1909. Borer JS1, Pouleur H, Abadie E, Follath F, Wittes J, Pfeffer MA, Pitt B, Zannad F.

Globalization of cardiovascularclinical research: the balance between meeting medical needs and maintaining scientific standards
American Heart Journal 2007;154:232-8 Stough WG1, Zannad F, Pitt B, Goldstein S. Am Heart J. 2007

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

PARTNERS

The **Association of Clinical Research Professionals (ACRP)** is located in more than 70 countries, ACRP's 13,000 diverse members work in a variety of practice settings, roles, and specialty areas, with a wide range of experience in clinical research. What's common about them all is their dedication and commitment to promoting excellence in clinical research.
www.acrpnet.org
Partnership: Jim Kremidas

The **Duke Clinical Research Institute (DCRI)** is 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
Partnership: Matthew Roe

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.
www.eacpt.org
Partnership: Tabassome Simone

The **European Medicines Agency (EMA)** is a decentralized 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 **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 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. Their 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.fondationforce.wixsite.com/fondationforce

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 **Food and Drug Administration (FDA)** is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
www.fda.gov

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.
www.hfsa.org
Partnership: Randall Starling & Wilson Tong

The **Heart Rhythm Society (HRS)** 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
Partnership: Thomas Deering

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

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
Partnership: Augusto Gallino

Kinexum guides, designs, and manages strategic and operational solutions to the regulatory, manufacturing, nonclinical, clinical development, and business challenges necessary to take scientific discoveries to proof of concept and through the product life cycle.
www.kinexum.com
Partnership: Thomas Seoh

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

PARADIGM is a public-private partnership and is co-led by the European Patients' Forum and EFPIA. PARADIGM's mission is to provide a unique framework that enables structured, effective, meaningful, ethical, innovative, and sustainable patient engagement (PE) and demonstrates the 'return on the engagement' for all players.
www.imi-paradigm.eu

The **Society for Clinical Trials (SCT),** a multidisciplinary society with membership spanning myriad disciplines that are all critical to the field of clinical trials: biostatistics, clinical areas, IT and systems, data management, ethics, regulatory bodies, behavioral science, research coordination, patient partners, health outcomes researchers, and many others.
www.sctweb.org
Partnership: Yves Rosenberg

Women as One will serve as a unifying thread across the many important organizations and individuals working to improve the recruitment, retention and treatment of women in medical specialties where they are highly underrepresented.
www.womenasone.org
Partnership: Roxana Mehran

Speaker biographies

Kirkwood F. Adams Jr. (Chapel Hill, USA)

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. Dr. Adams has been involved in more than 130 completed grant and industry funded research projects and is currently 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. 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). 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 is passionate about the role of physicians in leading the big data revolution in medicine.

Jodi Akin (Hawthorne Effect, USA)

Jodi Akin is the Founder and Chief Executive Officer of Hawthorne Effect, Inc. An entrepreneur and executive in health care since 1993, Jodi has worked in key executive leadership roles in start-ups, academia and public corporations with focus on clinical operations, product and market development, and regulatory and medical affairs throughout her healthcare career. Jodi has served as non-salaried clinical professor at the University of California, San Francisco, holds eight medical device patents and has published and presented extensively. Jodi also served as global humanitarian, leading international healthcare initiatives in underserved geographies including Heart To Heart International Children's Medical Alliance, The Heart Lung Institute of the East Bay, and The Nahapetov Friendship Foundation. She was co-founder of the China Heart Group, a joint venture with the United Nations Industrial Development Organization. Jodi holds a BS in Foreign Service from Georgetown University, an MS in Physiology/Nursing from Pace University, New York and certification in Advanced Critical Care Medicine from University of California, San Francisco.

Omar Ali (Portsmouth, GBR)

Omar Ali is a Formulary Advisor for Surrey & Sussex Healthcare NHS Trust, with the regional Joint Drugs & Therapeutics Committee and the CCG/Commissioning Prescribing Clinical Network. Omar was a visiting Lecturer at UCLH Pharmacy Programme, the Independent Prescribing V300 Course at the University of Surrey, and the University of Portsmouth. He is an Editorial Content Advisor to Guidelines, and was recently invited to be Associate Editor to the Canadian Journal of Population Therapeutics & Clinical Pharmacology. Omar served on the External Reference Group on Cost Impact Modelling for NICE and the Adoption & Impact Program Reference. Last year he addresssed the Italian Healthcare Senate on

Pharmaco-economic Evaluation & Sustainability Models of Healthcare and featured as the Westminster Health Forum Keynote on the Future for Pharmacy Commissioning, Organisation & Delivery. He is currently working on a PhD with his doctorate thesis entitled "Value Based Pricing & Outcomes Based, Innovative Contracting of New Medicines."

Jacqueline Deloach Alikhaani (Los Angeles, USA)

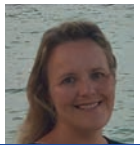
Jacqueline Deloach Alikhaani is a Los Angeles based Heart Survivor/Patient/Volunteer. She is a graduate of the University of Southern California and serves as a PCORI-American Heart Association Organizational Ambassador, Citizen Scientist, American Heart Association 2019-20 Know Diabetes by Heart Campaign Ambassador Spokesperson, and WomenHeart Champion. She also serves as an FDA Consumer Representative. As a Patient-Centered Outcomes Research Engagement Patient-Partner/ADAPTOR, she serves as a patient representative for several Patient-Centered Outcomes Research Institute CER PCORnet projects. 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 to help determine best-practices that help advance clinical care and daily quality-of-life for healthcare-consumers/patients, family members and caregivers by better use of 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. Sadegh is 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 improve patient-centered care.

Angeles Alonso (EMA, GBR)

Angeles Alonso Garcia is the 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), and an active member of the Scientific Advice Working Party Honorary Consultant in Cardiology. Dr Alonso graduated from the School of Medicine at the Universidad Autónoma de Madrid, with a PhD at the Medical School (1991). She has served as General Secretary of the Spanish Society of Cardiology: 2001-2003, President of the International Relations Department of the Spanish Society of Cardiology, and Member of the Editorial Committee of the Spanish Heart Journal. She has been a fellow of the European Society of Cardiology since 2001 and is a nucleus member of Cardiovascular Pharmacology Working Group.



Brenda Alsemgeest (Amsterdam, NED)

Brenda Alsemgeest is 39 and was diagnosed six years ago with 2 congenital heart diseases: Wolff-Parkinson White Syndrome (WPW) and Sick Sinus Syndrome/Sinus Arrest. She took Beta blockers for the WPW for a long time to little affect, now she mainly uses them when her heartbeat won't go down by itself. Brenda is married and works as a legal adviser in the financial sector, often appearing in court to advocate for her clients.

Charalambos Antoniades (Oxford, GBR)

Charalambos Antoniades is a Professor of Cardiovascular Medicine at University of Oxford, and a Consultant Cardiologist at Oxford University Hospitals. He graduated with honors from Athens Medical School. His research is focused on the study of cross-talk between adipose tissue and cardiovascular system, with specific interest in molecular imaging of inflammation. He currently directs the Oxford Heart Vessels and Fat programme and the Oxford Academic Cardiovascular CT programme. He has published over 220 papers and received the prestigious "K Samaras" award by University of Athens. In 2016, he gave "John French" lecture at the British Atherosclerosis Society and received the outstanding achievement award of the ESC. He currently serves as an editor for Cardiovascular Research, British Journal of Pharmacology, and Hellenic Journal of Cardiology. He is a board member of the British Atherosclerosis Society and one of the founders of Scientists of Tomorrow of the ESC, as well as Chief Scientific Officer of Caristo Diagnostics, a University of Oxford spinout company.

Paul Armstrong (Alberta, CAN)

Paul Armstrong is a Distinguished University Professor at the University of Alberta. 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. Dr. Armstrong's commitment to the education, training, and mentoring of healthcare professionals, research trainees, and faculty spans over 40 years and is a key signature of his career. He is internationally recognized for his expertise in acute coronary disease and heart failure and has a particular interest in novel approaches to the design of clinical trials and their interpretation. Dr. Armstrong is the founding Director of the Canadian VIGOUR Centre (Virtual Coordinating Centre for Global Collaborative Cardiovascular Research), 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.

Sameer Ather (Xpert Dox, USA)

Sameer Ather is a cardiologist and data scientist based in Birmingham, Alabama. Dr. Ather did his medical residency and PhD at Baylor College of Medicine, Houston, TX, and completed a cardiology fellowship at the University of Alabama at Birmingham. During his clinical practice, Dr. Ather saw patients struggling to navigate the complex world of health care. XpertDox was built to help improve patient access to healthcare and clinical trials by leveraging big data analytics. XpertTrial, a product of XpertDox, is a custom built white labeled clinical trial search engine and patient recruitment platform for healthcare organizations, including universities, hospitals, clinical research sites, and patient advocacy organizations.

Michel Azizi (Paris, FRA)

Michel Azizi is Professor of Vascular Medicine at Paris Descartes University and Head of the Hypertension Unit and of the Clinical Investigation Center, Georges Pompidou University Hospital, Paris. He is member of the European Society of Hypertension, the European Society of Cardiology, and was the past Vice-President of the European Society of Hypertension. He has published more than 240 papers in peer reviewed journals, many of which have focused on the renin-angiotensin-system and resistant hypertension. Azizi received the Jean Hamburger prize for Medical Research in 2007, the Peter van Zwieten award of the European Society of Hypertension in 2011, Milan, Italy, and the Paul Milliez award at the European Society of Hypertension in 2017.

George Bakris (Chicago, USA)

George Bakris is a tenured Professor of Medicine and Director of the ASH Comprehensive Hypertension Center in the Department of Medicine at the University of Chicago. He received his medical degree from the Rosalind Franklin School of Medicine and completed residency in Internal Medicine at the Mayo Graduate School of Medicine as well as a fellowship in Physiology and Biophysics. He also completed fellowships in Nephrology and Clinical Pharmacology at the University of Chicago. 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 committee, and 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 and edits Am J Nephrology, Up-to-Date, Nephrology & Hypertension Section and Assoc. Ed of Diabetes Care.

Jeroen Bax (Leiden, NED)

Jeroen Bax is Director of non-invasive imaging and Director of the echo-lab at the Leiden University Medical Center, as well as the ESC Immediate Past-President (2018 – 2020). His main interests include clinical cardiology, heart failure, cardiac resynchronization therapy and the application of all different imaging modalities to these clinical fields. Professor Bax has authored numerous papers and holds several positions in national and international scientific organizations, as well as serving on the editorial boards of many different journals.

Agim Beshiri (Abbott Diagnostics, USA)

Agim Beshiri is Senior Medical Director of Medical and Scientific Affairs for Abbott Diagnostics. Prior to his work at Abbott, Dr. Beshiri's medical background encompassed internal medicine and laboratory medicine. His clinical experience includes the Brooke Army Medical Center in Texas, the 452nd Combat Support Hospital in Wisconsin and Aurora/Advocate Clinical Laboratories in Wisconsin and Illinois as well as the Ministry of Health in Macedonia. Dr. Beshiri completed his studies and training at the University of Wisconsin, UNIBE School of Medicine and the Academy of Health Sciences (U.S. Army). Dr. Beshiri served as the American Association of Clinical Chemistry Industry Division Secretary. He is a member of several organizations, including the International Council for Standardization in Hematology, International Society for Laboratory Hematology, European Hematology Association, American Society of Hematology, and American Society of Clinical Oncology. He has also served on guideline subcommittees for the Clinical and Laboratory Standards Institute.

Elisabeth Björk (AstraZeneca, SWE)

Elisabeth Björk is Vice President and Global Head of the late phase development for Cardiovascular, Renal and Metabolism at AstraZeneca, and overall accountable for development strategy and delivery across the company's CVRM portfolio. Under her leadership, the team has built a strong CVRM portfolio and delivered a large number of new medicines and additional indications, often based on CV outcomes studies where a world-class center of excellence has been established. Elisabeth is an endocrinologist, trained at the Karolinska Institute, and an associate professor in medicine at Uppsala University. Prior to joining AstraZeneca in 2002, she was the head of the diabetes and endocrinology unit at the Uppsala University Hospital. Elisabeth spent several years in the US leading the development of dapagliflozin

(FORXIGA). She is a Board Member for Chalmers University of Technology. Elisabeth has published more than 50 peer-reviewed articles in scientific journals.

Maria Borentain (BMS, USA)

Maria Borentain is a graduate of University of Paris Medical School. She trained in Cardiology with subsequent sub-specialization in Echocardiography and Sports Medicine, and holds a Master in Cardiovascular Pharmacology and Biostatistics. She is currently a Medical Director in Global Drug Development Cardiovascular at Bristol-Myers Squibb. After several years in clinical practice, Dr. Borentain joined Bristol-Myers Squibb 14 years ago and held various positions in Medical Affairs, Field Medical management and Global Clinical Development. Dr Borentain is involved in early and late clinical development of several assets in Heart Failure. Her interests also include Innovative clinical trial designs and patient engagement.

Jeffrey Borer (New York, USA)

Jeffrey Borer is Professor of Medicine, Cell Biology, Radiology, Surgery and Public Health at SUNY Downstate Medical University, where he formerly served as Chairman, Department of Medicine, and Chief, Division of Cardiovascular Medicine, and where he directs two research institutes. While Senior Fullbright Hays Scholar at Guy's Hospital (London), he completed the first clinical demonstration of nitroglycerin's utility in acute MI. Returning to NIH, he developed stress radionuclide cineangiography, introducing non-invasive assessment of cardiac function with exercise. He then returned to Cornell for 30 years as Harriman Professor of Cardiovascular Medicine and Chief, Division of Cardiovascular Pathophysiology. His current research focuses on valve diseases and clinical pharmacology. He has been a USFDA Advisor for 42 years, chaired multiple Advisory Committees, has served several national professional societies, has published more than 500 scientific articles/chapters and 8 books, edited the journal, Cardiology, for 14 years and has received several awards/recognitions.

Martin Borggrefe (Heidelberg, GER)

Martin Borggrefe is Chair of the Department of Medicine at the University Medical Centre in Mannheim. He attended medical school at the University of Düsseldolf and University of London, and was a fellow and consultant cardiologist at the University of Düsseldolf and University Münster. He has served on the programme committee, as Councillor, and Vice President of the ESC. Most recently he served as a member of the ESC Nominating Committee.

Pierre Boutouyrie (Paris, FRA)

Pierre Boutouyrie is a full professor of Pharmacology and Cardiology at University Paris Descartes Sorbonne PARIS Cité. He is Medical officer at Hopital Européen Georges Pompidou and head of the Pharmacology Unit and INSERM U970 Team 7. His scientific topics are large arteries, hypertension, clinical pharmacology, space cardiovascular physiology. His participates in cardiovascular and pharmacological research from rare vascular diseases to large epidemiological cohorts , and currently serves as president of the ARTERY society and chairman of the ESH working group on large artery structure and function.

Uli Broedl (Boehringer, CAN)

Uli Broedl is Country Medical Director, Vice President Medical and Regulatory Affairs, and Co-Chair of the BI Incubator, an innovation lab that aims to create novel solutions to

serve the needs of patients and the healthcare system, at Boehringer Ingelheim Canada. Dr. Broedl is passionate about fostering innovation and new disruptive technologies that hold promise to improve patient access and care. Prior to this assignment, Dr. Broedl served as global Deputy Therapeutic Area Head Metabolism at Boehringer Ingelheim. Dr. Broedl is adjunct Professor of Medicine at the University of Munich, Germany, and holds a Doctorate of Medicine degree from the University of Munich. He completed a Postdoctoral Fellowship in Dr. Daniel J. Rader´s lab, Institute for Translational Medicine and Therapeutics, University of Pennsylvania School of Medicine, and completed his training in Internal Medicine, Endocrinology and Metabolism at the Medical Center of the University of Munich.

Philippe Brudi (Kinexum, CAN)

Philippe Brudi specialized in primary care from University of Nancy II, France. He moved to the Industry in the 1990s and evolved at clinical development and medical affairs positions at ICI/Zeneca Pharma, Bristol-Myers Squibb, Novartis, and Merck. He acquired experiences in registration/prelaunch phases and late stage clinical development in the cardiometabolic field. Dr Brudi joined recently Liquidia Technologies as head of Medical Affairs.

