

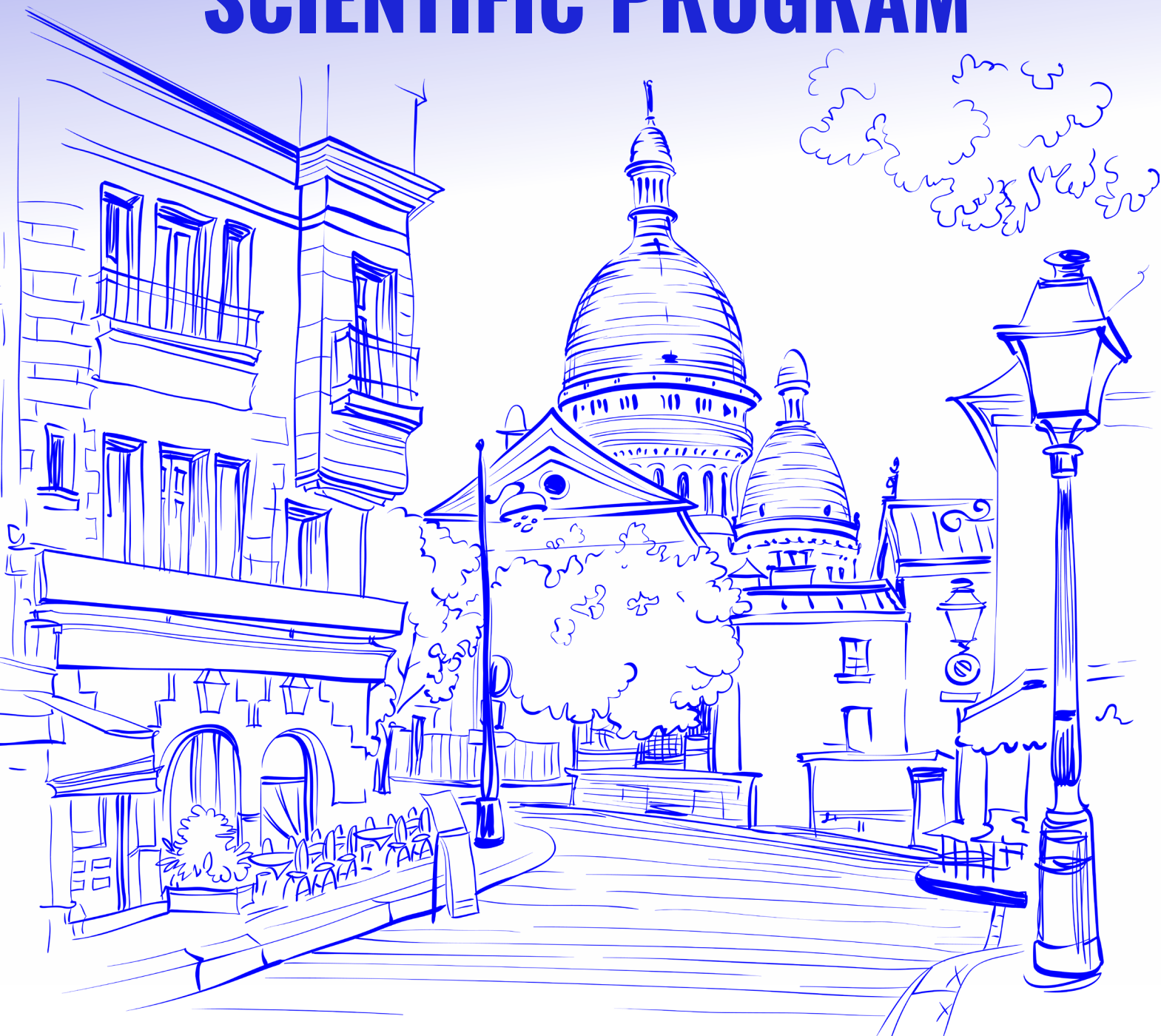
**19th Global Cardio Vascular
Clinical Trialists Forum**

CVCT

1st -3rd December 2022

**At The Marriott at Metro Center Hotel
775 12th Street, NW, Washington DC, 20005**

SCIENTIFIC PROGRAM



FACULTY

ACADEMY

1. William Abraham (Columbus, USA)
2. Tariq Ahmad (New Haven, CT, USA)
3. Rasha Al-Lamee (London, UK),
4. Dominick Angiolillo (Jacksonville, FL, USA),
5. Stefan Anker (Berlin, GER)
6. Usman Baber (Oklahoma City, OK, USA),
7. Guiomar Mendieta Badimon (CVCT Future trialist, Madrid, ESP)
8. Emilia Bagiella (New York, NY, USA)
9. George Bakris (Chicago, IL, USA)
10. Laurent Bertoletti (Saint Etienne, FRA)
11. Tor Biering-Sørensen (CVCT Future Trialist, Copenhagen, DEN)
12. Vera Bittner (Birmingham, AL, USA)
13. Marc Bonaca (Denver, CO, USA)
14. Jan Boren (Goteborg, SWE)
15. Biykem Bozkurt (Houston, TX, USA)
16. Daniel Burkhoff (New York, NY, USA)
17. Javed Butler (Jackson, TX, USA)
18. Jawad Butt (CVCT Future Trialist, Glasgow, UK)
19. Marc Buyse (IDDI, BEL)
20. Jose Castellano (Madrid, ESP)
21. Davide Cao (New York, USA),
22. Clara Chow (Sydney, AUS)
23. Brian Claggett (Boston, MA, USA)
24. John Cleland (Glasgow, UK)
25. David Cohen (Roslyn, NY, USA)
26. Alain Cohen Solal (Paris, FRA)
27. Maria Rosa Costanzo (Naperville IL, USA)
28. Gad Cotter (INSERM UMR-S 942, Paris, FRA)
29. Donald Cutlip (Boston, MA, USA),
30. Nikolaos Dargès (Leipzig, GER)
31. Issa Dahabreh (Boston, MA, USA)
32. Beth Davison (Paris, FRA)
33. Jeroen Dauw (Gent, BEL)
34. Thomas Deering (Atlanta, GA, USA)
35. David DeMets (Madison, WI, USA)
36. Philip Devereaux (Hamilton, CAN)
37. Kieran Docherty (CVCT Future Trialist, Glasgow, UK)
38. Pamela Douglas (Durham, NC, USA)
39. Mark Dweck (Edinburgh, UK)
40. Scott Evans (Washington DC, USA)
41. Guoqing Diao (Washington DC, USA)
42. Phil McEwan (HEOR, UK)
43. Justin Ezekowitz (Edmonton, CAN)
44. Brian Ference (Cambridge, UK)
45. Joao Ferreira (Porto, PRT)
46. Gemma Figtree (Sydney, AUS)
47. Marat Fudim (Durham, NC, USA)
48. Prakriti Gaba (Boston, MA, USA)
49. Mario Gaudino (New York, NY, USA)
50. Tom Gaziano (Boston, MA, USA)
51. Annetine Gelijns (New York, NY, USA)
52. Bernard Gersh (Rochester, MN, USA)
53. Michael Gibson (Boston, MA, USA)
54. Nicolas Girerd (Nancy, FRA)
55. Mardi Gomberg-Maitland (Washington, DC, USA)
56. Sascha Goonewardena (Ann Arbor, MI, USA)
57. Christopher Granger (Durham, NC, USA)
58. Barry Greenberg (San Diego, CA, USA)
59. Martha Grogan (Rochester, MN, USA)
60. Edip Gurol (Boston, MA, USA)
61. Rebecca Hahn (New York, NY, USA),
62. Josh Hare (Miami, FL, USA)
63. Paul Hassoun (Baltimore, MA, USA)
64. Hiddo Heerspink (Groningen, NED)
65. William Herrington (Oxford, UK)
66. Adrian Hernandez (Durham, NC, USA)
67. Stephane Heymans (Maastricht, NED)
68. Howard Herrmann (Philadelphia, PA, USA)
69. Carolyn Ho (Boston, MA, USA)
70. Marc Humbert (Paris, FRA)
71. Peter Johnston (Baltimore, MD, USA)
72. Philip Joseph (Hamilton, CA)
73. Parminder Judge (Oxford, UK)
74. Sander Kersten (Wageningen, NED)
75. Muhammad Shahzeb Khan (Durham, NC, USA)
76. Liviu Klein (San Francisco, CA, USA)
77. Darae Ko (CVCT Future trialist, Boston, MA, USA)
78. Marlys Koschinsky (London, CAN)
79. Mikhail Kosiborod (Kansas City, MO, USA)
80. Harlan Krumholz (New Haven, CT, USA)
81. Vijay Kunadian (Newcastle, UK)
82. André Lamy (Hamilton, CA)
83. Anne Langsted (Copenhagen, DEN)
84. Matthew Lee (CVCT Future trialist, Glasgow, UK)
85. Joann Lindenfeld (Nashville, TN, USA)