Javed Butler (Jacksonville, USA)

Javed Butler is the Patrick H. Lehan Chair in Cardiovascular Research and Professor/ Chairman of the Department of Medicine at the University of Mississippi Medical Center. He received his medical degree from the Aga Khan University, residency at Yale University, several fellowships at Vanderbilt University, and cardiac imaging fellowship at the Massachusetts General Hospital at the Harvard Medical School. He has a Master of Public Health from Harvard University and Master in Business Administration from Emory University. Dr. Butler is board certified in cardiovascular medicine and advanced heart failure and transplant medicine. He serves on several committees for the American College of Cardiology, American Heart Association, National Institutes of Health, and the Heart Failure Society of America. He is the recipient of the Simon Dack Award by the American College of Cardiology as well as the Time, Feeling, and Focus Award by the American Heart Association.

John Camm (London, GBR)

John Camm is Emeritus Professor of Clinical Cardiology at St George's Hospital Medical School, University of London, UK, and Professor of Cardiology at Imperial College, London. He is president of the European Heart Rhythm Association and the Arrhythmia Alliance, founder and trustee of the Atrial Fibrillation Association, trustee of the Drug Safety Research Unit, and director of Richmond Pharmacology. Professor Camm is Editor-in-Chief of Clinical Cardiology and European Heart Journal Case Repots, Editor of European Heart Journal, and editorial board member of a further 15 journals. Professor Camm has been involved in the production of numerous guidelines, including the ESC guidelines for the management of atrial fibrillation and the NICE guidelines for the treatment of unstable angina and non-ST elevation ACS. Professor Camm was awarded the ESC Gold Medal in 2005 and the British Cardiovascular Society Mackenzie Medal in 2008.

Kimberly A. Chapman (Washington, USA)

Kimberly Chapman is an Associate Professor with tenure of Pediatrics and Systems Biology at the George Washington Medical School and Health Sciences Center. She is also an attending

geneticist and metabolist at the Children's National Health System in Washington DC and part of the Children's National Rare Disease Institute. She received her Bachelors from St. Louis University and M.D. and PhD from the University of Nebraska. She did residencies in Internal Medicine and Pediatrics at Pittsburgh Health Sciences Center, Clinical Genetics and Clinical Biochemical Genetics, and a fellowship at the Children's Hospital of Philadelphia. Her clinical time is spent at Children's National seeing predominantly individuals with secondary energy deficiencies and intoxication type disorders. Her basic science research focuses on the intersection between the propionate pathway and the tricarboxylic acid pathway as well as pursuing the proof of principle experiments required to bring new therapeutics for Propionic Acidemia and Methylmalonic Aciduria to patients.

Cynthia Chauhan (Wichita, USA)

Cynthia Chauhan had stage III heart failure with preserved ejection fraction and multiple comorbidities, including stage IV kidney failure, kidney cancer and nephrectomy. Unfortunately there are no reliable treatment options for HFpEF patients and 50% of patients die within the first five years of diagnosis. Having been diagnosed over five years ago, Cynthia enters every clinical trial for HFpEF for which she is eligible. Although heart failure has seriously impacted her life, she remains an engaged and contributing member of society, working to increase awareness of HFpEF and bring the patient perspective to cancer/cardiology research tables and professional discussions.

Alan Cheng (Medtronic, USA)

Alan Cheng is an Associate Professor who earned his MD degree from Yale Medical School and served as an intern and resident in internal medicine on the Osler Medical Service at The Johns Hopkins Hospital. He remained at Hopkins for his general cardiology and cardiac electrophysiology fellowship training. He joined the faculty at Johns Hopkins University and served as Director of the Arrhythmia Device Service. He has mentored several postdoctoral fellows and has co-authored numerous publications in cardiac electrophysiology. He has been awarded NIH R01 grants focused on sudden cardiac death and atrial fibrillation. In 2016, he became the Vice President of Clinical Research for Medtronic focused on implantable cardiac devices. He has maintained his appointment at Johns Hopkins as part time faculty in the Division of Cardiology. Dr. Cheng is a Diplomat of the American Board of Internal Medicine in Internal Medicine, Cardiovascular Diseases and Cardiac Electrophysiology.

Julio Chirinos (Philadelphia, USA)

Julio Chirinos is a cardiologist with a sub-specialty in non-invasive cardiac imaging. He is an Associate Professor of Medicine at the University of Pennsylvania. His research focuses on pathophysiologic mechanisms and novel therapeutic targets in Heart Failure with Preserved Ejection Fraction (HFpEF), with an emphasis on whole-system dysfunction. He is particularly interested in the role of arterial dysfunction and arterial pulsatile hemodynamics in cardiovascular disease and the role of deep phenotyping (including functional phenomics, proteomics and other approaches) for a better characterization of human heart failure. He is the Principal Investigator of the Cardiovascular Consequences of Sleep Apnea (COSA) trial and the KNO3CK OUT HFpEF trial (a phase IIb trial investigating the role of inorganic nitrate therapy in HFpEF). He is also an Associate Editor of Circulation Heart Failure and is part of the Editorial Board of various other cardiovascular journals.

Jillianne Code (Vancouver, CAN)

Jillianne 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, 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 advocated 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. She is 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.

Robert Cody (Flemington, USA)

Robert J. Cody is the Principal of AlchemyChase, assessing emerging approaches to human disease. He is also Chairman of the Board of Trustees of Hunterdon Healthcare System, where he served as Interim President and CEO in 2018. His prior senior executive positions were with Merck, Janssen, and CVRx, developing novel therapies for cardiovascular disease. His long research career has focused on pathophysiologic mechanisms of heart failure and cardiovascular disorders. His early research of the renin-angiotensin-aldosterone pathway, natriuretic peptides and autonomic dysfunction held to shape the concept of "neurohormonal" control of the cardiovascular system. He has over 250 publications, and led the design and monitoring of international clinical trials in heart failure. His appointments in Cardiovascular Medicine were with the University of Michigan, The Ohio State University, and the Weill-Cornell Medical Center. He received his advanced degrees from Penn State University, and the University of Michigan. He completed Medical and Cardiovascular training at the Cleveland Clinic, and Massachusetts General Hospital, respectively.

David J. Cohen (Kansas City, USA)

David Cohen is Professor of Medicine at the University of Missouri-Kansas City and the former Director of Cardiovascular Research at Saint Luke's Mid America Heart Institute, where he also served as Director of the Health Economics and Technology Assessment Group. His research focuses on the application of formal cost-effectiveness methodology to novel interventions for the diagnosis and treatment of cardiovascular disease, the extension of traditional cardiovascular outcomes research to include collection of patient-centered outcomes among patients undergoing treatment for cardiovascular disease, and the development of instruments for evaluating health status among patients with cardiovascular disease. Dr. Cohen has published more than 450 original articles in leading journals, including the New England Journal of Medicine, Lancet, JAMA, Circulation, and Journal of the American College of Cardiology. Dr. Cohen is former Associate Editor for JACC and currently serves on the editorial board for the American Heart Journal, JACC Interventions, and Circulation.

Deborah J. Cohen (Portland, USA)

Deborah Cohen is a collaborative leader in qualitative and mixed methods primary care research. Cohen – a professor and research vice chair of family medicine in the OHSU School of Medicine – is known as an innovative change agent in her field. She has nearly 100 peer-reviewed publications, and more than $25 million in grant funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, Patient-Centered Outcomes Research Institute, and the Robert Wood Johnson Foundation.

Sidney Cohen (Medtronic, USA)

Sidney Cohen received his MD and PhD degrees from the University of Pennsylvania School of Medicine in 1982. He is Board Certified in both Internal Medicine and Cardiovascular Disease. He was an Assistant Professor of Medicine in the Cardiovascular Division of the University of Pennsylvania from 1987-1998 and currently holds the title of Adjunct Associate Professor of Medicine at the same institution. Dr. Cohen has worked in the pharmaceutical and medical device industries since 1998 at both start-up companies (Centocor and Conor Medsystems) as well as at large companies (Johnson & Johnson/Cordis) He has worked in both clinical research and medical affairs studying cardiovascular drugs and cardiovascular medical devices. In 2012, Dr. Cohen moved to Medtronic Corporation where he focuses on clinical research in coronary, renal denervation, and structural heart programs.

Lisa Cooper (Baltimore, USA)

Lisa Cooper is the James F. Fries Professor of Medicine and the Bloomberg Distinguished Professor of Equity in Health and Healthcare at Johns Hopkins Schools of Medicine, Nursing, and Public Health. She was one of the first scientists to document disparities in the quality of relationships between physicians and ethnic minority patients. She then designed innovative interventions targeting physicians' communication skills, patients' self-management skills, and healthcare systems' abilities to address the needs of socially-at-risk groups. Currently, she directs the Johns Hopkins Center for Health Equity, where she and her team work with stakeholders from health care and the community to achieve the center's namesake goal. Their efforts include the conduct of clinical trials to identify solutions to alleviate racial and income disparities in social determinants, healthcare quality and cardiovascular disease outcomes. Dr. Cooper received a 2007 MacArthur Fellowship. She is an elected member of the National Academy of Medicine.

Jacqueline Corrigan-Curay (FDA, USA)

Jacqueline Corrigan-Curay serves as Director of the Office of Medical Policy (OMP) in the Center for Drug Evaluation and Research, FDA. Dr. Corrigan-Curay leads the development, coordination, and implementation of medical policy programs and strategic initiatives, including policy development on real world evidence, drug labeling, prescription drug promotion, clinical trial oversight and innovative trial design. She works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes. Dr. Corrigan-Curay earned her law degree from Harvard Law School, her medical degree from University of Maryland School of Medicine, and a bachelor's from Harvard/Radcliffe College in Cambridge, MA.

Gadi Cotter (Momentum Research, USA)

Gadi Cotter co-founded 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.

Kennedy Cruickshank (London, GBR)

Kennedy Cruickshank is a professor at King's College and consultant physician at both St Thomas' and Guy's Hospitals. His past research interests have included HTLV-1/ spastic paraparesis between Caribbean migrants in London-Jamaica, arterial function and stiffness, and origins of high BP/ T2 diabetes among others. He was recently the President of the Artery Society and has worked overseas in regards to childhood malnutrition and pregnancy malaria.

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.

Björn Dahlöf (Cereno, SWE)

Björn Dahlöf is an Associate Professor of Medicine at the Institute of Medicine, Department of Molecular and Clinical Medicine, Sahlgrenska Academy, University of Gothenburg, Sweden. Dr Dahlöf's interests center on cardiovascular medicine and hypertension, the Renin-Angiotensin-System, epigenetic modulation as well as large Cardiovascular mortality and morbidity studies. He is a member of several professional societies including the Swedish Medical Association, European and International Societies of Hypertension and a fellow of European Society of Cardiology. He is also an international fellow of American College of Cardiology and the American Heart Association's Council for High Blood Pressure Research. Dr Dahlöf is an ESH certified Hypertension specialist as well. Currently Dr Dahlöf is involved in the development HDAC inhibition to restore endogenous fibrinolysis for thrombo-embolic prevention and other applications for epigenetic modulation for cardiovascular disease.

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. Beth 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, 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.

David L. DeMets (Madison, USA)

David L. DeMets is the Emeritus Max Halperin Professor of Biostatistics at the University of Wisconsin-Madison. He received his PhD in biostatistics from the University of Minnesota. He has co-authored four texts, Fundamentals of Clinical Trials, Data Monitoring in Clinical Trials: A Case Studies Approach, Data Monitoring Committees in Clinical Trials: A Practical Perspective, and Statistical Methods for Clinical Trials. He served on the Board of Directors of the Society for Clinical Trials, American Statistical Association, and was President of the Society for Clinical Trials and the Eastern North American Region (ENAR) of the Biometric Society. He has been the Elected Fellow of the International Statistics Institute, American Statistical Association, Association for the Advancement of Science, Society for Clinical Trials, and American Medical Informatics Association. He is also an Elected Member of the National Academy of Medicine.

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

Lorenzo A. DiCarlo (Livanova, GBR)

Lorenzo DiCarlo is a cardiologist and Vice President for Clinical and Medical Affairs at LivaNova USA with responsibility for the clinical development of Autonomic Regulation Therapy (ART) for heart failure. He has held previous positions at Pfizer, Guidant CRM, and Proteus Digital Health, leading global clinical development programs that resulted in successful approvals of first-in-class implantable, pharmaceutical, and combination drug-device products.

Kenneth Dickstein (Stravanger, NOR)

Kenneth Dickstein was born in Philadelphia and has medical degrees from the University of London and the Royal College of Surgeons in Dublin. He was a research fellow at Harvard Medical School and completed his PhD in exercise physiology at the University of Bergen. He was in charge of the coronary care unit at Stavanger University Hospital, full professor of medicine and coordinator for the medical student teaching program at the University of Bergen. He was President of the Heart Failure Association of the European Society of Cardiology, a councillor on the ESC Board, and Chairman of the Task Forces for two of the ESC Guidelines on Heart Failure.

He received the National Research Prize from the Norwegian National Society and the Falch Research Prize from the University of Bergen. He is the founder of the ESC patient website heartfailurematters.org, a member of numerous editorial boards and steering committees, and an active associate editor of the European Journal of Heart Failure.

Wilfried Dinh (Bayer, GER)

Wilfried Dinh is currently employed at Bayer AG, Pharmaceuticals, R&D working as early clinical leader and holding the position of medical director. He studied medicine in Germany and obtained education in internal medicine, cardiology and a diploma in tropical medicine. He is board certified in invasive and non-invasive cardiology and internal medicine in Germany and USMLE certified in the US. Dinh has received the highest German academic grade - the "Habilitation" and obtained the postdoctoral lecture qualification at the University Witten/Herdecke, the first private University and medical school in Germany.

Jay Edelberg (Myokardia, USA)

Jay M. Edelberg is the Senior Vice President of Clinical Development at Myokardia. Dr. Edelberg is a clinical cardiologist and vascular biologist, having served in leadership roles for two decades in both academic medicine and the biopharmaceutical industry. Prior to joining Myokardia, Dr. Edelberg led cardiovascular drug development at Sanofi, where he spearheaded the development of Praluent®. Previously at Bristol-Myers Squibb, Dr. Edelberg directed cardiovascular biomarker research.

Murray Epstein (Miami, USA)

Murray Epstein is Professor of Medicine at the University Of Miami Miller School Of Medicine. He was a recipient of the 1990 Distinguished Scientist Award of the National Kidney Foundation. In May 2011, he was awarded the American Society of Hypertension's prestigious Marvin Moser Award for Clinical Hypertension. Dr. Epstein was awarded an established Investigatorship of the Howard Hughes Medical Institute. He is a member of many prestigious professional societies including the American Society for Clinical Investigation. Dr. Epstein served as a member of the National High Blood Pressure Education Program Coordinating Committee and is a contributor to the 6th Report of the Joint National Committee. Dr. Epstein is listed in Who's Who in America (59th, 60th and 61st edition) and Who's Who in Medicine. Dr. Epstein has authored over 440 journal articles and book chapters. He served as the Editor of four editions of The Kidney in Liver Disease, and three editions of Calcium Antagonists in Clinical Medicine.

Steven Farmer (CMS, USA)

Steven A. Farmer is the Chief Strategy Officer for Coverage and Analysis at the Centers for Medicare and Medicaid Services (CMS). He previously served as Senior Advisor and Senior Medical Officer at the Center for Medicare and Medicaid Innovation, where he was a lead consultant on the Bundled Payments for Care Improvement Advanced payment model. He is a practicing noninvasive cardiologist and remains an Associate Professor of Medicine and Health Policy and Management at George Washington University. He is also Adjunct Associate Professor of Medicine and Business Strategy and distinguished fellow of Law, Regulation, and Economic Growth at Northwestern University. He graduated from Stanford University with a degree in International Relations and an emphasis in international public health. He completed his PhD at the London School of Hygiene and Tropical

Medicine as a British Marshall Scholar and his MD at Yale University. He completed his residency in internal medicine and fellowship in cardiology at the University of Pennsylvania.

Dean Fergusson (Ottawa, CAN)

Dean Fergusson is a Senior Scientist and Director of the Clinical Epidemiology Program (CEP) at the Ottawa Hospital Research Institute and a Full Professor in the Department of Medicine with cross-appointments to the School of Epidemiology & Public Health and the Department of Surgery at the University of Ottawa. He has served or chaired CIHR panels (RCT, New Investigator, Mentoring) and is an active member on editorial boards (Transfusion Medicine Reviews, Transfusion Medicine, Clinical Trials, Trials). He has also been an active member of renowned disease clinical trial networks in transfusion, critical care, and thrombosis.

Holly Fernandez Lynch (Philadelphia, USA)

Holly Fernandez Lynch is John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics in the Department of Medical Ethics and Health Policy at the Perelman School of Medicine, University of Pennsylvania. Her scholarly work focuses on the ethics and regulation of research with human subjects, including payment to research participants, research with biospecimens, use of social media in research settings, patient-engaged research, research risks to bystanders, and IRB effectiveness. She is founder and co-chair of the Consortium to Advance Effective Research Ethics Oversight. Professor Fernandez Lynch was named a Greenwall Faculty Scholar in 2019, with a project addressing ethical and policy issues around access to investigational therapies outside clinical trials. She attended college at the University of Pennsylvania, was a Levy Scholar in Law and Bioethics at Penn Law, and earned a Master of Bioethics there as well.

João Pedro Ferreira (Nancy, FRA)

João Pedro Ferreira is a cardiovascular physician (hypertension, co-morbidities and heart failure with preserved ejection fraction clinics), university teacher and researcher at the University of Lorraine and Nancy hospital in France. He is also an invited professor at the University of Porto, Portugal, and a visiting fellow at the University of Glasgow. His main research interests are all things around mineralocorticoid receptor antagonists, fibrosis, health quality and outcomes, clinical trials, biostatics and trial methodology, and implementation science in axis that incorporate the availability, accessibility, affordability, and acceptability of treatments that may improve people's lives.

Gerasimos Filippatos (Athens, GRE)

Gerasimos Filippatos is Dean of the School of Medicine, University of Cyprus and Professor of Cardiology, University of Athens, GR. He studied Medicine at the University of Patras, GR, and earned his doctorate Cum Laude from the University of Athens. He completed his clinical training in Chicago, USA; and Cambridge, UK. He is past President of the Heart Failure Association of the ESC. He has served in the ESC Practice Guidelines Committee and the ACC/AHA Heart Failure Guidelines Writing Committee and as International Governor of the ACCP. He is Associate Editor of the European Heart Journal and Senior Consulting Editor of JACC-HF and has published over 500 articles and 30 book chapters. Prof. Filippatos is in the Thomson Reuters list of Highly Cited Researchers. Honorary Member of many Cardiac Societies including French, Romanian and Hungarian Cardiac Societies.

Mona Fiuzat (Washington, USA)

Mona Fiuzat is an Associate Professor of Medicine at Duke University, Scientific Advisor at the FDA, Executive Editor of JACC: Heart Failure, and Former Senior Scientific Advisor to the FDA Commissioner. She received her PharmD at Mercer University School of Pharmacy in Atlanta, Georgia. Dr. Fiuzat worked in the pharmaceutical industry for Solvay Pharmaceuticals and SmithKline Beecham Pharmaceuticals, and was Director of Clinical Development at ARCA biopharma, Inc. Her clinical research experience has been in cardiovascular trials with a focus on pharmacogenetics in heart failure, and she helped file an NDA for the first proposed pharmacogenetically targeted heart failure drug. She worked in the Heart Failure Research Program at Duke on a number of key clinical trials as an investigator and steering committee member, and has authored or co-authored over 100 papers in the field of heart failure.

Bruno Flamion (Namur, BEL)

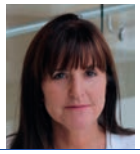
Bruno Flamion is Full Professor of Clinical Pharmacology at the University of Namur, Belgium and Head of Strategic Development at Idorsia Pharmaceuticals in Allschwil, Switzerland. Bruno is a Belgian national, MD/PhD with clinical expertise in internal medicine and nephrology. He was Research Associate at the National Institutes of Health, Bethesda, USA, and the Belgian National Fund for Scientific Research, and he headed the Laboratory of Physiology and Pharmacology at the University of Namur. In parallel, he worked at the European Medicines Agency in London, as member of the CHMP and chair of the Scientific Advice Working Party. Bruno also chaired the Federal Committee for Reimbursement of Medicines (Health Technology Assessment and Payers' recommendations) at the National Institute for Health and Disability Insurance in Belgium for three years.

Alexander Fleming (Kinexum, USA)

Alexander Fleming is Founder and Executive Chairman of Kinexum. He is also President and Chief Executive Officer of Tolerion. Dr. Fleming received his M.D. and internal medicine training from Emory. He completed fellowship training in endocrinology at Vanderbilt and metabolism at National Institutes of Health, where he was a senior fellow. At the US Food and Drug Administration from 1986-98, Dr. Fleming was responsible for the therapeutic areas of diabetes, other metabolic and endocrine disorders, growth and development, nutrition, lipid-lowering compounds, and reproductive indications. He led reviews of landmark approvals, including metformin and the first statin, insulin analog, PPAR-agonist, and growth hormone for non-GH deficiency indications. He also helped shape FDA policies and practices related to therapeutic review and regulatory communication. Dr. Fleming's regulatory and technical expertise has been requested in numerous international settings, including the World Health Organization and working groups of the International Conference on Harmonization.

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.



Jane Freedman (Worcester, USA)

Jane Freedman is the Edward Budnitz Professor of Cardiovascular Medicine at University of Massachusetts Medical School, attends in the Division of Cardiology and is Director of Translational Research for the UMass Memorial Heart & Vascular Center. She is the acting Director of Cardiovascular Research. Dr. Freedman graduated from Yale University, Tufts University School of Medicine, and completed residency and cardiology fellowship at the Massachusetts General Hospital and Brigham and Women's Hospital, respectively. Dr. Freedman has received various investigator awards from both the AHA and the ACC, was been elected to the A.S.C.I. and the A.U.C. She was a previous Associate and Senior Editor for Circulation and is the Editor-in-Chief for Circulation Research. The major research initiatives in Dr. Freedman's laboratory emphasize the regulation of pathways contributing to atherothrombotic and cardiometabolic disease using both basic, clinical and population studies.

Elizabeth Galle (CVRx, USA)

Elizabeth Galle has spent the past 30 years in clinical research, mostly focusing on cardiovascular trials. After receiving her degree in biostatistics, she began designing and analyzing large, pivotal clinical trials. Liz held various roles in the clinical department of Guidant (Boston Scientific) focusing on expanding device indications for heart failure and other cardiac conditions. Currently, Liz is leading the global clinical research department at CVRx, a private Minnesota company with a proprietary implantable technology for the treatment of high blood pressure and heart failure.

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 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 serves as Quality Insights Renal Network 5 Chair, Patient Advisory Committee & Member of Medical Review Board of Directors, American Association of Kidney Patients' BOD and Ambassador, UNOS Ambassador, and PCORI Ambassador, among several other roles.

Jyothis George (Boehringer, GER)

Jyothis George is Global Head of Diabetes Clinical Development, Boehringer Ingelheim and Associate Clinical Professor at the University of Warwick, UK. His previous 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. George is fully accredited in Internal medicine with fellowships from the Royal College of Physicians and the American College of Endocrinology. He 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 J. Gersh (Rochester, USA)

Bernard J. Gersh is a Professor of Medicine at Mayo Clinic College of Medicine, and a Consultant in Cardiovascular Medicine. His past positions include The W. Proctor Harvey Teaching Professor of Cardiology and Chief of the Division of Cardiology at Georgetown University Medical Center. Dr. Gersh received his MB, ChB, from the University of Cape Town in South Africa. He received his Doctor of Philosophy degree from Oxford University where he was a Rhodes Scholar. He received the degree of Ph.D. (honoris causa) from The University of Coimbra, Portugal in 2005. In 2014 & 2015 he was named in the Thomson Reuters list of individuals with the greatest number of cited scientific papers 2002-2012. Dr. Gersh is the editor of 15 books and is on the editorial board of 27 journals and Deputy Editor of The European Heart Journal. He is also Editor-in-Chief of UpToDate in Cardiology.

Nadia Giannetti (Montréal, CAN)

Nadia Giannetti received her MD from McGill University. She became an attending cardiologist at the McGill University Health Centre after completing a Fellowship at Stanford University, California in Heart Failure and Cardiac Transplantation. She is the founder and Medical Director of the Heart Failure and Heart Transplant Centre at the McGill University Health Centre in Montreal, Quebec. She is a clinical researcher with interests in outcomes in cardiomyopathy causes, treatments and outcomes. For the past 15 years, she has been a primary member of the Canadian Heart Failure and Heart Transplant Guidelines. She is a full time cardiologist at the McGill University Health Centre with responsibility for the care of over 1000 patients with Heart Failure. Since 2010, she has been the Chief of Cardiology at the McGill University Health Centre overseeing all activities in the Division of Cardiology.

C. Michael Gibson (Boston, USA)

C. Michael Gibson is an interventional cardiologist, cardiovascular researcher and educator. Gibson founded and has led his own Academic Research Organization (PERFUSE) for over 25 years, and his work has been presented in over 1000 manuscripts, abstracts, & trial summaries. PERFUSE offers a full line of trial management, social media portals, CEC, DSMB and core lab services for phase 1-4 trials worldwide. In November 2012, Gibson was appointed Professor of Medicine at Harvard Medical School. Gibson is also the Chairman of the Board for the WikiDoc Foundation; the world's largest, free, living textbook of medicine viewed over 400,000 times daily. As Principal Investigator, Dr. Gibson is responsible for the overall scientific leadership throughout the trial period. He works closely with the study personnel on protocol development, case report development, FDA meeting attendance, EC/SC/DSMB committee assembly, overall project management, development of the statistical analysis plan, and manuscript preparation.

Natasha Giordano (PLx Pharma, USA)

Natasha Giordano became President and Chief Executive Officer of Aceto in 2016. Previously, she served as the Interim Chief Executive Officer of ClearPoint Learning, Inc. She also served on the ClearPoint board of directors and as Chief Executive Officer of Healthcare Corporation of America. She was Chief Operating Officer and then as Chief Executive Officer, President and a member of the board of directors of Xanodyne Pharmaceuticals, Inc., a branded specialty pharmaceutical company with development and commercial capabilities focused on pain management and women's health. Earlier in her career, she worked nine years with Parke-Davis, then owned by Warner Lambert, in several sales and marketing positions including Strategic Alliance management and Sales Integration. Ms. Giordano holds a Bachelor of Science degree in nursing from Wagner College.

Rachel Gold (Portland, USA)

Rachel Gold, is an epidemiologist and health services researcher. She is jointly appointed as a Senior Investigator at the Kaiser Permanente NW Center for Health Research and the Lead Research Scientist at OCHIN, Inc. Her work focuses on using health information technology to reduce health disparities, and the implementation methods needed to support adoption of such technologies. She studies how to take practices that improved care quality in well-resource settings and implement them in safety net community health centers. She has also developed electronic health record-based tools for collecting and acting on patient-reported social determinants of health, and is now studying how to help community clinics implement social determinants screening. Dr. Gold co-authored the National Academies of Science, Medicine and Engineer report on integrating social needs care into clinical settings. Her earlier research included analyzing the impact of state insurance policies on care quality in safety net clinics.

Stephen Gough (Novo Nordisk, DEN)

Stephen Gough joined Novo Nordisk A/S, as Senior Principal Clinical Scientist in Copenhagen, Denmark in 2015 in the Chief Medical Office, to provide advice and clinical guidance on the development of new molecules and drugs, from early through to phase III and beyond, for the treatment of diabetes and obesity. In 2018, Stephen became Senior Vice President and Global Chief Medical Officer. Stephen was Head of the Oxford Centre for Diabetes Endocrinology and Metabolism and served as Professor of Diabetes to the University of Oxford and Consultant Physician at the Oxford University of Hospitals NHS Trust. He was also the Diabetes Clinical Lead for the Local Clinical Research Network and the Academic Health Science Network in Oxford. His research interests have resided in the fields of the genetics of autoimmune disease, glucose homeostasis, incretin biology in pancreas whole organ and islet transplantation, and clinical trials of GLP-1 based therapies.

Christopher Granger (Durham, USA)

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 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).

John Gregson (London, GBR)

John Gregson is an Assistant Professor in Medical Statistics at the London School of Hygiene and Tropical Medicine where he has been working for six years, having previously studied for a Masters in Medical Statistics and PhD in Cardiovascular Epidemiology. He has a range of experience in the analysis and planning of major cardiovascular clinical trials. He is interested in how to better design and analyze future clinical trials in cardiovascular design, by improving their design or statistical analysis, and by making better use of statistical methods that are not currently widely used or well understood.

Christian Grimstein (FDA, USA)

Christian Grimstein is a Team Leader in the Division of Translational and Personalized Medicine (DTPM) in the Office of Clinical Pharmacology at the U.S. FDA. He is a pharmacist by training and received his Ph.D. in Pharmaceutics from the University of Florida/USA in 2008. His expertise is in the area of clinical pharmacology and public health genomics, specifically as related to precision medicine strategies in drug development and utilization. At the FDA, he reviews investigational and new drug applications, contributes to regulatory policy development, and conducts research that supports FDA's core public health mission.

Kendra Grubb (Atlanta, USA)

Kendra J. Grubb, Surgical Director Emory University Structural Heart and Valve Center, is dedicated to improving the lives of patients through innovation and building collaborative teams to promote patient-centered treatment of cardiovascular disease. Previously, she was Director of Minimally Invasive Cardiac Surgery and the Heart Valve Program at University of Louisville. Dr. Grubb has led and participated in numerous clinical trials of innovative technologies, including studies of transcatheter aortic valve replacement, mitral valve percutaneous therapies, endovascular treatment of descending thoracic aortic aneurysms, and transcatheter heart failure devices. Dr. Grubb attended University of Southern California, where she received her MD degree from Keck School of Medicine and her Master of Health Administration. She completed general surgery residency at University of Illinois at Chicago (2010), fellowship in cardiothoracic surgery at University of Virginia (2012), and fellowship in interventional cardiology and transcatheter therapies at New York Presbyterian-Columbia University (2013).

Kolbeinn Gudmundsson (CHMP, EMA, ICE)

Kolbeinn Gudmundsson is an attending physician at Children's Hospital/Landspítali University Hospital in Reykjavik, Iceland. He currently serves as the Chief Medical Officer and Deputy Executive Officer for Icelandic Medicines Agency. He is a member of the CHMP European Medicines Agency, SAWP European Medicines Agency, and Vice Chair of the SAWP European Medicines Agency.

Penilla Gunther (Stockholm, SWE)

Penilla Gunther served as Member of Swedish Parliament between 2010-2018. She founded The Parliamentarian Network for Equal Care, which held a great number of seminars for patients and their associations, professionals in health care and in the Life Science industry. Penilla is a patient herself, surviving lymphoma, breast cancer, and a sudden severe heart failure that led to a heart transplant. Because of her experience, she is a frequent speaker in all kind of meetings; talking about the importance of seeing the whole patient – not only the disease. Penilla founded 2019 a platform for Patient Associations in Sweden, FOKUS Patient® for common areas as equality, security, quality etc. Penilla is a member of the Steering Committee of the Heart Failure Policy Network, the Osteoporosis and Fragility Fracture Policy Network and is (e.g) a former member of the European Working Group for Value Assessment and Funding Processes in Rare Diseases (ORPH-VAL).

Andrey Gurevich (Vifor Fresenius, CHE)

Andrey Gurevich qualified as a physician in St.Petersburg, Russia, and obtained Internal Medicine and Nephrology specializations. He

completed a fellowship at the University of Colorado School of Medicine, and practiced nephrology in Russia and the UK. As an Associate Professor of nephrology, he contributed to research and teaching at the St.Petersburg Medical Academy for Postgraduate Studies in Russia. Since 2010, Gurevich has become part of the industry in various progressive roles in clinical development and medical affairs with Amgen, Shire, Takeda, and most recently Vifor Pharma. His main research and clinical interests remain with clinical nephrology, cardiology, metabolics, and rare diseases.