86. Lars Lund (Stockholm, SWE)
87. Mary Lynne Hedley (TESARO, USA)
88. Darren K McGuire (Dallas, TX, USA)
89. Vallerie McLaughlin (Ann Arbor, MI, USA)
90. Martin Maron (Boston, MA, USA)
91. Guillaume Marquis Gravel (Montreal, CAN)
92. Mathew Maurer (New York, MA, USA)
93. Alexandre Mebazaa (Paris, FRA)
94. Douglas Mann (St Louis, MO, USA)
95. Bradley Maron (Boston, MA, USA)
96. Ahmad Masri (Portland, OR, USA)
97. Roxana Mehran (New York, NY, USA)
98. Robert Mentz (Durham, NC, USA)
99. Reza Mohebi (Boston, MA, USA)
100. Charbel Noujaim, (New Orleans, LA, USA)
101. Borge Nordestgaard (Copenhagen, DEN)
102. Chris Packard (Glasgow, UK)
103. Douglas Packer (Rochester, MN, USA)
104. Milton Packer (Dallas, TX, USA)
105. Ambarish Pandey (Dallas, TX, USA),
106. Guillaume Pare (Hamilton, CAN)
107. Manesh Patel (Durham, NC, USA)
108. Emerson Perin (Houston, TX, USA)
109. Marc Pfeffer (Boston, MA, USA)
110. John Piccini (Durham, NC, USA)
111. Ileana Pina (Detroit, MI, USA)
112. Fausto Pinto (Lisbon, PRT)
113. Bertram Pitt (Ann Arbor, MI, USA)
114. Stuart Pocock (London, UK)
115. Paul Poirier (Quebec, CAN)
116. Piotr Ponikowski (Wroclaw, POL)
117. Ioana Preston (Boston, MA, USA)
118. Yogesh Reddy (Rochester, MN, USA)
119. Paul Ridker (Boston, MA, USA)
120. Frank Rockhold (Durham, NC, USA)
121. Hannah Rosenblum (New York, NY, USA)
122. Robert Rosenson (New York, NY, USA)
123. Alexander Rothman (Sheffield, UK)
124. Marc Sabatine (Boston, MA, USA)
125. Arun Sanyal (Richmond, VA, USA)
126. Naveed Sattar (Glasgow, UK)
127. Gregory Schwartz (Denver, CO, USA)
128. Tabassome Simon (Paris, FRA)
129. Gérald Simonneau (Paris, FRA)
130. Daniel Singer (Boston, MA, USA),
131. Jagmeet Singh (Boston, MA, USA)
132. Olivier Sitbon (Paris, FRA)
133. John Spertus (Kansas City, MO, USA)
134. Sachin Shah (Boston, MA, USA)
135. Benjamin Scirica (Boston, MA, USA)
136. Scott Solomon (Boston, MA, USA)

137. Edda Spiekerkoetter (Stanford, CA, USA)
138. Erik Stroes (Amsterdam, NED)
139. Thenappan Thenappan (Minneapolis, MN, USA)
140. Shelley Zieroth (Manitoba, CAN)
141. Thomas Thum (Hannover, GER)
142. Jan Tijssen (Narnden, NED)
143. Katherine Tuttle (Washington, DC, USA)
144. Muthiah Vaduganathan (Boston, MA, USA)
145. Harriette Van Spall (Hamilton, CAN)
146. Hilary Vernon (Baltimore, MD, USA)
147. Jason Weatherald (Edmonton, CAN)
148. Michael Weber (New York, NY, USA),
149. Cindy Westerhout (Edmonton, CAN)
150. Stephen Wiviott (Boston, MA, USA)
151. Joseph Wu (Stanford, CA, USA)
152. Benjamin Yeh (Boston, MA, USA)
153. Salim Yusuf (Hamilton CAN)
154. Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

JOURNAL/MEDIA

155. Joe Hill (Circulation, USA)
156. Rita Redberg (Archives Internal Medicine, USA)
157. Chana Sacks (NEJM Evidence, USA)
158. Jennifer Sargent (Nature Medicine, USA)
159. Stuart Spencer (The Lancet, UK)
160. Ron Winslow (Wall Street Journal, Ret, No. Conway NH, USA)

INDUSTRY

161. Siddique Abbasi (Amgen, USA)
162. Robert Adamczyk (American Regent, USA)
163. Philip Adamson (Abbott, USA)
164. Roberto Álvarez (Ferrer, ESP),
165. Tomas Andersson (AstraZeneca, SWE)
166. Florian Baeres (Novonordisk, DEN),
167. Felix Balazard (Owkin, FRA),
168. Puja Banka (Merck, USA),
169. Elliot Barnathan (JnJ, USA)
170. Arnaud Bastien (BMS, FRA),
171. Robert Blaustein (MSD, USA)
172. Maria Borentain (BMS, USA)
173. Gabriel Brooks (Pfizer, USA)
174. Kristine Buchholtz (NovoNordisk, DEN)
175. Joan Buenconsejo (BMS, USA)
176. Jim Carr (Stealth, USA)
177. Martin Cowie (AstraZeneca, USA)
178. Björn Dahlof (Cereno, SWE)
179. Ben Dake (Aerovate, USA)
180. Larry Deckelbaum (CSL, AUS)

181. Janethe de Oliveira Pena (Merck, USA)
182. Samuele Doratori (Servier, FRA)
183. Thao Duong-Verle (GossamerBio, USA)
184. Nancy Dreyer (IQVIA, USA)
185. Mads David Engelmann (NovoNordisk, DEN)
186. Fredrik Erlandsson (CSL Behring, GER)
187. Andy Fish (MDIC, USA)
188. Richard Flaaten (NovoNordisk, DEN),
189. JoAnn Foody (Esperion, USA)
190. Leonard Ganz (Abbott, USA)
191. Joe Gatewood (Advamed, USA)
192. Richard George (Regeneron, USA)
193. Alberto Gimona (Idorsia, CH),
194. Steve Goedeke (Cardionomic, USA)
195. Craig Granowitz (Lexicon, USA)
196. Stefan Hantel (Boehringer, GER)
197. Stephen Heitner (Cytokinetics, USA)
198. Lars Johansson (Antaros Medical, SWE)
199. Helina Kassahun (Amgen, USA)
200. Simos Kedikoglou (Impulse Dynamics, USA)
201. Amit Khera (Verve Therapeutics, USA)
202. So-Young Kim (Bayer, GER)
203. Silviu Itescu (Mesoblast, USA)
204. Francesca Lawson (Corteria, FRA)
205. Anna Maria Langkilde (AstraZeneca, SWE)
206. Kelly Lewis (Novartis, USA),
207. Ciaran McMullan (Merck, USA)
208. Alessandro Maresta (Janssen, USA),
209. Hank Mansbach (89bio, USA)
210. Evan Mills (Olink, SWE)
211. James Min (Clearly, USA)
212. Puneet Mohan (BMS, USA)
213. Nick Morrell (Centessa Pharmaceuticals, USA)
214. Hardi Mundl (Bayer, GER)
215. Pieter Muntendam (G3P, USA)
216. Masahiro Murakami (Lilly, USA)
217. Ken Ouriel (NAMSA, USA)
218. Mahesh Patel (Merck, USA)
219. Michaela Petrini (Boehringer Ingelheim, GER)
220. Jeffrey Popma (Medtronic, USA)
221. Robert Porody (Regeneron, USA)
222. Curtis Rambaran (Silence Therapeutics, UK),
223. Jason Rashkin (Sanofi, USA)
224. Matthew T. Roe (Astrazeneca, USA)
225. Jérôme Rossert (AstraZeneca, USA)
226. Harry Rowland (Endotronix, USA)
227. Hartmut Ruetten (Boehringer, GER)
228. Giacomo Ruotolo (Lilly, USA)
229. Carol Satler (Respira Therapeutics, USA)
230. Alka Shaunik (CSL Behring, GER)
231. Eugene Schneider (Ionis, USA)

232. Markus Schwertfeger (Roche, CHE)
233. Amy Sehnert (BMS, USA)
234. Maria Sejersten Ripa (NovoNordisk, DEN)
235. Marc Semigran (Renovacor, USA)
236. Craig Sponseller (Kowapharma, USA)
237. Kenneth Stein (Boston Scientific, USA)
238. Karsten Strauss (Olink, SWE)
239. Peter Szecsödy (CSL Behring, GER),
240. Sotirios Tsimikas (Ionis, USA)
241. Szilard Voros (G3 therapeutics, USA)
242. Martin Unverdorben (Daiichi Sankyo, USA)
243. Nick West (Abbott, USA)
244. Steve Williams (Somalogic, USA)
245. Janet Wittes (Wittes LLC, USA)
246. Fred Yang (KBP, USA)
247. Nadim Yared (CVRx, USA)
248. Antoine Yver (Centessa, USA)
249. Cordula Zeller, (Boehringer, GER)
250. André Ziegler (Roche, CHE)

REGULATORY

251. Rosalyn Adigun (FDA, USA)
252. Angeles Alonso (MHRA, UK)
253. Robert Califf (FDA, USA)
254. Alison Cave (MHRA, UK)
255. Asma Dilawari (FDA, USA)
256. Andrew Farb (FDA, USA)
257. Ann Farrell (FDA, USA)
258. Charu Gandotra (FDA, USA)
259. Lydia Glaw (FDA, USA)
260. Elizabeth Hart (FDA, USA)
261. Laura Higginbotham (FDA, USA)
262. Maciej Kostrubiec (EMA, POL)
263. Adrian Magee (FDA, USA),
264. Janet Maynard (FDA, USA)
265. Peter Mol (EMA, NED)
266. Mitch Psootka (FDA, USA)
267. Mark Rothmann (FDA, USA),
268. Fortunato Senatore (FDA, USA)
269. John Sharretts (FDA, USA)
270. Meir Shinnar (FDA, USA)
271. David Strauss (FDA, USA)
272. Norman Stockbridge (FDA, USA)
273. Bob Temple (FDA, USA)
274. Steffen Thirstrup (Amsterdam, NED)
275. Aliza Thompson (FDA, USA)
276. George Van Hare (FDA, USA)
277. Bernard Vasseur (FDA, USA)
278. Changfu Wu (FDA, USA)
279. Bram Zuckerman (FDA, USA)