Nick Hartshorne-Evans (London, GBR)

Nick Hartshorne-Evans was diagnosed with Heart Failure in January 2010 at 39. His experience as a patient stimulated him into developing the only dedicated patient led Heart Failure charity in the UK, the Pumping Marvellous Foundation. He additionally serves as Patient expert with NHS England, NICE, HFA of the ESC and BSH, Patient expert for NICE Chronic Heart Failure Guidelines 2018, and Board Advisor Canadian HeartLife Foundation. He has received the following recognition for his work: Total Business Global Award for Outstanding Contribution 2019, Winner CEO Today Magazine European Business Awards 2019, Crain's Business 40 under 40 Manchester 2008, and National Business Awards Entrepreneur of the Year finalist 2006.

Koji Hasegawa (Kyoto, JAP)

Koji Hasegawa is the former President of the International Society of Cardiovascular Pharmacotherapy, a visiting Professor at the University of Shizuoka, and involved in the Cardiovascular Research Network and National Hospital Organization. His interests include risk factor control, smoking cessation, obesity, heart failure, and biomarkers. Hasegawa obtained his MD from Kyoto University and PhD from the Graduate School of Medicine Kyoto University.

Maxime He (Paris, FRA)

Maxime He graduated from Ecole Polytechnique (FR) and Columbia University (USA). He began his career as a Data Scientist at Riminder and then joined Owkin. As the Group Leader of Clinical Data Research, he currently focuses on data science combining machine learning and statistics on clinical and text information in observational and experimental data.

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. He is the Coordinating Center Principal Investigator for multiple networks and clinical trials such as the NHLBI's Heart Failure Research Network, PCORI's National Patient-Centered Clinical Research Network (PCORnet) and NIH's Health System Collaboratory. Dr. Hernandez has over 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. He received his bachelor's degree from Rice University and his medical degree from the University of Texas-Southwestern School of Medicine. He completed an internship, residency in the Department of Medicine at University of California-San Francisco and cardiology fellowship at Duke University.

Joseph Hill (Circulation, USA)

Joseph Hill is a cardiologist-scientist whose research focuses on molecular mechanisms of remodeling in the disease-stressed myocardium. He graduated with an MD, PhD from Duke University, pursued postdoctoral scientific training at the Institut Pasteur in Paris, and 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 before moving 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. He serves on several editorial boards, including Circulation Research: Senior Consulting Editor, American Journal of Physiology, Heart and Circulatory Physiology, and American Journal of Cardiology. He received the 2018 Research Achievement Award from the International Society for Heart Research. Dr. Hill maintains an active clinical practice focusing on general cardiology, heart failure, and hypertension.

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 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 the Chief Medical Officer of the whole Heart Center Leipzig and General Manager of the Leipzig Heart Institute and served as President of EHRA from June 2015 to June 2017. He has been for many years Deputy Editor of the European Heart Journal in the field of electrophysiology and cardiac arrhythmia and served as Senior Guest Editor on Circulation: Arrhythmia and Electrophysiology in North America. He has been Editor-in-Chief of EP Europace since 2017.

Jemma Hopewell (Oxford, GBR)

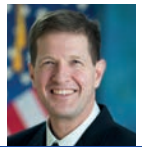
Jemma Hopewell is an Associate Professor of Genetic Epidemiology & Clinical Trials at the Clinical Trial Service Unit & Epidemiological Studies Unit, University of Oxford, UK, and a British Heart Foundation Fellow. Dr Hopewell leads a programme of precision medicine and big data research focusing on the use of genetic and clinical trial-based studies to investigate the causes of and treatments for cardiovascular disease and arrhythmias. She has particular interests in determining predictors of patient response to therapy, using genetics to improve our understanding of drug targets and disease mechanisms, and genomic characterization of vascular disease and its risk factors (e.g. lipoprotein[a]). Dr Hopewell directs a range of pharmacogenetic and other large-scale research projects involving cardiovascular mega-trials (such as HPS, THRIVE, and REVEAL), observational studies and international consortia, and is a member of various Data Monitoring, Steering and Scientific Advisory Boards.

Yoran Hummel (Singapore, SIN)

Yoran Hummel is the current president and co-founder of eko.ai, a Singapore based machine learning start-up, focusing on preparing echocardiographic datasets for machine learning and automating the analysis workflow of echocardiographic exams, as well as disease prediction. He has a background in echocardiography, having worked in the University Medical Center Groningen and attained a PhD on the topic of echocardiography and the detection of subtle cardiac damage.

Larry Husten (New York, 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.



Joseph Hutter (CMS, USA)

Joseph Dolph Hutter serves at the Centers for Medicare & Medicaid Services. His portfolio spans evidence and technology evaluation, clinical decision support, quality improvement, and innovation. He has served on numerous interagency and public-private task forces, and has represented CMS internationally. He was a co-author of the Aspen Institute white paper series "Reinventing Healthcare" and of the National Science and Technology Council white paper, "Roadmap for Medical Imaging Research and Development." He was a scholar in Harvard Medical School's Global Clinical Scholars Research Training program. Prior to public service, he was a Fellow at the Institute for Health Care Delivery Research at Intermountain Healthcare, and a Brookings Institution Congressional Fellow serving as staff on the Senate HELP Committee. Previously, he was a partner in private practice, and Director of Cardiac CT and Non-invasive Vascular Imaging and a QI lead at the Washington Hospital Center.

Ilan Irony (FDA, USA)

Ilan Irony joined FDA CBER in 2000 as a clinical reviewer after training at UCSF and NIH and years of practice in Internal Medicine and Endocrinology. He also worked in the Endocrine Division in CDER as a reviewer and team leader. In 2011, he returned to CBER as the branch chief, and recently became Deputy Director in the Division of Clinical Evaluation and Pharmacology / Toxicology in the Office of Tissues and Advanced Therapies. Over the course of his career at FDA, he has reviewed many trials using biologics or devices intended for treatment of cardiovascular disorders, and trials assessing cardiovascular safety.

Stephan James (Uppsala, SWE)

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

Denis Janssen (Zuid, NED)

Denis Janssen is a heart patient live who was told his heart was damaged beyond repair after two open heart procedures and twelve coronary stents. However, after beginning an experimental stem cell treatment at the University Hospital "Lumc" in Leiden/The Netherlands, Denis' health made a huge improvement. Since 2010, he has received 4x intramyocardial autologous stem cell injections. In order to thank medical scientists in general, he has committed himself to contributing in patient participation, as he strongly believes this involvement can improve medical practices.

James Januzzi (Boston, USA)

James L. 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 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.

Meg Jardine (Sydney, AUS)

Meg Jardine is a clinical researcher at The George Institute for Global Health. She is currently supported by a Next Generation Clinical Researchers Program - Career Development Fellowship funded from the Australian government Medical Research Future Fund. She is Head of George Clinical Renal Trials, a Conjoint A/ Professor of Medicine at The University of UNSW and a practicing nephrologist. She current serves as Deputy Chair (Chair Elect) of the Scientific Committee of the Australasian Kidney Trials Network and was the former Chair of the Haemodialysis Working Group. She is a Member of the ISN Advancing Clinical Trials Committee and a member of the national nephrology association (ANZSN) Research Advisory Committee

as well as a Can-SOLVE CKD International Research Advisory Committee member. She has contributed to Working Groups and Conferences of the International Society of Nephrology and the international KDIGO guidelines group and is on the Editorial Board for CJASN.

Tomas Jernberg (Stockholm, SWE)

Tomas Jernberg is a Professor in the Department of Clinical Sciences of Danderyds University Hospital, Karolinska Institutet, and is leading one of the research groups at the Department of Cardiology, Danderyds University Hospital, Stockholm, Sweden. Jernberg is the chair of RIKS-HIA (National Quality Registry of Acute Coronary Syndrome) since 2010 and chair of SWEDEHEART (National Quality Registry of Coronary Artery Disease and Valve Disease) since 2012. His research is mainly about prognosis and treatment of acute coronary syndrome and he has more than 170 original publications in peer review journals. He is a member and chair of several steering committees including both randomized and observational studies.

Peter Jüni (Toronto, CAN)

Peter Jüni is the Director of the Applied Health Research Centre 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. 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.

David E. Kandzari (Atlanta, USA)

David E. Kandzari is the Director, Interventional Cardiology of the Piedmont Heart Institute and Chief Scientific Officer for the Piedmont Healthcare in Atlanta, Georgia. Dr. Kandzari specializes in cardiovascular disease, peripheral arterial disease and interventional cardiology. A graduate of Duke University School of Medicine, he completed his internship and residency at The John Hopkins University School of Medicine in Baltimore, Maryland. He completed his general and interventional cardiology fellowship at Duke University where he joined the faculty as the John B. Simpson Assistant Professor of Interventional Cardiology and Genomic Sciences. He formerly served as Director of Interventional Cardiology Research at the Scripps Clinic, Chief Medical Officer for the Cordis Corporation, and a Medical Officer for the Center for Devices and Radiological Health for the United States Food and Drug. He has been consecutively voted as one of Atlanta's Top Doctors by Atlanta Magazine from 2011 to 2019, and is peer-nominated in the top 1% of cardiologists by U.S News and World Report.

Helina Kassahun (Amgen, USA)

Helina Kassahun is an Executive Medical Director within the Cardiovascular and Metabolic and Bone Therapeutic Areas 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 entering Phase 2 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.

Korey Kennelty (Iowa City, USA)

Korey A. Kennelty is an Assistant Professor in the College of Pharmacy and the Department of Family Medicine in the Carver College of Medicine at the University of Iowa. Her clinical practice is through the University of Iowa Hospital and Clinics as a geriatrics pharmacist. Dr. Kennelty received her B.B.A. from the University of Toledo, Pharm.D. from Midwestern University- Glendale, and M.S. and Ph.D. from the University of Wisconsin-Madison. She then completed a 3-year Advanced Fellowship at the William S. Middleton Memorial Veterans Hospital specializing in geriatrics and implementation science. She is an implementation scientist whose research focuses on increasing effective medication management and optimizing safe medication use for our patients living with multiple chronic conditions. In her work, Dr. Kennelty utilizes social and behavioral health theories as well as employs both qualitative and quantitative methodologies.

David Kent (Boston, USA)

David M. Kent is Director of the Tufts Predictive Analytics and Comparative Effectiveness Center at the Institute for Clinical Research and Health Policy Studies (ICRHPS), Tufts Medical Center, and Director of the Clinical and Translational Science (CTS) MS/PhD Program at the Sackler School of Graduate Biomedical Sciences. He is the Director and PI of a NIH-funded Training Program for Postdoctoral Trainees and Professor of Medicine, Neurology, and CTS at Tufts Medical Center/Tufts University School of Medicine. Dr. Kent is a clinician-methodologist with a broad background in clinical epidemiology with a focus on predictive modeling, individual patient data meta-analysis, and observational comparative effectiveness research. His applied research spans several fields, but is concentrated mostly in cardiovascular disease (especially stroke). A considerable portion of Dr. Kent's time is also spent educating and mentoring future clinical researchers in his various roles.

Muhammad Shahzeb Khan (Chicago, USA)

Muhammad Shahzeb Khan is a Resident Physician at Cook County Health Sciences. Shahzeb completed his medical training from Dow Medical College, Pakistan before joining Cook County Health Sciences. He is currently completing his Masters of Clinical Sciences from Rush University Medical Center. He has authored or co-authored more than 100 publications. He has also authored a book chapter on "Non-cardiac pathology" in the 3rd edition of Cardiovascular Magnetic Resonance: A Companion to Braunwald's Heart Disease. His research interests include heart failure management and clinical research methodology.

Scott Kim (NIH, USA)

Scott Kim is a Senior Investigator in the Department of Bioethics, National Institutes of Health, USA. He received his MD from Harvard and PhD in moral philosophy from the University of Chicago, and trained in adult psychiatry at the Massachusetts General Hospital. Dr. Kim combines philosophical, clinical, and empirical research approaches to address a variety of ethical issues (ethical issues in invasive neurological trials, ethics of pragmatic clinical trials, assessment of decision-making capacity,

surrogate consent for incapacitated patients, theory and practice of informed consent, and physician assisted death). Dr. Kim's work has been supported by the NIMH, NINDS, NIA, NHGRI, Michael J. Fox Foundation, American Association for Geriatric Psychiatry, and the Greenwall Foundation. His work has appeared in New England Journal of Medicine, Nature, JAMA, and other key journals.

Sverre E. Kjeldsen (Oslo, NOR)

Sverre E. Kjeldsen is Professor and Senior Consultant at the Department of Cardiology, Oslo University Hospital Ullevaal, and Adjunct Professor at the Division of Cardiovascular Medicine, University of Michigan. He is currently working on Oslo Ischemia Study, IDA, Oslo RDN, ENCOReD, DISTINCT, BEAUTY and TOMMORROW. Dr. Kjeldsen was President of the European Society of Hypertension 2005-2007, fellow of ESC and past-member of Working Group Hypertension and the Heart, fellow the American Heart Association - the Council for High Blood Pressure Research, fellow of American College of Cardiology, and a member of several ESH/ESC Hypertension Guidelines Committees. Dr. Kjeldsen received his medical degree from University of Oslo, his PhD degree from University of Oslo, and was a medical resident and fellow in Cardiology at Ullevaal University Hospital and Assistant Professor at University of Michigan. He organized the 20th Scientific Meeting of the European Society of Hypertension in Oslo, 2010. In 2018 he received the Alberto Zanchetti Life Time Achievement Award by the European Society of Hypertension.

Susheel Kodali (New York, USA)

Susheel K. Kodali is the director of the Heart Valve Center at NY-Presbyterian/ Columbia University Medical Center. Dr. Kodali is also an associate professor in medicine at CUMC. Dr. Kodali specializes in the percutaneous treatment of coronary artery and structural heart disease, and cardiac catheterization. Dr. Kodali was named New York Metro Area's Top Doctor in 2012, 2013, 2014, 2015, 2016, 2017, 2018 and 2019 by Castle Connolly's Top Doctors™ and New York Magazine's Top Doctors in 2012, 2013 and 2014. Dr. Kodali serves as the institutional co-investigator of the PARTNER trials and associated registries as well as the principal investigator for the Sentinel Trial. Dr. Kodali attended medical school at the University of California, Los Angeles. He did his residency and a fellowship program in clinical cardiology at the University of California, San Francisco, and a fellowship program in interventional cardiology at Columbia University Medical Center.

Wolfgang Koenig (Munich, GER)

Wolfgang Koenig is a Professor of Medicine/ Cardiology at the University of Ulm Medical School, Germany. He is a board-certified internist and interventional cardiologist specialized in intensive care medicine and has extensive experience in the molecular epidemiology of cardiovascular diseases. A former Director of the WHO-MONICA Augsburg Myocardial Infarction Register, Professor Koenig has held multiple clinical positions at the University of Ulm Medical Center. In 2015 he joined the Deutsches Herzzentrum München, Technische Universität München and became an established investigator of the Munich Heart Alliance within the German Centre for Cardiovascular Research and is the Head of the Cardiometabolic Unit. Professor Koenig also serves on the steering committee of multiple international randomized 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. In 2014 he received the Rudolf Schönheimer Award from the German Atherosclerosis Society.

Marvin Konstam (Boston, USA)

Marvin A. Konstam is Chief Physician Executive of The CardioVascular Center at Tufts Medical Center and Professor of Medicine at Tufts University. He has provided leadership to numerous clinical trials, including, currently, ANTHEM-HFrEF, investigating vagal nerve stimulation in heart failure. Dr. Konstam served on guideline panels for the Agency for Health Care Policy and Research (Chair) and the AHA/ACC/HFSA, on FDA's Cardiovascular and Renal Advisory Committee and, presently, Endocrine and Metabolic Drug Advisory Committee. Dr. Konstam has previously been President of HFSA, President of the Association of Professors of Cardiology, Senior Advisor for Cardiovascular Diseases at NHLBI, and Chair of ACC's Academic Cardiology Council. He presently serves on ACC's Health Affairs Committee and is HFSA's Publications Committee Chair. Dr. Konstam is a recipient of TUSM's Distinguished Faculty Award and has been named among "Best Doctors in America" for 17 consecutive years. In 2018, he received HFSA's Lifetime Achievement Award. In 2019 he received Massachusetts AHA's Paul Dudley White Award.

Jim Kremidas (Alexandria, USA)

Jim Kremidas is Executive Director for ACRP, a not-for-profit association that represents the clinical research enterprise. Prior to ACRP, Jim consulted for a variety of clients such as investigator sites, academic institutions, sponsors, and suppliers. He was Senior Vice President, Patient Recruitment, at two different large CROs for over six years where he and his team were responsible for developing and implementing patient enrollment strategies for global clinical trials.

Harlan Krumholz (New Haven, USA)

Harlan Krumholz, the Harold H. Hines, Jr. Professor of Medicine at Yale School of Medicine, is a cardiologist and the Director of the Center for Outcomes Research and Evaluation at Yale-New Haven Hospital, where he leads initiatives to improve the quality and outcomes of clinical decisions and healthcare delivery. He founded HugoHealth—a patient-centric platform to engage people as partners in research and leverage the secure movement of digital health data—and is a founder of medRxiv.

Valentina Kutyifa (Rochester, USA)

Valentina Kutyifa is an Associate Professor of Medicine at the University of Rochester Medical Center, Rochester, NY, USA. Dr. Kutyifa holds a PhD in cardiac electrophysiology, a Masters' degree in health care management, and a certificate in clinical research from Harvard Medical School, and has a research interest in cardiac arrhythmias and sudden cardiac death. Her research work encompasses a wide array of studies related to diabetes, implantable cardioverter–defibrillators, cardiac resynchronization therapy, echocardiography, and technology innovations including the wearable cardioverter–defibrillator, subcutaneous ICD, left ventricular assist devices, and new disruptive wearable technologies improving health care delivery.

Reijo Laaksonen (Zora Biosciences, FIN)

Reijo Laaksonen is a clinical pharmacologist specialized in cardiovascular pharmacology. He spent more than six years at the Clinical Research Institute of Montreal and at the Laboratory of

Experimental Neurology, ULB, Brussels as a post-doctoral fellow and visiting scientist. Prior to joining Zora, Reijo has worked as Chief Research Scientist at Viikki Drug Discovery Technology Center, Helsinki and served as a consultant for pharmaceutical and biotechnology companies. Dr. Laaksonen is co-inventor of more than 20 biomarker patents and has published nearly 200 original scientific articles. Reijo has also served research professor at Tampere University and medical director of the Finnish Clinical Biobank Tampere. Reijo's interest in cardiovascular disease prevention and statin intolerance work are key assets for the development of the Zora portfolio. He was recently awarded 20 million € by the EU for a randomized clinical trial to evaluate efficacy of personalized prevention in high risk CHD patients.

Fouzia Laghrissi-Thode (DalCor, CHE)

Fouzia Laghrissi-Thode, CEO of DalCor Pharmaceuticals, has more than 20 years of pharmaceutical industry leadership experience. Most recently, Dr. Laghrissi-Thode was Vice-President at AstraZeneca of the US Renal-Cardiology Therapeutic Area. Her previous roles include Head of the Cardiovascular and Metabolism Therapeutic Area, Global Product and Portfolio Strategy at AstraZeneca and Roche. She has a wealth of experience in US and Europe through working in clinical development, global strategic marketing, business development, licensing and M&A in a variety of therapeutic areas including cardiovascular, diabetes, renal and the central nervous system. She has served as a board member of the Healthcare Businesswomen's Association (HBA) Europe and was recognized by HBA in 2012 for her work in developing and promoting women leadership in healthcare. She served as a faculty member at the University of Pittsburgh Medical Center. Dr. Laghrissi-Thode is board certified in Psychiatry and holds Doctorate in Medicine from the University of Tours School of Medicine in France.

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 won the award for the JCI Ten Outstanding Young Persons of the World for 2014. 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), as well as a multinational Asian registry of diabetes in collaboration with the American College of Cardiology's Diabetes Collaborative Registry.

Hiddo Lambers Heerspink (Groningen, NED)

Hiddo Lambers Heerspink is Professor of Clinical Trials and Personalized Medicine and a clinical pharmacologist/trialist at the Department of Clinical Pharmacy and Pharmacology at the University Medical Center Groningen. He studied pharmacy at the University of Groningen and subsequently received his PhD from the University Medical Center Groningen. He worked as a Postdoctoral Fellow at The George Institute for Global Health, Sydney, Australia, where he investigated the effects of blood pressure-lowering regimens on renal and cardiovascular outcomes in patients with chronic kidney disease. Professor L. Heerspink has received a VENI and VIDI Award from the Netherlands Organization of Scientific Research, the Young Investigator

Research Award from the European Foundation for the Study of Diabetes. He is an editorial board member of the Clinical Journal of the American Society of Nephrology. He has authored and co-authored over 250 peer-reviewed publications.

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 Anna Maria 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. Anna Maria 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.

Andrea Laslop (CHMP, EMA, AUT)

Andrea Laslop joined the Austrian Federal Office for Safety in Healthcare on January 1st, 2006, where she heads the Scientific Office. She is a member of the EMA Scientific Advice Working Party and the Committee for Human Medicinal Products at the EMA. In addition to her general coverage of all medicinal products to be licensed via EMA, her expertise specifically includes biosimilars, blood and plasma products and medicines for the treatment of osteoporosis. Prior to her regulatory engagement Andrea Laslop worked as an associate professor of pharmacology and toxicology at the Medical University of Innsbruck, Austria, where she earned her MD and later on specialized as a pharmacologist. Her professional career included several sojourns for joint research projects at the NIMH in Bethesda, the Albert Einstein College of Medicine in New York and the Clinical Research Institute of Montreal. Over several years, Andrea Laslop served as president and vice president of the Austrian Pharmacological Society.

Jack Lawrence (Janssen, USA)

Jack Lawrence joined Janssen R&D in January 2019 as Head of Global Development for Cardiovascular & Metabolism where he is responsible for all development activities and provides global leadership and direction to clinical research staff. Prior to joining Janssen, he was Chief Medical Officer at Portola Pharmaceuticals where he led product development and clinical and regulatory strategies for andexanet, betrixaban and cerdulatinib. He spent 17 years at Bristol-Myers Squibb where as Vice President and Cardiovascular Therapeutic Area Head he was responsible for global clinical development and regulatory activities for apixaban and other CV programs. He received an Sc.B. degree in Biomedical Engineering from Brown University, an S.M. degree in Electrical Engineering from Massachusetts Institute of Technology and his medical degree from the University of Virginia. He completed cardiology fellowship training at The Johns Hopkins University School of Medicine, where he later served as an Associate Professor before joining pharma.

Francesca Catella Lawson (Applied Therapeutics, USA)

Francesca Catella Lawson has devoted most of her professional career to the clinical development of cardiovascular drugs and the evaluation of the cardiovascular effects of investigational drugs. When she worked 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. She 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.

Martin Lefkowitz (Novartis, USA)

Martin Lefkowitz is the Cardiovascular and Renal Therapeutic Area Head at Novartis Pharmaceuticals Corporation. Over his 20-year career, Dr. Lefkowitz has focused on the clinical development of compounds for heart failure, hypertension, thrombosis and renal disease. He was closely involved in the design and execution of several major outcome trials including ACCOMPLISH, PARADIGM-HF, PARAGON-HF and PARADISE-MI. Dr. Lefkowitz received a medical degree from New York University and did his internal medicine training at the University of Michigan. Subsequently, he completed a fellowship in nephrology at the University of Pennsylvania. Prior to joining the pharmaceutical industry, Dr. Lefkowitz was in the clinical practice of nephrology.

Joseph Loscalzo (Boston, USA)

Joseph Loscalzo is the Hersey Professor of the Theory and Practice of Medicine at Harvard Medical School, and Chairman of the Department of Medicine and Physician-in-Chief at Brigham and Women's Hospital. He is a summa cum laude graduate of the University of Pennsylvania, where he also obtained his M.D. and Ph.D. in biochemistry. He has published over 1,000 scientific articles, written or edited 50 books, and holds 32 patents. His research focus has been in the areas of vascular and redox biology, systems biology, and network medicine, with continuous funding from the NIH for over 35 years. He is a member of the American Society of Clinical Investigation, the Association of American Physicians, the National Academy of Medicine, and the American Academy of Arts and Sciences.

Douglas Losordo (Caladrius, USA)

Douglas Losordo is Executive Vice President, Global Head of Research and Development and Chief Medical Officer of Caladrius Biosciences. A native of Brooklyn, NY, he received his medical degree from the University of Vermont and completed an internship, residency and fellowship at St. Elizabeth's Medical Center, Boston, Massachusetts. As a member of the faculty and Professor at Tufts University and later as an endowed, tenured professor at Northwestern University he developed clinical programs in gene therapy and cell-based tissue repair including developing VEGF gene therapy for myocardial ischemia and diabetic neuropathy, CD34+ cell therapy for refractory angina, critical limb ischemia, severe claudication and coronary microvascular dysfunction. Two of these candidates advanced to phase 3. At Caladrius Dr. Losordo has recently initiated a study of CD34 cell therapy for critical limb ischemia targeting conditional approval under the new Japanese regulatory rules governing regenerative therapies. This program achieved Sakigake designation, a breakthrough status.

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. 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). He is on steering committees for several trials and observational studies. He is or has been Associate Editor for or on the Editorial Boards of numerous journals including Circulation, European Journal of Heart Failure, Circulation: Heart Failure, JACC: Heart Failure, and Journal of Cardiac Failure.

Thomas Lüscher (Zurich, CHE)

Thomas Lüscher studied medicine at the University of Zurich and obtained board certification in internal medicine and cardiology. He trained in cardiovascular research and in cardiology at the Mayo Clinic in Rochester, MN, USA and was later Professor of Pharmacotherapy at the University of Basel, Professor of Cardiology at the University of Berne, before assuming a position as Professor and Chairman of Cardiology and Director of the University Heart Center at the University Hospital Zurich and Director of the Center for Molecular Cardiology at the University of Zurich, Switzerland. Since 2017 Director of Research, Education & Development and Consulting Cardiologist at the Royal Brompton & Harefield Hospital Trust and Professor of Cardiology at the Imperial College in London. Professor Lüscher has published extensively, authoring or co-authoring over 500 original research articles and more than 200 reviews, book chapters and monographs including 3 editions of the ESC Textbook of Cardiovascular Medicine, including its electronic database ESC CardioMed.

Theodore Lystig (Medtronic, USA)

Theodore Lystig is the Senior Director of Corporate Biostatistics and a Technical Fellow at Medtronic, where he provides leadership and guidance in the use of robust statistical and research design methods throughout the company. He also holds the position of Adjunct Assistant Professor within the Division of Biostatistics at the University of Minnesota. Dr. Lystig is an elected Fellow of the American Statistical Association (ASA). He received his B.A. degree in Mathematics from St. Olaf College in Northfield, Minnesota, his M.S. and Ph.D. degrees in Biostatistics from the University of Washington in Seattle, and was a Postdoctoral Fellow at Chalmers Technical University in Gothenburg, Sweden, in statistical genetics.

Carolyn Magill (Aetion, USA)

Carolyn Magill is the CEO of Aetion. Over a period of 8 years at UnitedHealth Group (UHG), Carolyn served in multiple executive roles, including the national Vice President for Medicare Special Needs for individuals with chronic illnesses and for Dual Eligibles. She was also the COO of New Jersey's Medicaid and Medicare plan, covering over 400,000 lives. Subsequently, Carolyn served as EVP of Payer Strategy and Operations at Evolent Health. Most recently before joining Aetion, Carolyn served as CEO of Remedy Partners, a bundled payment company serving payers and providers. Carolyn earned her BA at Harvard University and MBA in Health Care Management from Wharton. She is on the Board of Directors of Parity.org, which advocates for gender parity in the c-suite and board rooms, and of the Center for Health Policy Development, which oversees the National Academy for State Health Policy. Carolyn has been recognized by Goldman Sachs, MM&M, and Crain's New York for her leadership in health care.

Martin Magnusson (Lund, SWE)

Martin Magnusson is a highly innovative and productive clinical scientist, and he represents one of Lund University future core group of young researchers (those who develop strong clinical activities relating to research of both direct clinical and complex molecular, genetic and biological nature). Magnusson heads a research group of 9 people; four PhD students, three post docs and two research nurses. Magnusson is the head (PI) of three major on-going prospective major research projects: Competence Centre Heart

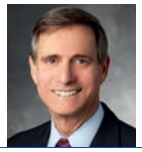
and Diabetes, SCAPIS sub-echocardiographic examination trail, and Heart and Brain Failure Investigation study (HARVEST). Magnusson has published 50 international original scientific publications, one book chapter and one book and he has 1538 citations (source Scopus) with an h-index = 14. Magnusson has 46 international conference contributions and 11 submitted manuscripts currently under review.

Fady Malik (Cytokinetics, USA)

Fady I. Malik is the Executive Vice President of Research and Development at Cytokinetics, a biotechnology company based in South San Francisco. Dr. Malik has been with Cytokinetics since its inception in 1998, in a variety of roles, including Vice President, Biology and Therapeutics, all focused towards building the company's cardiovascular and muscle therapeutic programs. Since 2000, Dr. Malik has held an appointment in the Cardiology Division of the University of California, San Francisco, where he is currently a Clinical Professor of Medicine and formerly was an Attending Interventional Cardiologist at the San Francisco Veterans Administration and UCSF Medical Centers. Dr. Malik received a B.S. in bioengineering from the University of California at Berkeley, and a M.D./Ph.D. from the University of California at San Francisco where he also completed an internal medicine residency and fellowship in cardiology.

Louise Marais (Issy les Moulineaux, FRA)

Louise Marais received her M.Sc. degree in biomedical engineering from the French School of Mines Saint-Etienne in 2012 and a PhD degree at the Paris-Est University in 2016 on the mechanical characterization of arteries. She then joined the INSERM unit led by Pr S. Laurent and Pr P. Boutouyrie in the Paris Cardiovascular Research Center (PARCC) and the Hôpital Européen Georges Pompidou in Paris as a postdoctoral researcher, where she worked on the development and clinical validation of innovative methods for arterial stiffness measurement (CARDIS H2020 project). She recently entered Withings, a French pioneering company in connected health, as clinical project leader.



David J. Maron (Stanford, USA)

David Maron's research and clinical work are focused on secondary prevention and management of stable ischemic heart disease. He was a member of the VA-funded COURAGE trial Executive Committee and Chair of its Optimal Medical Therapy Committee. He is the PI and Co-Chair of the NHLBI-funded ISCHEMIA trial and Co-Chair of the ISCHEMIA-CKD trial. At Stanford School of Medicine he is the Chief of the Stanford Prevention Research Center and Director of Preventive Cardiology. He is on the Board of Directors of the American Society for Preventive Cardiology.

Felipe Martinez (Cordoba, ARG)

Felipe Martinez graduated from Cordoba National University, where he currently serves as distinguished Emeritus Professor of Medicine. He attended post graduate training at Brussels University, Belgium and Toronto University, Canada. He is the Director of Rusculleda Foundation. Dr. Martinez is a former President of the Argentinean Federation of Cardiology and the International Society of Cardiovascular Pharmacotherapy and the previous Governor of the Argentina Chapter of the American College of Cardiology. He has edited three books about Cardiovascular Therapeutics and published more than 200 articles in international journals. His main fields of interest are Heart Failure and Hypertension with special focus in drug treatment and clinical research, having participated as Member of Executive, Steering and Endpoint Committees in 43 multinational trials.

Robin Martinez (Denver, USA)

Robin Martinez is an online community coordinator for Smart Patients Inc. As many patient advocates/ advisors come to this vocation by necessity, Robin did as well. 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 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. They encourage people to become leaders in their own science-based, research-oriented medical care coupled with persistence, advocacy, and hope.