NIH / NHLBI

- 280. Denis Buxton (NIH, USA)
- 281. Patrice Desvigne-Nickens (NHLBI, USA)
- 282. Kathleen Fenton (NIH, USA)
- 283. Lawrence Fine (NHLBI, USA)
- 284. Laurie Friedman Donze (NHLBI, USA)
- 285. Dean Follmann (NIH, USA)
- 286. Yves Rosenberg (NIH, USA)

PATIENTS/PATIENTS REPRESENTATIVES

- 287. Naomi Buntsma (Amsterdam, NED)
- 288. Philip Collis (British Heart Foundation, UK)
- 289. Inga Drossart (ESC patient forum, GER)
- 290. Pisana Ferrari (Milan, ITA)
- 291. Robin Gage (Lakeland, FL, USA)
- 292. Patrick Gee (Chesterfield, MO, USA)
- 293. Trudie Lobban (London, UK)
- 294. Steven Macari (Poitiers, FRA)
- 295. Robin Martinez (Denver, CO, USA)
- 296. Greg Merritt (Brighton, CO, USA)
- 297. Caius Ovidiu Mersa (European Heart Network, ROM)
- 298. Rhonda Monroe (Baltimore, MD, USA)
- 299. Wanda F Moore (Tucson, Arizona, USA)
- 300. Lisa Salberg (HCMA, Denville, NJ, USA)
- 301. Ilse Verstraaten (Amsterdam, NED)
- 302. Reinier Versluis (Amsterdam, NED)

LAWYERS

- 303. Evelyne Friedel (Paris, FRA)
- 304. Frank Sasinowski (HPM, USA)
- 305. Ellis Unger (HPM, WA, USA)
- 306. Alex Varond (Goodwin, USA)

PAYER / ECONOMISTS

- 307. Steven Farmer (CMS, USA)
- 308. Roger Longman (Real Endpoints, USA)
- 309. Piotr Szymański (Warsaw, POL)
- 310. William S. Weintraub (Washington, DC, USA)

INVESTORS

- 311. Catherine Arnold (Centerview, USA)
- 312. Francesco deRubertis (Medicxi, CH)
- 313. Ramin Farzaneh-Far (RA Capital Aventure, USA)
- 314. Craig Gordon (GordonMD Global Investment LP, Beverly Hills CA, USA)
- 315. Alex Strasser (RA Capital Aventure, USA)

THURSDAY, DECEMBER 1ST

LONDON

10:30 - 12:45

**ATHERO
TRIGLYCERIDE**

[view details >>](#)

12:30

13:30



13:30 - 15:30

ATHERO LP (a)

[view details >>](#)

15:30

16:00



16:00 - 19:00

**ATHERO
CHOLESTEROL**

[view details >>](#)

LUNCH SERVED AT THE MEETING VENUE

BALLROOM AB

08:00 - 10:00

**EARLY FEASIBILITY
DEVICE TRIALS**

[view details >>](#)

10:00

10:30



10:30 - 12:30

**INCREMENTAL EP
TECHNOLOGIES**

[view details >>](#)

12:30

13:30



13:30 - 15:30

**INTERVENTIONAL
ELECTROPHYSIOLOGY**

[view details >>](#)

15:30

16:00



16:00 - 18:00

**ATRIAL
FIBRILLATION
DRUG THERAPY**

[view details >>](#)

LUNCH SERVED AT THE MEETING VENUE

BALLROOM CD

09:00 - 10:00

**DSMB MASTER
CLASS 1**

[view details >>](#)

10:00

10:30



10:30 - 12:30

**DSMB MASTER
CLASS 2**

[view details >>](#)

12:30

13:30



13:30 - 15:30

**STAT INNOVATION
WIN RATIO**

[view details >>](#)

15:30

16:00



16:00 - 19:00

POLYPILL TRIALS

[view details >>](#)

OFF SITE NETWORKING DINNER
19.30-21.00
(INSTRUCTIONS TO FOLLOW SOON)

FRIDAY, DECEMBER 2ND

LUNCH SERVED AT THE MEETING VENUE

BALLROOM AB

08:00 - 10:00

CARDIORENAL TRIALS. PART 1: SGLT2i CKD

[view details >>](#)

10:00

10:30



NEW TARGETS FOR RESISTANT HYPERTENSION AND CKD

[view details >>](#)

12:30

13:00

13:00

13:00

14:00



DEVICE IN CHF (PART1)

[view details >>](#)

16:00

16:30



DEVICE IN CHF (PART2)

[view details >>](#)

16:30 - 19:00

BALLROOM CD

08:00 - 10:00

TRANSLATION TO EARLY PHASE CLINICAL TRIALS

[view details >>](#)

10:00

10:30



ACCELERATING CV CLINICAL TRIALS PART1

[view details >>](#)

12:30

13:00

13:00

14:00

KEY NOTE 1

13:00

14:00

13:00

14:00

13:00

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14:00 - 16:00

THROMBOSIS 1

[view details >>](#)

16:00

16:30



THROMBOSIS 2

[view details >>](#)

16:30 - 19:00

LONDON

08:00 - 10:00

CV MULTI-ORGAN SYSTEMIC DISEASES

[view details >>](#)

10:00

10:30



PRIMARY PREVENTION. BEYOND EVENT DRIVEN TRIALS?

[view details >>](#)

10:30 - 12:30

14:00 - 16:00

OBESITY 1

[view details >>](#)

16:00

16:30



OBESITY 2

[view details >>](#)

16:30 - 19:00

BALLROOM E

08:00 - 10:00

DEVICE IN ADHF 1

[view details >>](#)

10:00

10:30



HOW TO GET HEART FAILURE PATIENTS FAST ON GDMT

[view details >>](#)

10:30 - 12:30

14:00 - 16:00

LAWYERS & STATS

[view details >>](#)

16:00

16:30



iCVCT1

[view details >>](#)

16:30 - 19:00

KEYNOTE : THE BROKEN MIRACLE THE PAUL CARDALL STORY WITH ADITYA "AK" KAZA
PIANO PERFORMANCE "MUSIC FOR THE HEART" WITH PAUL CARDALL
ON SITE DINNER AND RECEPTION 19.00-21.00, BALLROOM A,B,C,D

SATURDAY, DECEMBER 3RD

LUNCH SERVED AT THE MEETING VENUE

LONDON

08:00 - 10:00

INVESTORS 1

[view details >>](#)

10:00
-
10:30



INVESTORS 2

[view details >>](#)

10:30 - 12:30

12:40

13:15



13:15
-
14:00



14:00 - 16:00

ARE TRIALS AND TRIALISTS MEETING THE SOCIETY'S NEEDS?

[view details >>](#)

16:00
-
16:30



SGLT2i in HF DELIVER

[view details >>](#)

16:30 - 19:00

BALLROOM AB

08:00 - 10:00

IMPLEMENTATION HEART FAILURE 1

[view details >>](#)

10:00
-
10:30



IMPLEMENTATION HEART FAILURE 2

[view details >>](#)

10:30 - 12:30



KEY NOTE 2

13:15
-
14:00



14:00 - 16:00

iCVCT 4

[view details >>](#)

16:00
-
16:30



ACCELERATING CV CLINICAL TRIALS PART 2

[view details >>](#)

16:30 - 19:00

BALLROOM CD

08:00 - 10:00

PAH 1

[view details >>](#)

10:00
-
10:30



PAH 2

[view details >>](#)

10:30 - 12:30



13:15
-
14:00



14:00 - 16:00

CELL GENE THERAPY

[view details >>](#)

16:00
-
16:30



CARDIOMYOPATHIES

[view details >>](#)

16:30 - 19:00

Room : LONDON
Thursday 01 December, 2022
10:30 -12:45

**Atherosclerosis CardioVascular Clinical Trialists (aCVCT)
TRIGLYCERIDE TRIALS**

Chairpersons : Anne Langsted (Copenhagen, DEN) & Borge Nordestgaard (Copenhagen, DEN)

Atherosclerosis CardioVascular Clinical Trialists (aCVCT):
Overview of recent years meetings and forward looking guidance on atherosclerosis trial design.
Robert Rosenson, aCVCT course director (New York, NY, USA)

Triglyceride associated cardiovascular risk
Borge Nordestgaard (Copenhagen, DEN)

What is the role of genetics in understanding triglyceride associated cardiovascular risk?
Brian Ference (Cambridge, UK)

Understanding the failure of Triglyceride lowering using fibrates:

Latest results from the PROMINENT trial
Paul Ridker (Boston, MA, USA)

Evaluating triglyceride associated risk – particles vs ApoB, End of sPARMS or end of triglyceride-rich lipoprotein cholesterol in Cardiovascular disease?
Chris Packard (Glasgow, UK)

Why are apoC-III inhibiting strategies likely to differ from the fibrate experience?
Erik Stroes (Amsterdam, NED)

Targets identified from natural selection studies

Emerging therapies targeting Apolipoprotein C-III
Jan Boren (Goteborg, SWE)

Emerging therapies targeting Angiotensin like 3 and 8 proteins
Sander Kersten (Wageningen, NED)

Industry viewpoints

Richard George (Regeneron, USA), Hank Mansbach (89bio, USA), Giacomo Ruotolo (Lilly, USA), Craig Sponseller (Kowapharma, USA), Sam Tsimikas (Ionis, USA)