Manuel Mayr (London, GBR)

Manuel Mayr qualified in Medicine from the University of Innsbruck (Austria) in 1999. He soon decided that his interests lay in research and therefore took up full-time research training in 2001, when he moved to London to undertake a PhD. Upon completion of his PhD, he achieved promotion to Professor in 2011. He held a British Heart Foundation (BHF) Intermediate Research Fellowship, two BHF Senior Research Fellowships and has recently been awarded a prestigious BHF Personal Chair. His academic achievements have been recognised by the inaugural Michael Davies Early Career Award of the British Cardiovascular Society (2007), the inaugural Bernard and Joan Marshall Research Excellence Prize of the British Society for Cardiovascular Research (2010), and the Outstanding Achievement Award by the European Society of Cardiology Council for Basic Cardiovascular Science (2013).

Laura Mauri (Medtronic, USA)

Laura Mauri was named Vice President, Global Clinical Research and Analytics, in the Medtronic Strategic Scientific Operations organization, in September 2018. Laura has held an array of major leadership positions and has served as the Chief Scientific Advisor for the Harvard Clinical Research Institute (also known as the Baim Institute for Clinical Research). She received her A.B. from Harvard College and her M.D. from Harvard Medical School, both magna cum laude, and her M.Sc. (Clinical Epidemiology) from Harvard School of Public Health. Laura is a member of the American Society of Clinical Investigation, the Association of University Cardiologists, a Fellow of the American College of Cardiology, a Fellow of the American Heart Association, and member of the Society of Cardiac Angiography and Intervention. She served as a Senior Editor for the journal Circulation, and was awarded the Joseph A. Vita Award for Clinical Research by the American Heart Association in 2017.

Finnian McCausland (Boston, USA)

Finnian R. McCausland is an Assistant Professor of Medicine, Faculty Director in Postgraduate Medical Education, and Co-Director of the Master of Medical Sciences in Clinical Investigation program at Harvard Medical School. He is also an Associate Physician and attending Nephrologist at Brigham and Women's Hospital. Dr. Mc Causland received his medical training in Ireland, graduating with honors from University College Dublin. He completed his medicine residency at the Mater Misericordiae University Hospital, before embarking on combined higher specialist training in Nephrology and Medicine. In 2009 he moved to Boston to complete a clinical and research fellowship at the BWH and Massachusetts General Hospitals. He subsequently joined the BWH faculty and served

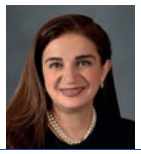
as Associate Program Director of the nephrology fellowship. He graduated from Harvard Medical School with a Master's in Medical Science Degree in Clinical Investigation. He became a Fellow of the Royal College of Physicians of Ireland in 2017.

Darren McGuire (Dallas, USA)

Darren K. McGuire is Distinguished Teaching Professor of Medicine at the University of Texas Southwestern Medical Center in the Division of Cardiology, where he holds the Dallas Heart Ball Chair for Research on Heart Disease in Women. Dr. McGuire is the Lead Physician of the Parkland Health System Cardiology clinics. Dr. McGuire's expertise is in large scale CV Outcomes clinical trial design and execution, and drug registration/regulation, with a focus in the area of diabetes and cardiovascular disease. He presently has leadership roles for numerous international cardiovascular clinical outcomes trials, including T2DM, obesity, and lipid trials. Dr. McGuire is a previous member of the FDA Cardiovascular and Renal Drugs Advisory Committee and remains an FDA ad hoc consultant. He is Deputy Editor of Circulation, Senior Editor of Diabetes and Vascular Disease Research and co-editor of the textbook: Diabetes in Cardiovascular Disease: A Companion to Braunwald's Heart Disease.

John McMurray (Glasgow, GBR)

John McMurray is Professor of Medical Cardiology and Deputy Director (Clinical) of the Institute of Cardiovascular and Medical Sciences at the University of Glasgow and Honorary Consultant Cardiologist at the Queen Elizabeth University Hospital, Glasgow. McMurray received his MB ChB and postgraduate MD degree from the University of Manchester. He was a member of the 2008 European Society of Cardiology Heart Failure Guidelines Task Force, Chair of the 2012 Task Force, a member of the 2013 American College of Cardiology/American Heart Association Heart Failure Guidelines Committee, and a member of the 2014 National Institute for Health and Care Excellence (NICE) Acute Heart Failure Guideline Committee. He is a member of NICE Appraisal Committee A. McMurray was awarded the MacKenzie medal of the British Cardiovascular Society and the Louis and Artur Lucian Award for Research in Circulatory Diseases in June 2017. In 2019 he was awarded an OBE OBE by Her Majesty The Queen, in recognition of his services to cardiovascular research.



Roxana Mehran (New York, USA)

Roxana Mehran is a Professor of Medicine, Cardiology, and Population Health Science and Policy at the Icahn School of Medicine at Mount Sinai, and Director of the Center for Interventional Cardiovascular Research and Clinical Trials at Mount Sinai. She is a founder and Chief Scientific Officer of the Cardiovascular Research Foundation (CRF) and recently founded Women as One. Dr. Mehran has been the Chair of the Interventional Council for the American College of Cardiology (ACC); Program Chair of the 2016 Annual Scientific Sessions of the Society for Cardiovascular Angiography and Interventions (SCAI), where she is also a co-founder of the Women in Innovations (WIN) Committee; and is a member of the American Heart Association's (AHA) Go Red for Women Scientific Advisory Group. Dr. Mehran is a recipient of several awards including the 2016 American College of Cardiology Bernadine Healy Leadership in CV disease award, the 2018 Nanette Wenger Award from Women's Heart for excellence in research and education and the 2019 Ellis Island Medal of Honor.

George Mensah (NIH, USA)

George Mensah is a clinician-scientist who currently serves as the Director of the Center

for Translation Research and Implementation Science at the National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH). Dr. Mensah is an honors graduate of Harvard University. He obtained his medical degree from Washington University and trained in Internal Medicine and Cardiology at Cornell. His professional experience includes more than 20 years of public health service between the U.S. Department of Veterans Affairs, the Centers for Disease Control and Prevention (CDC), and the NIH. In addition to his public service, Dr. Mensah had 15 years of experience in direct patient care, teaching, and research at Cornell, Vanderbilt, and the Medical College of Georgia (MCG). He was a full professor with tenure at MCG and is currently a Visiting Full Professor at the University of Cape Town, South Africa.

Robert Mentz (Durham, USA)

Robert Mentz is an Assistant Professor of Medicine in the Advanced Heart Failure Program at Duke University and is the Director of the Duke University Cooperative Cardiovascular Society. He is the clinical lead for the international EXSCEL trial and the HEART-FID trial. He is the lead coinvestigator 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. He was recently named a "Rising Star" by the American College of Cardiology (ACC). He participated in the Duke 2015 LEADER program as well as the ACC Emerging Faculty Program designed to develop the next generation of medical leaders. He is an established mentor for medical study, residents and cardiology fellows and received the 2016 Robert M. Califf Mentorship award at the DCRI.

Erin Michos (Baltimore, USA)

Erin Michos is an Associate Professor of Medicine in the Division of 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. She is the Director of Women's Cardiovascular Heath and the Associate Director of Preventive Cardiology with the Johns Hopkins Ciccarone Center for the Prevention of Cardiovascular Disease. Dr. Michos is an internationally known expert in Women's Health and Preventive Cardiology. Her research has focused on cardiovascular disease among women, risk prediction including the use of coronary artery calcium scores and inflammatory markers, lipids, physical activity, and vitamin D. Dr. Michos is the recipient of independent investigator funding from the National Institute of Health. She is the Training Director for the AHA Fellowship program for the Go Red for Women Strategic Focus Research Network at Johns Hopkins.

Brian Mittman (Pasadena, USA)

Brian S. Mittman is a Senior Scientist at Kaiser Permanente's Department of Research and Evaluation with additional affiliations at the University of Southern California (USC) 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 convened 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 peer review panel 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.

Claudio Mori (Vifor Fresenius, CHE)

Claudio Mori is the Medical Strategy/Portfolio Lead and Global Medical Lead Ferroportn-Inhibitor, Director, at Vifor Pharma Ltd, Zurich, Switzerland. He graduated from the University of Zurich Medical School, Switzerland. After basic research in Microbiology and clinical experience in General and Internal Medicine, always focusing on Cardiology, he joined the pharmaceutical industry as Medical Advisor Cardiovascular at Bristol Myers Squibb GmbH, Baar, Switzerland. He started to build up the Medical Affairs functions and was appointed as Medical Affairs Director Cardiology and Nephrology to launch ferric carboxymaltose (Ferinject®). He is member of the European Society of Cardiology, Heart Failure Association, the European Renal Association - European Dialysis Transplant Association, the American Heart Association, the American Society of Nephrology, and a reviewer for different international journals on topic of iron deficiency and anaemia.

Rajat Mukherjee (Cytel, USA)

Rajat Mukherjee, Managing Consultant at Cytel, has over 20 years of professional experience as a statistician both in industry and academia. He works in several areas of statistics including Bayesian design and analysis of clinical trials, design and analysis of complex epidemiological studies, statistical computing, survival and longitudinal analysis, nonparametric and semiparametric inference, statistical classification, machine-learning and high-dimensional data.

Theresa Mullin (FDA, USA)

Theresa Mullin leads FDA Patient Focused Drug Development and heads FDA delegation to ICH. She is a principal advisor on strategy and leads international negotiation, regulatory harmonization, and other initiatives. 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 she 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.

Linda Mundy (American Regent, USA)

Linda M. Mundy is Vice President and Chief Medical Officer at American Regent, Inc., a Daiichi Sankyo Group Company. As a pharmaceutical executive, she leads teams with responsibilities for Clinical Research and Development, Pharmacovigilance and Drug Safety, Clinical Regulatory Affairs, Quantitative Sciences, and Medical Affairs. Prior to joining ARI, Dr. Mundy held a Director role at GlaxoSmithKline in WorldWide Epidemiology with work focused on global antibacterial drug discovery and development. Dr. Mundy earned a Bachelor's Degree with Honors at Pace University and was inspired to go to medical school after humanitarian work in southeast Asia with the International Rescue Committee. She completed her medical degree, internal medicine residency, and infectious diseases fellowship training at The Johns Hopkins University School of Medicine and then a doctoral degree, with a concentration in epidemiology, at the Saint Louis University School of Public Health.

Christopher O'Connor (Washington, USA)

Christopher M. O'Connor is the Executive Director and CEO of the Inova Fairfax Heart and Vascular Institute. He is a Professor of Medicine in Cardiology at Duke University, and was previously the chief of the Division of Cardiology and director of the Duke Heart Center. He was the Principal Investigator of the landmark HF-ACTION clinical trial. He is currently the editor-in-chief of the Journal of the American College of Cardiology: Heart Failure, and serves on the editorial boards for several journals, including the New England Journal of Medicine, Journal of the American Medical Association, and Journal of the American College of Cardiology. Dr. O'Connor is a Fellow of the American College of Cardiology (ACC), the European Society of Cardiology (ESC), and the Heart Failure Society of America (HFSA). He currently serves as Editor-in-Chief of JACC: Heart.

Rachel Ostroff (Somalogic, USA)

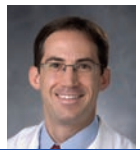
Rachel Ostroff is the Senior Director of Clinical R&D at SomaLogic, Inc. Rachel leads collaborative programs with prominent academic and industrial partners to develop the clinical evidence for blood-based proteomic models of current health and future health risks.

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.

Magnus Petersson (AstraZeneca, SWE)

Magnus Petersson is the head of the CV Outcomes team at AstraZeneca, Global Clinical Lead, and responsible for AZ Outcome Trials from design and throughout execution. He is also the Global Clinical Lead for the Forxiga HFpEF CVOT 'DELIVER,' and previously served as medical director in a large-scale global ACVD outcome-study. He is engaged in refining design and delivery of large-scale outcome studies, as well as building new academic and pharma networks.



Jonathan Piccini (Durham, USA)

Jonathan P. Piccini is a clinical cardiac electrophysiologist and Associate Professor of Medicine with Tenure at Duke University Medical Center and the Duke Clinical Research Institute. His focus is on the care of patients with atrial fibrillation and complex arrhythmias, with particular emphasis on catheter ablation, left atrial appendage occlusion, and lead extraction. His research interests include the conduct of clinical trials and the assessment of innovative cardiovascular therapeutics for the care of patients with heart rhythm disorders. At

present, he is the Director of the Duke Center for Atrial Fibrillation. Dr. Piccini has more than 300 publications in the field of heart rhythm medicine.

Ileana L. Piña (Detroit, USA)

Ileana 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 Administration's (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. 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. Dr Pitt obtained his MD degree from the University of Basel in Switzerland. He completed a fellowship in cardiology at the Johns Hopkins University School of Medicine and remained on the faculty until he left to direct the division of cardiology at the University of Michigan. He is currently chairman of the steering committee of the NHLBI TOPCAT trial; co-chairman of the Emphasis-HF trial, 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. 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.

Geoffrey Pitt (New York, USA)

Geoffrey Pitt, the Ida and Theo Rossi Distinguished Professor of Medicine and Director of the Cardiovascular Research Institute at Weill Cornell Medicine, focuses on basic and translational investigations of ion channel disorders.

Francis Plat (Milestone, USA)

Francis Plat has served as Milestone's Chief Medical Officer since June 2015. He brings over 25 years of international experience in clinical research, having worked within several global pharmaceutical companies. Before joining Milestone, he was vice president and clinical development area head, Atherosclerosis and Cardiovascular, at Merck Research Laboratories. He has been involved in the development and repositioning of numerous cardiovascular compounds from 'proof of concept' through to registration and approval. He was Vice President of Cardiovascular Clinical Research at Novartis and Daiichi Sankyo. He began his career at Bristol Myers-Squibb in 1989. Dr. Plat received his MD from the University of Paris and is a board-certified cardiologist. He spent 10 years practicing medicine in France, including post-cardiovascular surgery at the intensive care unit at Hospital Marie Lannelongue and cardiac rehabilitation at Broussais Hospital.

Jon Plehn (Covance, USA)

Jon Plehn is Vice President of Cardiovascular Medicine at Covance Inc., a contract research organization (CRO) based in Princeton, NJ, USA. Starting his career at the Framingham Heart Study and Boston University School of Medicine, Dr. Plehn spent 25 years in various academic roles focusing on development of diagnostic and treatment modalities in heart failure. This work has ranged from epidemioogy at Framingham to mechanistic work in small animal models.

Stuart Pocock (London, GBR)

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

Krishna Prasad (MHRA, EMA, GBR)

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

Susan Quella (Rochester, USA)

Susan Quella 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 U.S. clinic Oncology research group (NCCTG, North Central Cancer Treatment Group), 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.

Cristina Rabadán-Diehl (Washington, USA)

Cristina Rabadán-Diehl joined Westat in 2018 after a 25-year career at the National Institutes of Health and the Department of Health and Human Services. She is a multidisciplinary scientist with vast experience in chronic non-communicable diseases and global health. During her tenure at the NIH, she spent 12 years at the National Heart, Lung, and Blood Institute as a Program Director in the Division of Cardiovascular Sciences and as the Deputy and Acting Director of the NHLBI

Office of Global Health. At HHS, she worked with international organizations on policy issues representing the United States in her role as the Director of the Americas. As an Associate Director at Westat, she supports the Clinical Trial Practice by serving as a scientific lead as well as developing partnerships. She is the Principal Investigator of a clinical trial sponsored by the U.S. Department of Defense.

Jeremy Rassen (Aetion, USA)

Jeremy A. Rassen is a pharmacoepidemiologist with 25 years of academic and industry experience. He is co-founder, president, and chief science officer at Aetion, a health care technology company that delivers real-world evidence for life sciences companies, payers, and regulatory agencies. Prior to founding Aetion, Dr. Rassen was Assistant Professor of Medicine at Harvard Medical School, where he focused on methods to improve the quality and validity of real-world data studies. He also worked in Silicon Valley in a variety of tech companies. Dr. Rassen received his bachelor's degree in Computer Science from Harvard College and his master's and doctorate degrees in Epidemiology from the Harvard T.H. Chan School of Public Health.