**THE aCVCT FORUM Multi-Stakeholder Moderated Debate
TRIGLYCERIDE TRIALS**

Chairpersons : Anne Langsted (Copenhagen, DEN) & Borge Nordestgaard (Copenhagen, DEN)

Panelists: Jan Boren (Goteborg, SWE), Pamela Douglas (Durham, NC, USA), Mark Dweck (Edinburgh, UK), Mads David Engelmann (NovoNordisk, DEN), Brian Ference (Cambridge, UK), Richard George (Regeneron, USA), Michael Gibson (Boston, MA, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Sander Kersten (Wageningen, NED), Amit Khera (Verve Therapeutics, USA), Helina Kassahun (Amgen, USA), Anne Langsted (Copenhagen, DEN), Hank Mansbach (89bio, USA), James Min (Clearly, USA), Borge Nordestgaard (Copenhagen, DEN), Chris Packard (Glasgow, UK), Robert Pordy (Regeneron, USA), Paul Ridker (Boston, MA, USA), Robert Rosenson (New York, NY, USA), Giacomo Ruotolo (Lilly, USA), Alka Shaunik (CSL Behring), John Sharretts (FDA, USA), Erik Stroes (Amsterdam, NED), Sam Tsimikas (Ionis, USA) and other invited panelists

Room : LONDON
Thursday 01 December, 2022
13:30 -15:30

**Atherosclerosis CardioVascular Clinical Trialists (aCVCT)
LIPOPROTEIN(a) TRIALS**

Chairpersons : Vera Bittner (Birmingham, AL, USA) & Marc Sabatine (Boston, MA, USA)

Lp(a) consensus statement 2022: current status and novel insights
Marlys Koschinsky (London, CAN)

Why understanding mechanisms of disease is relevant for Lp(a) associated risk assessment.
Sascha Goonewardena (Ann Arbor, MI, USA)

Lp(a): An important effect modifier for the clinical benefit of PCSK9 inhibition Gregory Schwartz (Denver, CO, USA)

Anti-sense oligonucleotides and RNA inhibitors
Erik Stroes (Amsterdam, NED)

Clinical trial considerations for Lp(a) lowering trials
Marc Sabatine (Boston, MA, USA)

The Need for Lp(a) lowering trials in aortic valve stenosis
Mark Dweck (Edinburgh, UK)

Regulatory viewpoint. Is there a need for high-risk primary outcome trial if secondary prevention trial in high Lp(a) patients is clearly positive?
Fortunato Senatore (FDA, USA)

Industry viewpoints
Helina Kassahun (Amgen, USA), Kelly Lewis (Novartis, USA), Curtis Rambaran (Silence Therapeutics, UK)

Patient viewpoint
Philip Collis (British Heart Foundation, UK)

THE aCVCT FORUM Multi-Stakeholder Moderated Debate

LIPOPROTEIN(a) TRIALS : HOW TO EXPAND TO NEW DRUGS AND TO PRIMARY PREVENTION
Chairpersons : Vera Bittner (Birmingham, AL, USA) & Marc Sabatine (Boston, MA, USA)

Panelists: Angeles Alonso (MHRA, UK), Vera Bittner (Birmingham, AL, USA), Jan Boren (Goteborg, SWE), Philip Collis (British Heart Foundation, UK), Pamela Douglas (Durham, NC, USA), Mark Dweck (Edinburgh, UK), Mads David Engelmann (NovoNordisk, DEN), Richard George (Regeneron, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Helina Kassahun (Amgen, USA), Sander Kersten (Wageningen, NED), Amit Khera (Verve Therapeutics, USA), Marlys Koschinsky (London, CAN), Kelly Lewis (Novartis, USA), James Min (Clearly, USA), Borge Nordestgaard (Copenhagen, DEN), Chris Packard (Glasgow, UK), Robert Pordy (Regeneron, USA), Curtis Rambaran (Silence Therapeutics, UK), Giacomo Ruotolo (Lilly, USA), Robert Rosenson (New York, NY, USA), Marc Sabatine (Boston, MA, USA), Gregory Schwartz (Denver, CO, USA), Fortunato Senatore (FDA, USA), Alka Shaunik (CSL Behring), Erik Stroes (Amsterdam, NED), Sam Tsimikas (Ionis, USA), and other invited panelists

Room : LONDON
Thursday 01 December, 2022
16:00 -19:00

Atherosclerosis CardioVascular Clinical Trialists (aCVCT)
ALTERNATIVE SCENARIOS FOR HYPERCHOLESTEROLEMIA TRIALS
Chairpersons : Michael Gibson (Boston, MA, USA) & Robert Rosenson (New York, NY, USA)

Residual cholesterol risk in an era of an expanding 'alternative' scenario – 2022 update?
Robert Rosenson (New York, NY, USA)

ANGPLT3 – monoclonal antibodies and, ASO, RNA inhibitors: same efficacy with different safety outcomes?
Robert Rosenson (New York, NY, USA)

ApoA-I Event Reducing in Ischemic Syndromes AGEIS trials
Vijay Kunadian (Newcastle, UK)

Primary Cardiovascular Disease Prevention in Human Immunodeficiency Virus: the REPRIEVE trial.
Pamela Douglas (Durham, NC, USA)

PCSK9– antibodies, oral and RNA inhibitors – at what point can we avoid endlessly repeating CVOTs?
Brian Ference (Cambridge, UK)

Industry viewpoints

Puja Banka (Merck, USA), Mads David Engelmann (NovoNordisk, DEN), JoAnn Foody (Esperion, USA), James Min (Cleerly, USA), Robert Pordy (Regeneron, USA), Matthew Roe (AstraZeneca, USA), Alka Shaunik (CSL Behring)

DISCUSSION

Gene editing and rare disease hypercholesterolemia trials

Gene editing: from fiction to multiple clinical ongoing trials: do's and don'ts, versus safety concerns in potential target selection

Amit Khera (Verve Therapeutics, USA)

Expanding 'rare' genetic disorders with Polygenic risk score versus CV-imaging to identify high-risk subjects for trials. Moving beyond lipid risk to integrated cardiovascular risk

Anne Langsted (Copenhagen, DEN)

Regulatory viewpoints.

Angeles Alonso (MHRA, UK)

John Sharretts (FDA, USA)

THE aCVCT FORUM Multi-Stakeholder Moderated Debate

ALTERNATIVE SCENARIOS FOR HYPERCHOLESTEROLEMIA TRIALS
Chairpersons : Michael Gibson (Boston, MA, USA) & Robert Rosenson (New York, NY, USA)

Panelists: Angeles Alonso (MHRA, UK), Puja Banka (Merck, USA), Jan Boren (Goteborg, SWE), Pamela Douglas (Durham, NC, USA), Mark Dweck (Edinburgh, UK), Mads David Engelmann (NovoNordisk, DEN), Brian Ference (Cambridge, UK), JoAnn Foody (Esperion, USA), Richard George (Regeneron, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Sander Kersten (Wageningen, NED), Amit Khera (Verve Therapeutics, USA), Helina Kassahun (Amgen, USA), Vijay Kunadian (Newcastle, UK), Anne Langsted (Copenhagen, DEN), James Min (Cleerly, USA), Borge Nordestgaard (Copenhagen, DEN), Chris Packard (Glasgow, UK), Robert Pordy (Regeneron, USA), Curtis Rambaran (Silence Therapeutics, UK), Giacomo Ruotolo (Lilly, USA), Matthew Roe (AstraZeneca, USA), Robert Rosenson (New York, NY, USA), Alka Shaunik (CSL Behring), John Sharretts (FDA, USA), NY, USA), Erik Stroes (Amsterdam, NED), Sam Tsimikas (Ionis, USA) and other invited panelists

**Room : BALLROOM AB
Thursday 01 December, 2022
08:00 -10:00**

EARLY FEASIBILITY STUDIES: EFFORTS TO INCREASE THE CLINICAL EVALUATION OF INNOVATIVE TECHNOLOGIES

Chairpersons : Daniel Burkhoff (New York, NY, USA) & Roxana Mehran (New York, NY, USA)

US Investigator perspective: Building an environment to encourage Early Feasibility Studies: Challenges and Opportunities

Daniel Burkhoff (New York, NY, USA)

US Regulatory perspective: FDA's Early Feasibility Studies Program

Andrew Farb (FDA, USA)

US Payer perspective on Early Feasibility Studies Reimbursement: A CMS perspective

William S. Weintraub (Washington, DC, USA)

The Medical Device Innovation Consortium: Efforts to Support Early Feasibility Studies in the US

Andy Fish (MDIC, USA)

What is it like, in Europe?

Nadim Yared (CVRx, USA)

Industry viewpoint on the Early Feasibility Studies landscape

Philip Adamson (Abbott, USA), Ken Stein (Boston Scientific), Nadim Yared (CVRx, USA)

Early Feasibility Studies implementation: Lessons Learned from Principal Investigators

Heart Failure

Daniel Burkhoff (New York, NY, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW TO PROMOTE INNOVATIVE TECHNOLOGIES THROUGH EARLY FEASIBILITY STUDIES

Chairpersons : Daniel Burkhoff (New York, NY, USA) & Roxana Mehran (New York, NY, USA)

Panelists: Philip Adamson (Abbott, USA), Daniel Burkhoff (New York, NY, USA), Andy Fish (MDIC, USA), Andrew Farb (FDA, USA), Roxana Mehran (New York, NY, USA), Kenneth Stein (Boston Scientific), Nadim Yared (CVRx, USA), William S. Weintraub (Washington, DC, USA) and other invited panelists

**Room : BALLROOM AB
Thursday 01 December, 2022
10:30 -12:30**

INCREMENTAL ELECTROPHYSIOLOGY TECHNOLOGIES TRIALS

Chairpersons : Nikolaos Dagnes (Leipzig, GER) & Thomas Deering (Atlanta, GA, USA)

Overview of incremental EP technology and treatment approaches trials
Jagmeet Singh (Boston, MA, USA)

What technology progress is clinically meaningful? What endpoints should we use in trials assessing iterative device improvements?

EP perspective
Douglas Packer (Rochester, MN, USA)

Clinical cardiology perspective
Daniel Burkhoff (New York, NY, USA)

Statistical perspective
Guoqing Diao (Washington DC, USA)

Industry viewpoint
Joe Gatewood (Advamed, USA), Jeffrey Popma (Medtronic, USA), Nadim Yared (CVRx, USA)

Patient's viewpoint
Inga Drossart (ESC patient forum, GER)

Regulatory requirements for approving new devices or technologies and approving new uses for incremental value of existing devices/technologies with incremental value
George van Hare (FDA, USA)

Payers' valuation of evidence from incremental devices/technologies trials
Steve Farmer (CMS, USA)
Piotr Szymański (Warsaw, POL)

Patient's viewpoint:
Reinier Versluis (Amsterdam, NED)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW TO STREAMLINE APPROVAL AND ADOPTION OF INCREMENTAL DEVICE TECHNOLOGIES

Chairpersons : Nikolaos Dagnes (Leipzig, GER) & Thomas Deering (Atlanta, GA, USA)

Panelists: Daniel Burkhoff (New York, NY, USA), Thomas Deering (Atlanta, GA, USA), Guoqing Diao (Washington DC, USA), Inga Drossart (ESC patient forum, GER), Steve Farmer (CMS, USA), Joe Gatewood (Advamed, USA), Douglas Packer (Rochester, MN, USA), Jeffrey Popma (Medtronic, USA), Jagmeet Singh (Boston, MA, USA), Piotr Szymański (Warsaw, POL), George van Hare (FDA, USA), Reinier Versluis (Amsterdam, NED), Nadim Yared (CVRx, USA) and other invited panelists

**Room : BALLROOM AB
Thursday 01 December, 2022
13:30 -15:30**

INTERVENTIONAL ELECTROPHYSIOLOGY TRIALS

Chairpersons : Douglas Packer (Rochester, MN, USA) & Jagmeet Singh (Boston, MA, USA)

Progress in Atrial Fibrillation ablation

'Early AF Rhythm' treatment
Nikolaos Dagues (Leipzig, GER)

Pulsed field ablation: the data we have and the data we need
Douglas Packer (Rochester, MN, USA)

Progress in cardiac resynchronisation therapy

Leadless Endocardial LV Resynchronization Rx vs. Conventional CRT
Jagmeet Singh (Boston, MA, USA)

New data on old questions: CRT-P vs. CRT-D
Nikolaos Dagues (Leipzig, GER)

Primary SCD prevention trials in times of quadruple therapy. Time to reassess?
Nikolaos Dagues (Leipzig, GER)

Industry viewpoints
Kenneth Stein (Boston Scientific), Leonard Ganz (Abbott, USA)

Regulatory viewpoint
George van Hare (FDA, USA)

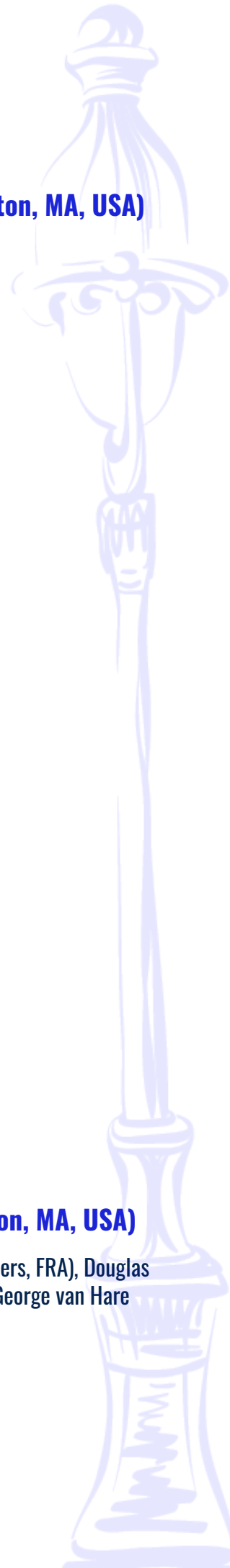
Patient viewpoint
Inga Drossart (ESC patient forum, GER)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

EXPLORING NEW SOLUTIONS AND REASSESSING OLD THERAPIES

Chairpersons : Douglas Packer (Rochester, MN, USA) & Jagmeet Singh (Boston, MA, USA)

Panelists: Nikolaos Dagues (Leipzig, GER), Inga Drossart (ESC patient forum, GER), Steven Macari (Poitiers, FRA), Douglas Packer (Rochester, MN, USA), Jagmeet Singh (Boston, MA, USA), Kenneth Stein (Boston Scientific), George van Hare (FDA, USA), Leonard Ganz (Abbott, USA) and other invited panelists



**Room : BALLROOM AB
Thursday 01 December, 2022
16:00 -18:00**

ATRIAL FIBRILLATION DRUG THERAPY

Chairpersons : Christopher Granger (Durham, NC, USA) & Jagmeet Singh (Boston, MA, USA)

Can the underlying pathophysiology of atrial fibrillation be mitigated?

The potential of anti-fibrosis mechanisms
Yogesh Reddy (Rochester, MN, USA)

MRI guided AF ablation
Charbel Noujaim (New Orleans, LA, USA)

Early rhythm control. Any pharmacological option left? Rationale and design of the CHANGE-AFib
John Piccini (Durham, NC, USA)

Atrial fibrillation management in heart failure patients: Need for a trial, or better implementation?
Christopher Granger (Durham, NC, USA)

Atrial myopathy and embolic events
Yogesh Reddy (Rochester, MN, USA)

Stroke prevention: Anticoagulation and/or interventional therapy?
Edip Gurol (Boston, MA, USA)

Industry viewpoint
Jason Rashkin (Sanofi, USA)

Regulatory viewpoint
Charu Gandotra (FDA, USA)

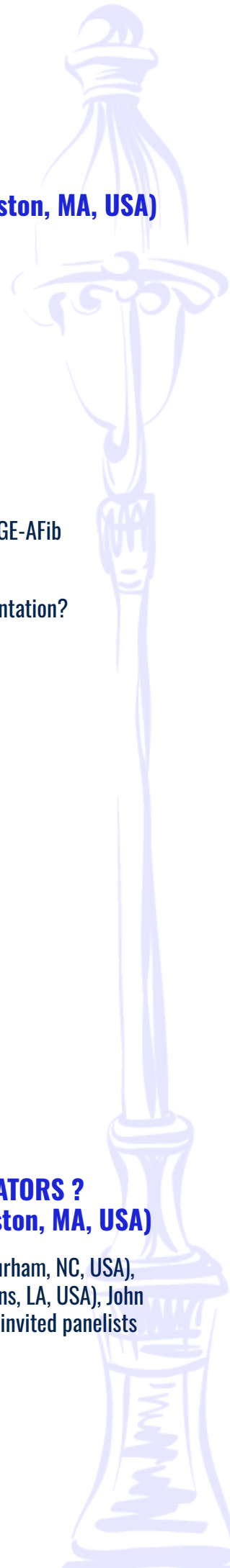
Patient's viewpoint
Trudie Lobban (Arrhythmias Alliance, UK)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

ANTIARRHYTHMIC DRUGS AND ABLATION: COMPETITORS OR COLLABORATORS ?

Chairpersons : Christopher Granger (Durham, NC, USA) & Jagmeet Singh (Boston, MA, USA)

Panelists: Yogesh Reddy (Rochester, MN, USA), Charu Gandotra (FDA, USA), Christopher Granger (Durham, NC, USA), Edip Gurol (Boston, MA, USA), Trudie Lobban (Arrhythmias Alliance, UK), Charbel Noujaim, (New Orleans, LA, USA), John Piccini (Durham, NC, USA), Jason Rashkin (Sanofi, USA), Jagmeet Singh (Boston, MA, USA), and other invited panelists



**Room : BALLROOM CD
Thursday 01 December, 2022
09:00 -12:30**

CVCT Masterclass

INDEPENDENT DATA MONITORING COMMITTEES: INSIGHTS INTO BEST PRACTICE AND DECISION MAKING

Chairpersons : David DeMets (Madison, WI, USA) & Stuart Pocock (London, UK)

Data Monitoring Committees (aka Data Safety Monitoring Boards) provide an important independent oversight for major randomized trials. This MasterClass brings together statistical and clinical experts with a vast experience of DMCs especially in cardiology trials.

Their aim is to provide a thorough understanding of how DMCs should best function. The first session focusses mainly on organizational aspects while the second session concentrates on how DMCs use the accumulating evidence of an ongoing trial to make recommendation, especially regarding early termination of a trial. Throughout the ethical needs for effective data monitoring underpin the MasterClass's goals and topical examples from cardiology trials illustrate both best practice and challenging scenarios.