Clare Relton (London, GBR)

Clare Relton specializes in the efficient and practical design of randomised controlled trials that generate real world evidence. She is interested in the development of recruitment and informed consent processes and data collection methods that can help health providers evaluate and learn from the care they deliver. Clare has a background in Philosophy and Complementary and Alternative Medicine. Her PhD in Pragmatic Trial Design developed an innovative trial design now known as Trials within Cohorts (TwiCs). Clare is currently part of an international team developing an extension to the CONSORT reporting guidelines for RCTs using cohorts and or routinely collected health data. In addition to her methodological research Clare also designs and leads intervention trials in public health nutrition and integrative medicine.

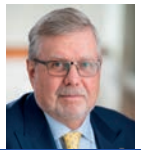
Jeffrey Riesmeyer (Eli Lilly, USA)

Jeffrey Riesmeyer is the Distinguished Medical Fellow 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. 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 Campaign Healthcare Policy Committee and testified before Congress on the 21st Century Cures Initiative. Dr. Riskin's medical credentials include a MD from Boston University, residency in surgery at UCLA, and fellowship in critical care and acute care surgery at Stanford University. He is board-certified

in four specialties, including surgery, critical care, palliative care, and clinical informatics. His earned a MBA with a focus in bioinformatics from the Massachusetts Institute of Technology.



Frank Rockhold (Durham, USA)

Frank Rockhold is a Professor of Biostatistics and Bioinformatics at Duke University Medical Center, Affiliate Professor of Biostatistics at Virginia Commonwealth University, and Managing Partner of HunterRockhold, Inc. His 40+-year career includes senior research positions at Lilly, Merck, and GlaxoSmithKline, where he retired as Chief Safety Officer and Senior Vice President of Global Clinical Safety and Pharmacovigilance. Dr. Rockhold served for 9 years on the board of directors of the non-profit CDISC, most recently as Chairman, and is past president of the Society for Clinical Trials. He is a past member of the PCORI Clinical Trials Advisory Panel and is currently on the boards of the Frontier Science and Technology Research Foundation, Datavant, and an advisor to EMA. Frank is an Elected Fellow of both the American Statistical Association and the Society for Clinical Trials, an Accredited Professional Statistician, PStat®, and a Chartered Statistician, CStat.

Matt Roe (Durham, USA)

Matt Roe has been a faculty member at Duke University School of Medicine and the Duke Clinical Research Institute (DCRI) since 1999. Dr. Roe is a senior investigator at the DCRI focusing upon innovative research initiatives that leverage real world data, patient engagement, and novel research networks to transform the processes and approaches for clinical research. Dr. Roe has been the principal investigator for numerous phase II-IV cardiovascular clinical trials and is currently a co-principal investigator for the ADAPTABLE trial (theaspirinstudy.org) which is the first, large-scale pragmatic trial being conducted in the PCORnet network. Additionally, Dr. Roe has also served in leadership roles for several observational registries focusing upon the treatment and outcomes of patients with cardiovascular disease and has served as the Director of the DCRI Clinical Research Fellowship since 2010.

Lothar Roessig (Bayer, GER)

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

Yves Rosenberg (NIH, USA)

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

Julio Rosenstock (Dallas, USA)

Julio Rosenstock is Director of the Dallas Diabetes Research Center at Medical City, and Clinical Professor of Medicine at the University of Texas Southwestern Medical Center, Dallas. He is board certified in Internal Medicine, and Endocrinology and Metabolism. Over the last 30 years, he has participated in hundreds of clinical trials and has had an active role in the development of new diabetes oral agents and insulin preparations often as a lead clinical investigator and scientific advisor. He has been the author or co-author of 533 publications, including 296 peer-reviewed manuscripts and numerous abstracts and has also contributed to 13 book chapters in the field of diabetes. Dr Rosenstock is a member of the National Board of Directors of the American Diabetes Association (ADA) and is currently Associate Editor of Diabetes Care. Dr Rosenstock has chaired or been a featured speaker at multiple lectures and presentations both nationally and internationally.

Patrick Rossignol (Nancy, FRA)

Patrick Rossignol is a professor of Therapeutics, a Nephrologist and Vascular medicine specialist, and Deputy Director of Nancy Plurithematic Clinical Investigation center (CIC)-Inserm. He has participated/is participating in several EU FP6-7 programs. He coordinates 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). He also coordinates 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 and steering committee member of several international randomized clinical trials. He was an EURECA-m elected board member, and now serves as scientific advisor. Since 2016 he is a Heart Failure Association of the European Society of Cardiology "Translational" and "Cardiorenal" board member. He is a cofounder of CardioRenal.

Sébastien Roux (Idorsia, CHE)

Sébastien Roux studied cardiology in both France (Paris) and Canada (Montreal Heart Institute). He did his MSc. in cell biology in the French research institute INSERM. He started his career in the pharmaceutical industry at F. Hoffmann La Roche (Switzerland) where he was leading drug discovery laboratories focused on antithrombotic research, vascular tone, atherosclerosis and angiogenesis. He moved to Actelion Pharmaceuticals Ltd. in 2000 to lead the clinical program for bosentan which eventually allowed the worldwide registration of the first orally active endothelin receptor antagonist for the treatment of pulmonary arterial hypertension. He led the pulmonary arterial hypertension development program that resulted in successful worldwide registrations of other oral therapies for pulmonary arterial hypertension such as macitentan and selexipag. In 2017, he moved to Idorsia Pharmaceuticals Ltd. where he initiated a new clinical program for on home-based treatment of myocardial infarction by auto-injection of a P2Y12 receptor antagonist (selatogrel).

Juddson Rupp (Charlotte, USA)

Juddson Rupp is a long-time volunteer lobbyist and advocate for the American Heart Association with a career as a sales and marketing executive. Juddson has been inspired by his poor cardiovascular health to work in the biopharma industry and help patients. He works cross-functionally to develop Milestone's patient engagement strategy, including the development and management of initiatives focused on patient education, disease state awareness,s and advocacy support. He champions the patient perspective in everything Milestone does. A graduate of UVA, father of two, he lives in

Charlotte, NC where his Montreal-based company has its US subsidiary.

Hani Sabbah (Detroit, USA)

Hani N. Sabbah is the Director of Cardiovascular Research at the Henry Ford Health System, tenured Professor of Medicine at Wayne State University, and Visiting Professor of Medicine at Columbia University. He received his Bachelor of Science degree in aerospace engineering from the University of Oklahoma and his Doctorate in Biomedical Sciences and Medical Physics from Oakland University. He is a fellow of the American College of Cardiology, American College of Chest Physicians, Heart Rhythm Society, American Heart Association, Heart Failure Society of America and member of the American Physiological Society. Dr. Sabbah was the 2009 Program Co-Chair of the American College of Cardiology. He is the recipient of the 2005 American Heart Association Seymour Gordon Award for Distinguished Achievement and 2002 Crain's Detroit Business Award for Advancement in Health Care. Dr. Sabbah is member of the editorial board of several peer-reviewed scientific journals and is the Co Editor-in-Chief of the journal Heart Failure Reviews.

Naveed Sattar (Glasgow, GBR)

Naveed Sattar, a clinically active academic, is one of the world's top diabetes/metabolic medicine experts. His research focuses on the prevention and management of diabetes, obesity and heart disease. He has published over 900 papers, participated in multiple guidelines and clinical trials, and received multiple award lectures including the prestigious Minkowski prize in 2011. He is amongst the world's most cited clinical academics (top 1% of field) in clinical medicine as reported in Clarivate Analytics Highly Cited Researcher lists 2014-2018. His main contributions have helped define CVD risks in diabetes including the relevance of age of onset, ethnicity, specific drugs, and sex. He has also helped define CVD risks in autoimmune conditions and has helped improve knowledge on general CVD risk factors including lipids, role of obesity, and alcohol. He also has a track record of work on novel biomarkers. He is involved in several ongoing trials.

Heribert Schunkert (Munich, GER)

Heribert Schunkert is Professor of Cardiology of the Technische Universität München and Director of the Cardiology Department, German Heart Centre Munich. He completed a research fellowship at Brigham and Women's Hospital, Boston, USA and clinical fellowships at Beth Israel Hospital, Universitätsklinikum Regensburg, and the Massachusetts General Hospital, Boston, USA, before he became assistant and associate professor in Regensburg. From 2002-2012 Prof. Schunkert was Director of Internal Medicine and Cardiology at the University of Luebeck. He conducts research in the molecular genetics of multifactorial cardiovascular disease and coordinates several EU- and BMBF-sponsored projects. He is the author of more than 600 publications in international journals.

Amy Sehnert (Myokardia, USA)

Amy Sehnert is a pediatric cardiologist with 25-year career spanning academia and industry. Dr. Sehnert has held a variety of executive roles designing and conducting ground-breaking prospective clinical trials in the biotech sector in both molecular diagnostics and therapeutics since 2005. She joined MyoKardia, Inc. in 2018 where she is Vice President of Clinical Science leading global programs, including the pivotal Phase 3 EXPLORER trial of mavacamten in symptomatic obstructive hypertrophic cardiomyopathy (NCT03470545). Her team also conducts earlier phase and long-term clinical studies in both non-obstructive and obstructive HCM. Amy received her B. S. in Mechanical Engineering and Doctor of Medicine at the U of MN. She completed pediatrics residency at U of CO and was a

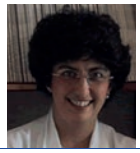
fellow of the pediatric-scientist training program at UCSF in pediatric cardiology where she was subsequently Assistant Professor. Her passion is to move scientific discoveries from the laboratory to the clinic.

Fred Senatore (FDA, USA)

Fred Senatore received his BA in Biochemistry and MS in Bio-engineering from Columbia University. He received his PhD in Chemical Engineering from Rutgers University. He was a professor of Chemical Engineering at Texas Tech University with expertise in artificial organ technology, biocompatibility, hemodynamics, fluid mechanics, and modeling/simulation of biological processes. Fred attended Medical School at Texas Tech University Health Sciences Center School of Medicine while on staff in the chemical engineering department. He trained in Internal Medicine at the Mayo Clinic and in Cardiology at the Massachusetts General Hospital. Fred served in the pharmaceutical industry with increasing responsibility over a span of 17 years and is currently a medical officer in the Division of Cardiovascular and Renal Products in the Office of New Drugs, Center of Drug Evaluation Research, Food and Drug Administration. He also holds an adjunct assistant professorship at the George Washington University School of Medicine.

Sanjiv J. 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 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 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. 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.

Scott 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. He led the NIH sponsored Celecoxib Cross-trials Safety Study and directs the Cardiac Imaging Center for the NHLBI Atherosclerosis Risk in Communities (ARIC) study and Hispanic Community Health Study – Study of Latinos (HCHS-SOL). 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.

Manish Sood (Ottawa, CAN)

Manish Sood is an Associate Professor of Medicine at the University of Ottawa with a cross appointment at the School of Epidemiology and Public Health, Scientist at the Ottawa Hospital Research Institute and the Institute for Clinical Evaluative Sciences, Deputy Editor- in- Chief and founder of the Canadian Journal of Kidney Health and Disease, and Jindal Research Chair for the Prevention of Kidney Disease. He began his career as a clinical nephrologist at the St Boniface Hospital in Winnipeg, Manitoba, gradually developing an interest in research and clinical epidemiology and in 2013 became a clinician scientist. He recently became the Associate Director of the Kidney, Dialysis, transplantation Program at the Institute for Clinical Evaluative Sciences, a Dialysis Outcomes and Practice Patterns (DOPPS) country investigator, a member of the American Society of Nephrology Highlights Team (ESKD) and the CSN Secretary Treasurer.

Stuart Spencer (The Lancet, 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. After graduating Stuart moved into research which started at the Brompton Hospital, London, looking at scoliosis in children before moving to the Veterinary School site at Bristol University. During this period he was invited to establish a research unit in The Netherlands. Later he set up a research team for a major pharmaceutical company in Switzerland, and then spent 9 years as a senior researcher in New Zealand. He has 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 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.

Francis Spinale (South Carolina, USA)

Francis G. Spinale is the Associate Dean for Research and Education at the University of South Carolina School of Medicine, Distinguished Professor of Personalized Medicine in the Departments of Cell Biology, Anatomy, and Surgery and Staff Physician at the Wm. Jennings Bryan Dorn VA. Currently, he guides the Cardiovascular Translational Research Center. He is also an entrepreneur with 8 patents that have generated several million dollars in collaborative industry-NIH ventures. He serves on the editorial board of prestigious scientific journals such as Circulation and Circulation Research and is a consultant to various pharmaceutical and biotechnology companies. He is a fellow of several societies, including the American Association for Thoracic Surgeons and the American College of Cardiology. He has been honored with both the Breakthrough Leadership in Research award and the Educational Foundation Research Award in Health Sciences at USC. Most recently, he established medical student fellowship programs including the prestigious AATS medical student fellowship.

Kenneth Stein (Boston Scientifc, USA)

Kenneth Stein is currently 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 MD from New York University School of Medicine. He completed his medical internship and residency at The New York-Presbyterian Hospital/Weill Cornell Medical Center, where he also completed his cardiology and cardiac electrophysiology training. Dr. Stein 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.

Norman Stockbridge (FDA, USA)

Norman Stockbridge, did 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 (NIH, 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.

Erik Stroes (Amsterdam, NED)

Erik Stroes is the department Chair of Vascular Medicine at the University Hospital Utrecht. He received his Master's in Medicine from Erasmus University and his PhD at the University of Utrecht, in the Netherlands. He specialized in Internal Medicine at the University of Utrecht and has a subspecialty in Vascular Medicine from the University of Amsterdam. He has served as Chair of the Dutch Atherosclerosis Society and member of the European Atherosclerosis Society Consensus panel.

Bobby Stutz (AtCor, USA)

Bobby Stutz is the Director of Pharmaceutical Markets and Scientific Affairs for AtCor Medical, Inc. where he collaborates with researchers and clinical trial sponsors on how to best incorporate central hemodynamic data into their clinical development programs. Bobby has spent the last thirteen years in the medical device industry after earning his Masters and undergraduate degrees in biomedical engineering at The Catholic University of America in Washington, D.C.

Robert Tagalicod (Clarksburg, USA)

Robert Tagalicod is the Senior Advisor in the Department of Health and Human Services' Office of the Chief Information Officer. He has contributed to critical strategic efforts that include the development of the HHS IT Strategic Plan, the HHS Interoperability Roadmap, the Federal Health IT Strategic Plan, and the Centers for Medicare & Medicaid Services' E-Health Strategic Plan. Prior, Dr. Tagalicod was the Director of CMS' Office of eHealth Standards and Services (OESS), leading a $25 billion health IT effort as part of nation-wide healthcare transformation. This effort included the Medicare and Medicaid EHR Incentive Programs and Administrative Simplification including ICD-10 implementation. Before Federal service, he oversaw several initiatives for state and county health systems in California, addressing community, regional and national health disparities, and infectious diseases. Also, he has worked extensively in the Pacific Rim collaborating with HRSA, CDC, WHO, and global health officials on clinical workforce development, and healthcare access.

Wilson Tang (Cleveland, USA)

Wilson Tang is Professor of Medicine at Cleveland Clinic Lerner College of Medicine at Case Western Reserve University (CWRU). He serves as director for Hub Research Capacity for CWRU's Clinical and Translational Sciences Collaborative for human mechanistic studies and Associate Director for Cleveland Clinic Coordinating Center for Clinical Research (C5Research) for multicenter cardiovascular clinical trials. He serves as the Medical Director for the Cleveland Clinic GeneBank Study. As a clinician-scientist and practicing heart failure/transplant cardiologist specialized in cardiomyopathies and kidney-/cancer-related heart diseases, Dr. Tang's translational research focuses on understanding the cellular and molecular mechanisms that contribute to disease progression in heart failure and cardio-renal disease. He has been elected as member of the American Society of Clinical Investigation in 2013 for his contributions to mechanistic understanding of cardio-renal syndromes, and the Association of American Physicians in 2018 for studying the contributing role of diet and 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. He graduated from the University of Montreal with his medical degree and completed his training in cardiology and research in Montreal and Boston. Dr Tardif holds the Canada Research Chair in personalized medicine and the University of Montreal endowed research chair in atherosclerosis. He is the Scientific Director of the Montreal Health Innovations Coordinating Centre (MHICC) and Chairman of the steering committees of the CIHR-funded Canadian Atherosclerosis Imaging Network (CAIN) and Medical Imaging Trials NEtwork of Canada (MITNEC). Dr Tardif has authored more than 600 scientific articles and 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 BIOQuébec and the Armand-Frappier Award of the Government of Québec.