Faculty

**David DeMets (Madison, WI, USA)
Scott Evans (Washington DC, USA)
Bernard Gersh (Rochester, MN, USA)
Stuart Pocock (London, UK)**

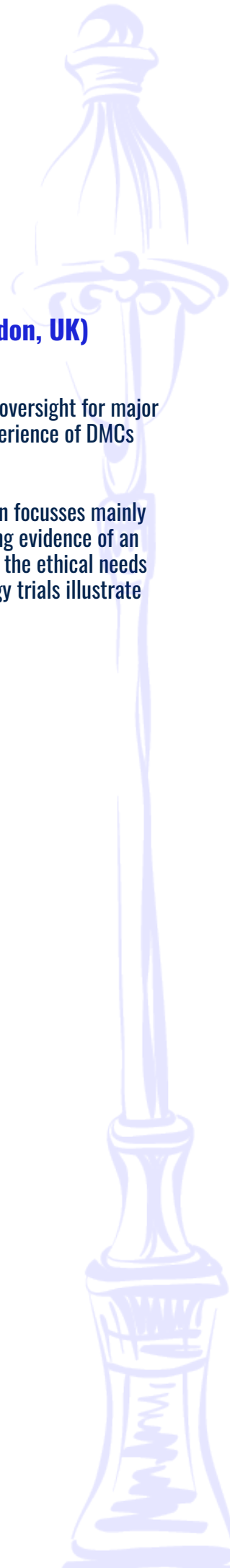
09.00– 10:30

**How a Data Monitoring Committee (DMC) should function:
David DeMets (Madison, WI, USA), Scott Evans (Washington DC, USA)
Background on development of DMCs
Responsibilities of DMC members
Structure of DMC meetings
Membership
DMC Charters
When DMCs are needed
Content of a DMC report**

11:00 – 12.30

**Early Termination and Decision-Making (with examples):
Bernard Gersh (Rochester, MN, USA), Stuart Pocock (London, UK)**

**Statistical stopping guidelines
Early stopping for superiority, futility, or harm
Adaptive sample size re-estimation
Wise DMC judgements based on totality of evidence
Interrelations between DMC, trial executive and sponsor**



**Room : BALLROOM CD
Thursday 01 December, 2022
13:30 -15:30**

**THE WIN RATIO AND OTHER GENERALIZED PAIRWISE COMPARISONS (GPC)
Chairpersons : Cindy Westerhout (Edmonton, CAN) & Janet Wittes (Wittes LLC, USA)**

The Win Ratio in CV trials

The essentials of the Win Ratio
Stuart Pocock (London, UK)

Differences between Win Ratio, Finkelstein-Schoenfeld, and related methods
Janet Wittes (Wittes LLC, USA)

What endpoints to include in a generalized pairwise comparisons analysis and in which order
Nicolas Girerd (Nancy, FRA)

How clinicians should interpret the results of a Win Ratio analysis. Case studies from recent trials.
Michael Gibson (Boston, MA, USA)
Hiddo Heerspink (Groningen, NED)

Endpoints competitive to the Win Ratio

Trialist perspective: Hierarchical composite, as in the HEART-FID trial
Robert Adamczyk (American Regent, USA)

Statistician viewpoint
Marc Buyse (IDDI, BEL)
Cindy Westerhout (Edmonton, CAN)

Clinician perspective
Joao Ferreira (Porto, PRT)

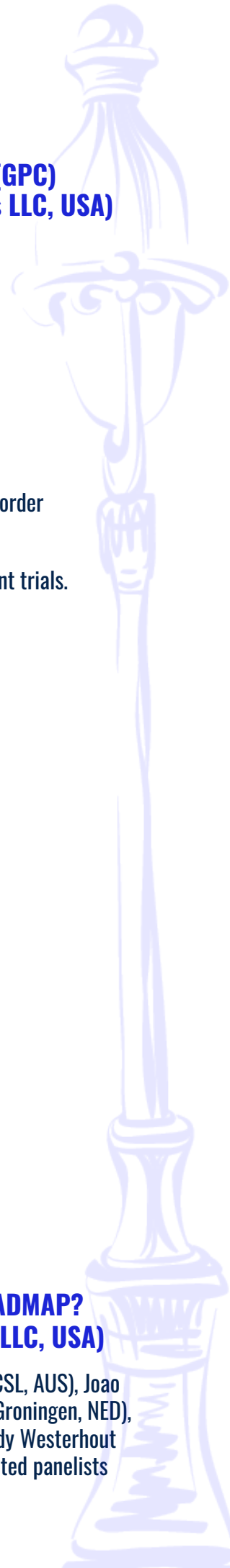
Regulatory Viewpoint
Norman Stockbridge (FDA, USA)

Industry viewpoint
Jeffrey Popma (Medtronic, USA), Cordula Zeller (Boehringer, GER)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**INTEGRATING BENEFIT AND RISK IN CLINICAL TRIALS. DO WE HAVE A ROADMAP?
Chairpersons : Cindy Westerhout (Edmonton, CAN) & Janet Wittes (Wittes LLC, USA)**

Panelists: Robert Adamczyk (American Regent, USA), Marc Buyse (IDDI, BEL), Larry Deckelbaum (GSL, AUS), Joao Ferreira (Porto, PRT), Michael Gibson (MA MA, USA), Nicolas Girerd (Nancy, FRA), Hiddo Heerspink (Groningen, NED), Stuart Pocock (London, UK), Jeffrey Popma (Medtronic, USA), Norman Stockbridge (FDA, USA), Cindy Westerhout (Edmonton, CAN), Janet Wittes (Wittes LLC, USA), Cordula Zeller (Boehringer, GER) and other invited panelists



**Room : BALLROOM CD
Thursday 01 December, 2022
16:00-19:00**

**POLYPILL AND FIXED DOSE COMBINATION STRATEGIES:
HOW TO ACT UPON THE ACCUMULATED EVIDENCE.
Chairpersons : Clara Chow (Sydney, AUS) & Salim Yusuf (Hamilton, CAN)**

History of the polypill and its essential role in global CVD prevention.
Salim Yusuf (Hamilton, CAN)

The evidence so far:

Summary of trials of the polypill in primary prevention
Philip Joseph (Hamilton, CA)

Summary of trials of the polypill in secondary prevention
Jose Castellano (Madrid, ESP)

Statistical viewpoint
Jan Tijssen (Narnden, NED)

Cost effectiveness of the polypill
André Lamy (Hamilton, CA)

Potential global Impact of the polypill and role of the polypill in achieving the UN Sustainable Development Goals 2030 goals
Tom Gaziano (Boston, MA, USA)

Can fixed dose combination improve adherence and prevent unnecessary deaths from cardiovascular disease?
Clara Chow (Sydney, AUS)

WHF strategy for advocacy of the polypills/FDC for global CVD prevention
Fausto Pinto (Lisbon, PRT)

Would polypills help with heart failure therapy implementation?
Ambarish Pandey (Dallas, TX, USA)

Industry viewpoint
Roberto Álvarez (Ferrer, ESP), Samuele Doratori (Servier, FRA)

Polypill and fixed dose combination approvability issues.
Rosalyn Adigun (FDA, USA)

Patient's viewpoint
Steve Macari (Poitiers, FRA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**POLYPILL STRATEGIES:
HOW TO ACT UPON THE ACCUMULATED EVIDENCE
Chairpersons : Clara Chow (Sydney, AUS) & Salim Yusuf (Hamilton, CAN)**

Panelists: Rosalyn Adigun (FDA,USA), Roberto Álvarez (Ferrer, ESP), Tomas Andersson (AstraZeneca, SWE), Guiomar Mendieta Badimon (CVCT Future trialist, Madrid, ESP), Clara Chow (Sydney, AUS), Issa Dahabreh (Boston, MA, USA), Samuele Doratori (Servier, FRA), Patrice Desvigne-Nickens (NHLBI, USA), Joao Ferreira (Porto, PRT), Lawrence Fine (NHLBI, USA), Tom Gaziano (Boston, MA, USA), Lars Johansson (Antaros, SWE), Philip Joseph (Hamilton, CA), André Lamy (Hamilton, CA), Matthew Lee (CVCT Future trialist, Glasgow, UK), Ciaran McMullan (Merck, USA), Steve Macari (Poitiers, FRA), Reza Mohebi (Boston, MA, USA), Pieter Muntendam (G3P, USA), Ambarish Pandey (Dallas, TX, USA), Fausto Pinto (Lisbon, PRT), Paul Ridker (Boston, MA, USA), Robert Temple (FDA, USA), Jan Tijssen (Narnden, NED), Salim Yusuf (Hamilton, CAN), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA) and other invited panelists

**Room : BALLROOM AB
Friday 02 December, 2022
08:00 -10:00**

**CARDIORENAL TRIALS.
PART 1: SGLT2i for CKD**

Chairpersons : George Bakris (Chicago, IL, USA) & Hiddo Heerspink (Groningen, NED)

Main results from the EMPA-Kidney trial
William Herrington (Oxford, UK)

Stopping the trial early. A good or a bad thing?
David DeMets (Madison, WI, USA)

Important subgroup findings and generalizability of the results
Parminder Judge (Oxford, UK)

The totality of evidence for kidney protection from the SMART-C SGLT2is trials
Hiddo Heerspink (Groningen, NED)

Applicability and clinical significance of the eGFR slope, albuminuria and other kidney outcome endpoints in diabetes, HF and CKD trials.

Muhammad Shahzeb Khan (Durham, NC, USA)
Milton Packer (Dallas, TX, USA)

Statistical viewpoints.
Brian Claggett (Boston, MA, USA)

Industry viewpoint:
Anna-Maria Langkilde (AstraZeneca, SWE), Michaela Petrini (Boehringer, GER), Jérôme Rossert (AstraZeneca, USA)

Regulatory viewpoint
Aliza Thompson (FDA, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

PART 1: SGLT2i for CKD. TOWARD A NEW NORMAL FOR TREATING CKD?

Chairpersons : George Bakris (Chicago, IL, USA) & Hiddo Heerspink (Groningen, NED)

Panelists: George Bakris (Chicago, IL, USA), Brian Claggett (Boston, MA, USA), David DeMets (Madison, WI, USA), Hiddo Heerspink (Groningen, NED), William Herrington (Oxford, UK), Parminder Judge (Oxford, UK), Muhammad Shahzeb Khan (Durham, NC, USA), Anna-Maria Langkilde (AstraZeneca, SWE), Milton Packer (Dallas, TX, USA), Michaela Petrini (Boehringer, GER), Jérôme Rossert (AstraZeneca, USA), Aliza Thompson (FDA, USA), and other invited panelists

**Room : BALLROOM AB
Friday 02 December, 2022
10:30 -12:30**

NEW TARGETS FOR RESISTANT HYPERTENSION AND CKD

Chairpersons : Bertram Pitt (Ann Arbor, MI, USA) & Katherine Tuttle (Washington, DC, USA)

Finerenone in diabetes kidney disease trials... and beyond?
Bertram Pitt (Ann Arbor, MI, USA)

Cardiorenal outcomes with GLP1 RAs. Rationale and the ongoing FLOW trial
Naveed Sattar (Glasgow, UK)

Compare them or combine them?
SGLT2i and MRAs combination therapy in CKD
Joao Ferreira (CVCT Future trialist, Porto, PRT)

Endothelin Receptor Antagonist Aprocitentan PRECISION trial in resistant hypertension.
Michael Weber (New York, NY, USA)

MRA therapy for resistant hypertension
Bertram Pitt (Ann Arbor, USA)

Actionable conclusions of resistant hypertension and CKD trials.

Nephrologist perspective
George Bakris (Chicago, IL, USA)

Cardiologist perspective
Mikhail Kosiborod (Kansas City, MO, USA)

Regulatory viewpoint
Peter Mol (EMA, NED)
Aliza Thompson (FDA, USA)

Industry viewpoint
Alberto Gimona (Idorsia, CH), Fred Yang (KBP, USA)

Patient's viewpoint
Wanda F Moore (Tucson, Arizona, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

SGLT2Is, MRAs and GLP1 RAs THERAPY

Part 2: WHAT SHOULD BE THE NEW NORMAL FOR TREATING CKD?

Chairpersons : Bertram Pitt (Ann Arbor, MI, USA) & Katherine Tuttle (Washington, DC, USA)

Panelists: Florian Baeres (Novonordisk, DEN), Joao Ferreira (Porto, PRT), Alberto Gimona (Idorsia, CH), Mikhail Kosiborod (Kansas City, MO, USA), Peter Mol (EMA, NED), Wanda F Moore (Tucson, Arizona, USA), Bertram Pitt (Ann Arbor, MI, USA), Naveed Sattar (Glasgow, UK), Jérôme Rossert (AstraZeneca, USA), Peter Szecsödy (CSL Behring, GER), Aliza Thompson (FDA, USA), Katherine Tuttle (Washington, DC, USA), Michael Weber (New York, NY, USA), Fred Yang (KBP, USA) and other invited panelists



KEYNOTE LECTURE
Steffen Thirstrup
(EMA Chief Medical Officer, Amsterdam, NED)

Room: Ballroom ABCD
Friday 02 December, 2022
12:30 -13:00

**Room : BALLROOM AB
Friday 02 December, 2022
14:00 -16:00**

**CHRONIC HEART FAILURE DEVICE AND REMOTE MONITORING TRIALS
Part 1. THE CURRENT COMPETITIVE LANDSCAPE**

Chairpersons : Stephan Anker (Berlin, GER) & JoAnn Lindenfeld (Vanderbilt, USA)

Chronic heart failure devices.
Current competitive landscape.

Neuromodulation
Marat Fudim (Durham, NC, USA)

Contractility Modulation
Javed Butler (Jackson, TX, USA)

LV Reshaping
Daniel Burkhoff (New York, NY, USA)

Implantable hemodynamic monitoring. Current competitive landscape.

The evidence so far and real-world implementation issues. Trials and real-world evidence (Cardiomems GUIDE-HF)
JoAnn Lindenfeld (Vanderbilt, USA)

Ongoing trials of competing technologies: Rapid fire.

Vectorious – The Vector-HF trial
William Abraham (Columbus, OH, USA)

Heart Logic. The MANAGE-HF trial
Adrian Hernandez (Durham, NC, USA)

Linq. The ALLEVIATE-HF trial
Muhammad Shahzeb Khan (Durham, NC, USA)

Cordella. The PROACTIVE-HF trial
Liviu Klein (San Francisco, CA, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**CHRONIC HEART FAILURE DEVICE AND REMOTE MONITORING THERAPY.
BUILDING THE PIPELINE OF INNOVATION**

Chairpersons : Stephan Anker (Berlin, GER) & Joann Lindenfeld (Nashville, TN, USA)

Panelists: William Abraham (Columbus, OH, USA), Stephan Anker (Berlin, GER), Daniel Burkhoff (New York, NY, USA), Javed Butler (Jackson, TX, USA), Marat Fudim (Durham, NC, USA), Adrian Hernandez (Durham, NC, USA), Liviu Klein (San Francisco, CA, USA), JoAnn Lindenfeld (Nashville, TN, USA), Muhammad Shahzeb Khan (Durham, NC, USA), Shelley Zieroth (Manitoba, CAN), and other invited panelists



**Room : BALLROOM AB
Friday 02 December, 2022
16:30 -18:00**

**CHRONIC HEART FAILURE DEVICE AND REMOTE MONITORING TRIALS
Part 2. BUILDING THE CLINICAL EVIDENCE**

Chairpersons : Biykem Bozkurt (Houston, TX, USA) & Christopher Granger (Durham, NC, USA)

What evidence is needed for devices?

For approval

Piotr Szymański (Warsaw, POL)
Bram Zuckerman (FDA, USA)

For guidelines. Why are devices approved but not in guidelines?

Biykem Bozkurt (Houston, TX, USA)

For payers

Steve Farmer (CMS, USA)
Piotr Szymański (Warsaw, POL)

Implementation issues of health care system-dependent solutions.

Joe Gatewood (Advamed, USA)

Industry viewpoints

Philip Adamson (Abbott, USA), Simos Kedikoglou (Impulse Dynamics, USA), Harry Rowland (Endotronix, USA), Kenneth Stein (Boston Scientific)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**CHRONIC HEART FAILURE DEVICE AND REMOTE MONITORING TRIALS
Part 2. HOW TO SATISFY THE REGULATORS AND THE PAYERS**

Chairpersons : Biykem Bozkurt (Houston, TX, USA) & Christopher Granger (Durham, NC, USA)

Panelists: Philip Adamson (Abbott, USA), Biykem Bozkurt (Houston, TX, USA), Steve Farmer (CMS, USA), Joe Gatewood (Advamed, USA), Christopher Granger (Durham, NC, USA), Simos Kedikoglou (Impulse Dynamics, USA), Cecilia Linde (Stokholm, SWE), Harry Rowland (Endotronix, USA), Kenneth Stein (Boston Scientific), Shelley Zieroth (Manitoba, CAN), Piotr Szymański (Warsaw, POL), Bram Zuckerman (FDA, USA), and other invited panelists



**Room : BALLROOM CD
Friday 02 December, 2022
08:00 -10:00**

**ACCELERATING TRANSLATION OF DISCOVERY AND INNOVATION TO EARLY PHASE CLINICAL TRIALS
Chairpersons : Gemma Figtree (Sydney, AUS) & Thomas Thum (Hannover, GER)**

Unmet needs in our drug armament from a patient perspective: it's not all solved! Patients' viewpoints
Inga Drossart (ESC patient forum, GER)

New global approaches to address unmet needs and accelerate cardiovascular drug development to clinical trials
Gemma Figtree (Sydney, AUS)

Precision-based biotechnology and drug development of novel drug targets for coronary artery disease.
Szilard Voros (G3 therapeutics, USA)

The heart failure syndrome "bucket" and need for precision phenotyping for therapeutic breakthroughs
Thomas Thum (Hannover, GER)

Phenocustering and multi-omics for new target identification and validation in dilated cardiomyopathy
Stephane Heymans (Maastricht, NED)

Clinical trial in a dish: de-risking drug development by improving "human-ness" of preclinical models.
David Strauss (FDA, USA)

Facilitating the leap to phase II trials

Advanced imaging endpoints in CAD
James Min (Cleerly, USA)

Advanced molecular biomarker in cardiomyopathy drug discovery
Thomas Thum (Hannover, GER)

Industry viewpoint
Gabriel Brooks (Pfizer, USA), Matthew T. Roe (Astrazeneca, USA), Marc Semigran (Renovacor, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**ACCELERATING TRANSLATION OF DISCOVERY AND INNOVATION TO EARLY PHASE CLINICAL TRIALS
Chairpersons : Gemma Figtree (Sydney, AUS) & Thomas Thum (Hannover, GER)**

Panelists: Gabriel Brooks (Pfizer, USA), Inga Drossart (ESC patient forum, GER), Gemma Figtree (Sydney, AUS), Stephane Heymans (Maastricht, NED), James Min (Cleerly, USA), Marc Semigran (Renovacor, USA), Matthew T. Roe (Astrazeneca, USA), David Strauss (FDA, USA), Thomas Thum (Hannover, GER), Szilard Voros (G3 therapeutics, USA), and other invited panelists