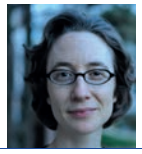
Nina Teicholz (New York, USA)

Nina Teicholz is an investigative science journalist, author, and adjunct professor of health policy at New York University. Her international bestseller, The Big Fat Surprise, has upended the conventional wisdom on dietary fat–especially saturated fat. The executive editor of "The Lancet" wrote, "this is a disquieting book about...ruthless silencing of dissent that has shaped our lives for decades...researchers, clinicians, and health

policy advisors should read this provocative book." The Big Fat Surprise was named a 2014 *Best Book* by The Economist, the Wall Street Journal, Forbes, Mother Jones, Kirkus Reviews and Library Journal. Teicholz is also the Executive Director of The Nutrition Coalition, a nonprofit, non-partisan group that promotes evidence-based nutrition policy. She is a graduate of Stanford and Oxford Universities and previously served as associate director of the Center for Globalization and Sustainable Development at Columbia University. Teicholz now lives in New York City with her husband and two sons.

Robert Temple (FDA, USA)

Robert Temple serves as CDER's Deputy Center Director for Clinical Science and Senior Advisor in the Immediate Office of the Office of New Drugs (OND). As the senior advisor, Bob is a consultant to the OND director and other FDA officials on matters related to clinical program objectives. Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972, he joined CDER as a Medical Officer in the Division of Metabolic and Endocrine Drug Products.



Aliza Thompson (FDA, USA)

Aliza Thompson is Deputy Director of the Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). The Division of Cardiovascular and Renal Products regulates and reviews Investigational New Drug applications and marketing applications for drug and biologic products for the treatment of cardiovascular and kidney diseases. Dr. Thompson joined the FDA in 2007. Prior to her current position, Dr. Thompson served as a clinical team leader for products being developed to treat kidney diseases. 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.

David Thompson (Syneos Health, USA)

David Thompson is Senior Vice President, Real World Research for Syneos Health. Dave is a health economist by training with 25+ years of experience conducting real-world research and consulting for clients in the biopharmaceutical sector. Dave is a frequent contributor to the International Society for Pharmacoeconomics & Outcomes Research (ISPOR), having functioned as Editor-in-Chief of ISPOR's publication, Value & Outcomes Spotlight, from 2008 to the present. Dave is a steering committee member of the Clinical Trials Transformation Initiative (CTTI), a multistakeholder initiative of Duke University and the US Food & Drug Administration, and a member of the CTTI initiative in real-world evidence (RWE). He also serves on the advisory board of the Duke-Margolis real-world evidence consortium. Dave holds degrees from the University of California Riverside (BS, Economics) and University of Massachusetts (MA, Economics; PhD, Economics).

Thomas Thum (Hanover, GER)

Thomas Thum is the Director of the Institute of Molecular and Translational Therapeutic Strategies (IMTTS) at MHH, and visiting Professor at the National Heart and Lung Institute at Imperial College London. Thomas is a key opinion leader in the development of noncoding RNA-based therapeutic strategies in cardiovascular medicine and the author of over 250 scientific publications. Thomas is also a member of the editorial boards for cardiovascular research (e.g. Circulation Research and European Heart Journal). Furthermore, Thomas is a nucleus member of national and international research committees in the cardiovascular field, such as the European Society of Cardiology (ESC), the American Heart

Association (AHA), and the International Society for Heart Research (ISHR). Thomas has received numerous awards for his work on non-coding RNAs in cardiovascular research. Thomas has filed over 20 patents, two of which have been successfully licensed pharma companies and are currently at phase II clinical development.

Benoît Tyl (Servier, FRA)

Benoit Tyl is the director of the cardiovascular translational research at Servier (France). He is a cardiologist with a strong experience as a clinician. He worked for the pharmaceutical industry R&D since more than 15 years in various companies as well as in various positions. Within Servier, he worked in the past years on several cardiovascular R&D projects related to ischemic cardiomyopathies, arrhythmia and Heart Failure. He serves now as director of translational cardiovascular R&D within the company. In this position he is supporting Servier's Cardiovascular projects from basic science to the marketing authorization, mainly on Heart Failure. His main focus is to help filling the gap between the idea (target) and the drug, especially with regards to target validation, population selection, preclinical and early clinical studies. He is working closely with researcher, developers, but also various specialists within Servier and outside. He is also leading for Servier several international public-private international efforts contributing to drug development.

Ellis Unger (FDA, USA)

Ellis F. Unger is the Director, Office of Drug Evaluation-I, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), US FDA. 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. 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 a Professor of Medicine and 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, 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 cardiologist at Brigham and Women's Hospital and Harvard Medical School, and is a CVCT Ambassador and Advisory Board Member. He is interested in drug

development and clinical trials of cardiometabolic therapies. He has authored or co-authored more than 275 peer-reviewed publications. Dr. Vaduganathan serves on the editorial board of the European Journal of Heart Failure and JACC Heart Failure (Social Media / CME Editor). He 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.

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. 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.

Bart Van der Schueren (CVWP, CHMP, BEL)

Bart Van der Schueren in currently an assistant professor in Endocrinology at the University of Leuven, Belgium. He obtained his medical degree from the same University in 2002. In 2009 he successfully defended his PhD on the topic of drug development for migraine treatment. In the same year he was recognized as a Clinical Pharmacologist by the Dutch Society of Clinical Pharmacology and Biopharmacy. Following his PhD, he finished his internship and graduated in 2010 as a Specialist in Internal Medicine and Endocrinology. Subsequently, he left for a post-doctoral scholarship at Columbia University College of Physicians and Surgeons, New York. He returned to Belgium in 2011 and is now responsible for the obesity and lipid clinic at the University Hospital in Leuven. He is also the Belgian member of the committee for medicinal products for human use (CHMP) and a member of the cardiovascular working party (CVWP) at the European Medicines Agency (EMA).

George Van Hare (FDA, USA)

George Van Hare is a Medical Officer on the Implantable Electrophysiology Devices Team of the Division of Cardiovascular Devices at the U.S. Food and Drug Administration, Center for Devices and Radiological Health. He is also a practicing pediatric cardiologist and electrophysiologist at Washington University School of Medicine in St. Louis, Missouri, and is a Past President of the Heart Rhythm Society.

Orly Vardeny (Minneapolis, USA)

Orly Vardeny is an Investigator at the Center for Chronic Disease Outcomes Research at the Minneapolis VA Health Care System and an Associate Professor of Medicine at the University of Minnesota Medical School. Dr. Vardeny's research interests include maximizing the benefit of pharmacologic therapy in patients with heart failure, and optimizing vaccination strategies in patients with cardiac disorders. She is a co-principal investigator on a NIH-funded clinical trial, investigating vaccination strategies in patients with high risk cardiovascular disease (www.INVESTEDtrial.org). She serves as the US National Lead Investigator for three trials investigating an SGLT2 inhibitor in patients with

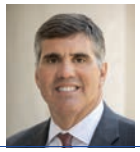
heart failure (DELIVER, DETERMINE-Reduced, DETERMINE-Preserved). Her clinical practice is in the outpatient management of patients with chronic heart failure. She is an Associate Editor for Circulation: Heart Failure and serves on the editorial board of several peer-reviewed cardiovascular journals.

Erkki Vartiainen (Helsinki, FIN)

Erkki Vartiainen is a Professor in National Institute for Health and Welfare in Finland. His main research interest has been cardiovascular disease prevention by risk factors and life style changes. He has 500 publications in international and national scientific journals. He has been working as a co-principal investigator in the North Karelia Project. Consult for World Bank, WHO and EU chronic diseases prevention.

Rajesh Vedanthan (New York, USA)

Rajesh Vedanthan is the Director of the Section for Global Health in the Department of Population Health at the New York University School of Medicine. He is Associate Professor in the Departments of Population Health and Medicine/Cardiology. His area of interest is implementation research, global health delivery, global cardiology, capacity-building, and the intersection of health and development. He is the Principal Investigator or co-investigator of multiple NIH grants, focusing on implementation research to develop and evaluate innovative solutions to optimize cardiovascular and risk factor care delivery in low-resource settings.



Eric Jose Velazquez (New Haven, USA)

Eric Jose Velazquez is the Robert W. Berliner Professor of Medicine (Cardiology) at Yale University, as well as chief of the Section of Cardiovascular Medicine in the Department of Internal Medicine, chief of cardiovascular medicine at Yale New Haven Hospital, and physician-in-chief of the Heart and Vascular Center for the Yale-New Haven Health System. Prior, he served as professor of medicine in the Division of Cardiology at Duke University and held appointments at the Duke Clinical Research Institute and Duke Global Health Institute. Dr. Velazquez has authored more than 250 peer-reviewed publications, chaired the American Society of Echocardiography's Taskforce on International Echocardiography, and is an associate editor for Circulation Cardiovascular Imaging. He is a fellow of the American College of Cardiology, American College of Physicians, American Society of Echocardiography, and American Heart Association.

Hector Ventura (Jefferson, USA)

Hector Ventura attended medical school at National University of Buenos Aires School of Medicine and did his Internal Medicine training at Ochsner and cardiovascular disease Fellowship at Ochsner. He is currently Section Head, Advanced Heart Failure/Heart Transplant at the John Ochsner Heart and Vascular Institute, and Professor of Medicine, Ochsner Clinical School-The University of Queensland School of Medicine in New Orleans. He has co-authored more than 600 articles, abstracts and book chapters and serves on 21 editorial boards, including the Journal of the American College of Cardiology and the American Journal of Cardiology, and is Associate Editor of Journal of Cardiac Failure, Current Hypertension Reviews and Journal of the American College of Cardiology: Heart Failure. He is also Editor-in-Chief of Current Problems in Cardiology.

Subodh Verma (Toronto, CAN)

Subodh Verma is a cardiac surgeon-scientist at Unity Health Toronto and Professor at the University of Toronto. Prior to his MD training at the University of Calgary, Dr. Verma completed his MPharm and conducted PhD studies in cardiovascular pharmacology at the University of British Columbia. Dr Verma is the Canada Research Chair (Tier 1) in Cardiovascular Surgery. He previously held the Canada Research Chair (Tier 2) in Atherosclerosis for 10 years (2007-2017). Dr Verma has received many accolades over his career, amongst which are the 2010 Howard Morgan Award for Distinguished Achievements in Cardiovascular Research and the 2013 Royal College of Physicians and Surgeons of Canada Gold Medal in Surgery. He served as Canada Research Chair in Atherosclerosis for 10 years from 2007-2017. He was appointed, in 2013, to the American Association of Thoracic Surgeons (AATS) and invested into the College of New Scholars, Artists and Scientists, Royal Society of Canada in 2015.

Patricia Vlasman (Amsterdam, NED)

Patricia Vlasman was born in 1971 with a genetic heart mutation: a hypertrophic cardiomyopathy. She works as a political scientist for the Dutch Ministry of Justice and Police Force. She developed severe heart failure and suffered serious arrhythmias after her pregnancy and after many cardioversions and ablations ended up on the waiting list for a heart transplant. She received her heart transplant in 2018. She now works as a cardiac expert at the Noordwest Ziekenhuisgroep in Alkmaar (the Netherlands) and became an international patient advocate for raising awareness for heart failure and cardiomyopathies at the global network iHHub and The Heart Failure Policy Network. Her memoir about life as a heart patient was translated in 2015 and is available on Amazone.com under the title: “Open-Hearted, My life with Heart Failure & Cardiomyopathy.” She writes quarterly columns for the magazine of the Dutch Society of Cardiovasular Nursing (NVHVV).

Christoph Wanner (Wurzburg, GER)

Christoph Wanner is Professor of Medicine and head of the Division of Nephrology at the University Hospital of Würzburg, Germany. He has published more than 700 scientific articles (HF 79) on diabetic kidney disease, lipid disorders, statin treatment and rare kidney diseases. He is steering committee member of the EMPA-REG Outcome, EMPEROR and EMPA-KIDNEY trials, aiming in slowing the progression of kidney disease and improving cardiovascular outcomes. He is an Associate Editor of the Clinical Journal of the America Society of Nephrology. He has received the 2016 Award from the ERA-EDTA for Outstanding Clinical Contributions to Nephrology and in 2018 from the DGfN the Franz Volhard medaille. He is President Elect of the ERA-EDTA.

Charles Weijer (London, CAN)

Charles Weijer is Professor at the Rotman Institute of Philosophy at Western University in London, Canada. He is the leading expert on the ethics of randomized controlled trials. Publications on the duty of care in clinical research, the ethical analysis of study benefits and harms, and empowering communities in research have been broadly influential. From 2008–2013 Charles co-led a collaboration that produced the first international ethics guidelines for cluster randomized trials. Charles’ current work explores ethical issues in pragmatic randomized controlled trials that evaluate health interventions in real-world conditions to better inform patients, health providers and health systems managers. In 2008, Charles founded the Rotman Institute of Philosophy, which is dedicated to fostering collaboration between the humanities and the sciences, and served as the Institute’s first director. In 2016, he was elected to the Royal Society of Canada.

Janet Wittes (Washington, USA)

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

Joseph Wu (Stanford, USA)

Joseph C. Wu is Director of the Stanford Cardiovascular Institute and Simon H. Stertzer, MD, Professor of Medicine and Radiology at the Stanford School of Medicine. His lab works on biological mechanisms of patient-specific and disease-specific induced pluripotent stem cells (iPSCs). Dr. Wu has published >350 manuscripts with H-index of 93 on Google scholar. Dr. Wu has received numerous awards, including NIH Director's New Innovator Award (2008), NIH Roadmap Transformative Award (2009), AHA Innovative Research Award (2009), Presidential Early Career Award for Scientists and Engineers given out by President Obama (2010), AHA Established Investigator Award (2012), AHA Merit Award (2017), and AHA Distinguished Scientist Award (2018). Dr. Wu currently serves on the Scientific Advisory Board for the Keystone Symposia (2014-2020), FDA Cellular, Tissue, and Gene Therapies Advisory Committee (2017-2020), AHA National Board of Directors (2017-2021), Chair of the AHA Basic Cardiovascular Science Council (2017-2019), and Chair of the AHA National Research Committee (2017-2021).

Lijing L. Yan (Kunshan, Jiangsu, 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. Fred 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. He 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.

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.

Emmanouil Zouridakis (MHRA, 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. 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 Cardovascular Devices (DCD) as a Medical Officer in 1992 and has been actively involved in development and review of clinical trials for many new cardiovascular devices. In May 2001 he was appointed a Deputy Director in DCD. Then in September 2002 he was appointed to his current position as Director of the FDA Division of Cardiovascular Devices.

Notes

SAVE the DATE

CVCT FORUM 2020

DECEMBER 3 - 5, 2020

GENERAL INFORMATION

CONGRESS VENUE

Embassy of France, 4101 Reservoir Rd NW, Washington D.C. 20007, USA

SCIENTIFIC SECRETARIAT

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REGISTRATION FEE

CVCT 2019 - Registration rates	ONSITE
CVCT Academia	$500,00
Only for doctors, physicians, clinicians or statisticians. This discount cannot be applied to industry	
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 2019 - 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, December 4th: 8:00 AM - 7:00 PM
- Friday, December 5th: 8:00 AM – 6:30 PM
- Saturday, December 6th: 8:00 AM - 6:30 PM

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: 16TH GLOBAL CARDIOVASCULAR CLINICAL TRIALISTS FORUM
Event ID: 34785AF - Valid for travel from November 28 to December 14 December, 2019

Event location: Washington, DC, USA

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