**Room : BALLROOM CD
Friday 02 December, 2022
10:30 -12:30**

**ACCELERATING CV CLINICAL TRIALS
PART 1: REGULATORY DIGITAL AND INVESTIGATOR SOLUTIONS
Chairpersons : Adrian Hernandez (Durham,NC, USA) & Yves Rosenberg (NHLBI, USA)**

Regulatory facilitation of innovative device and technology trials. US-EFS (Early feasibility studies)
Douglas Packer (Rochester, MN, USA)

Going more global

“A la COVID” non-competitive model
Philip Devereaux (Hamilton, CAN)

The Global CV Research Funders Forum
Yves Rosenberg (NHLBI, USA)

Conducting randomized clinical trials in developing countries and in resource challenged setting
Salim Yusuf (Hamilton, CAN)

Going digital: How eHealth resources may accelerate clinical trials?
Harlan Krumholz (New Haven, CT, USA)

Accelerating clinical trials using a data driven approach with artificial intelligence solutions

An AI Biotech perspective
Felix Balazard (Owkin, FRA)

An Industry Perspective
Joan Buenconsejo (BMS, USA)

The «new Danish take» automatic data sources and the eboks system
Tor Biering-Sørensen (CVCT Future Trialist, Copenhagen, DEN)

Industry viewpoint
Andy Fish (MDIC, USA)

Patients' viewpoint
Robin Martinez (Denver, CO, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW TO ATTRACT SPONSORS BACK TO CV TRIALS

Chairpersons : Adrian Hernandez (Durham,NC, USA) & Yves Rosenberg (NHLBI, USA)

Panelists: Felix Balazard (Owkin, FRA), Tor Biering-Sørensen (CVCT Future Trialist, Copenhagen, DEN), Joan Buenconsejo (BMS, USA), Philip Devereaux (Hamilton, CAN), Andy Fish (MDIC, USA), Adrian Hernandez (Durham,NC, USA), Harlan Krumholz (New Haven, CT, USA), Robin Martinez (Denver, CO, USA), Yves Rosenberg (NHLBI, USA), Salim Yusuf (Hamilton, CAN), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA), and other invited panelists



**Room : BALLROOM E
Friday 02 December, 2022
14:00 -16:00**

**LEGAL & STATISTICAL PRINCIPLES UNDERLYING DRUG REGULATION
OF CARDIOVASCULAR THERAPIES**

Chairpersons : Frank Sasinowski (Hyman, Phelps & MCHNamara, USA) & Janet Wittes (Wittes LLC, USA)

Legal & Statistical Principles Underlying Drug Regulation of Therapies for Cardiac Conditions.
Frank Sasinowski (HPM, WA, USA)

What is “substantial evidence of effectiveness?”
Ellis Unger (HPM, WA, USA)

Overview of Statistical Principles affecting design & analysis of trials of rare cardiac conditions.
Janet Wittes (Wittes LLC, USA)

Overview of competing risk analyses in time-to-event analyses
Jan Tijssen (Narnden, NED)

Industry perspective
Antoine Yver (Centessa, USA)

Legal & Statistical underpinnings of drug regulation in:

Europe
Evelyne Friedel (Paris, FRA)

USA
Alex Varond (Goodwin, USA)
Mark Rothmann (FDA, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**LEGAL AND STATISTICAL ISSUES IN RANDOMIZED TRIALS:
HOW DO THEY DOVETAIL WITH SCIENCE?**

Chairpersons : Frank Sasinowski (Hyman, Phelps & MCHNamara, USA) & Janet Wittes (Wittes LLC, USA)

Panelists: Marc Buyse (IDDI, BEL), Brian Claggett (Boston, MA, USA), David DeMets (WI, USA), Scott Evans (Washington DC, USA), Evelyne Friedel (Paris, FRA), Mary Lynne Hedley (TESARO, USA), Mark Rothmann (FDA, USA), Frank Sasinowski (Hyman, Phelps & MCHNamara, USA), Jan Tijssen (Narnden, NED), Ellis Unger (HPM, USA), Alex Varond (Goodwin, USA), Janet Wittes (Wittes LLC, USA), Antoine Yver (Centessa, USA) and other invited panelists

Room : BALLROOM E
Friday 02 December, 2022
16:30 -19:00

iCVCT Forum

TRANSCATHETER VALVES TRIALS AND SURGICAL TRIALS: A VIEW TO THE FUTURE Chairpersons : Bernard Gersh (Rochester, MN, USA) & Vijay Kunadian (Newcastle, UK)

Transcatheter and Surgical approaches to valvular heart disease 2022:

TAVR is 20 years old. A Lens into the Future - Implications for Trials?

8' Speaker : Howard Herrmann (Philadelphia, PA, USA)

2' Discussant : Roxana Mehran (New York, NY, USA)

Designing trials for Mitral Regurgitation: Trial and Tribulations

8' Speaker : Milton Packer (Dallas, TX, USA)

2' Discussant : Javed Butler (Jackson, TX, USA)

The Patient Needs: Patients reported outcomes as the endpoint.

8' Speaker : Rebecca Hahn (New York, NY, USA)

2' Discussant : Ileana Pinea (Detroit, MI, USA)

Pragmatic Surgical Trials

Endpoints, and design issues

8' Speaker : Emilia Bagiella (New York, NY, USA)

2' Discussant : Jan Tijssen (Narnden, NED)

Cardiologist view

8' Speaker : David Cohen (Roslyn, NY, USA)

2' Discussant : Benjamin Yeh (Boston, MA, USA)

Surgeon view

Mario Gaudino (New York, NY, USA)

CTSN network: Time for Interventional Cardiologists to join CTSN?!

8' Speaker : Roxana Mehran (New York, NY, USA)

2' Discussant : Bernard Gersh (Rochester, MN, USA)

2' Discussant: Annetine Gelijns (CTSN, New York, NY, USA)

Statistician perspective

Jan Tijssen (Narnden, NED)

Industry perspective

Jeffrey Popma (Medtronic, USA)

FDA perspective

Changfu Wu (FDA, USA)

NIH perspective

Kathleen Fenton (NIH, USA)

Patient's perspective

Naomi Buntsma (Amsterdam, NED)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

Chairpersons: Bernard Gersh (Rochester, MN, USA) & Vijay Kunadian (Newcastle, UK)

Panelists: Emilia Bagiella (New York, NY, USA), Naomi Buntsma (Amsterdam, NED), Javed Butler (Jackson, TX, USA), David Cohen (Roslyn, NY, USA), Kathleen Fenton (NIH, USA), Prakriti Gaba (Boston, MA, USA), Mario Gaudino (New York, NY, USA), Annetine Gelijns (New York, NY, USA), Bernard Gersh (Rochester, MN, USA), Michael Gibson (Boston, MA, USA), Rebecca Hahn (New York, NY, USA), Adrian Hernandez (Durham, NC, USA), Howard Herrmann (Philadelphia, PA, USA), Roxana Mehran (New York, NY, USA), Milton Packer (Dallas, TX, USA), Ileana Pinea (Detroit, MI, USA), Jeffrey Popma (Medtronic, USA), Jan Tijssen (Narnden, NED), Bernard Vasseur (FDA, USA), Nick West (Abbott, USA), Changfu Wu (FDA, USA), Benjamin Yeh (Boston, MA, USA) and other invited panelists

**Room : LONDON
Friday 02 December, 2022
08:00 -10:00**

**TRIAL OPPORTUNITIES FOR CV DISEASE AS PART OF MULTI-ORGAN SYSTEMIC DISEASES
Chairpersons : Douglas Mann (St Louis, MO, USA) & Paul Ridker (Boston, MA, USA)**

Targeting inflammation and fibrosis as a common mechanism in CV and systemic diseases.
NL3P3 – IL1B pathway inhibition in cardiorenal and non-CV outcome trials.
Paul Ridker (Boston, MA, USA)

Colchicine in the context of atherosclerotic and other systemic inflammation diseases
Guillaume Marquis Gravel (Montreal, CAN)

Opportunities for Mineralocorticoid Receptor Antagonists in Rheumatoid arthritis and other CV systemic inflammatory fibrotic diseases
Joao Ferreira (CVCT Future trialist, Porto, PRT)

Inflammation as a biotarget in heart failure and comorbidities
Douglas Mann (St Louis, MO, USA)

CV outcome trials in NASH as a multi-organ system disease. The MOSAIC project
Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

The potential of integrated clinical imaging of heart, liver and kidneys in systemic diseases trials.
Lars Johansson (Antaros, SWE)

Industry viewpoints
Florian Baeres (NovoNordisk, DEN), Ciaran McMullan (Merck, USA), Pieter Muntendam (G3P, USA)

Patients' viewpoint
Patrick Gee (Chesterfield, MO, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**HOW TO DE-SILO TRIALS WITH CV AND MULTI-ORGAN ENDPOINTS
Chairpersons : Douglas Mann (St Louis, MO, USA) & Paul Ridker (Boston, MA, USA)**

Panelists: Florian Baeres (NovoNordisk, DEN), Guiomar Mendieta Badimon (CVCT Future trialist, Madrid, ESP), Larry Deckelbaum (CSL, AUS), Joao Ferreira (Porto, PRT), Patrick Gee (Chesterfield, MO, USA), Lars Johansson (Antaros, SWE), Matthew Lee (CVCT Future trialist, Glasgow, UK), Ciaran McMullan (Merck, USA), Guillaume Marquis Gravel (Montreal, CAN), Pieter Muntendam (G3P, USA), Paul Ridker (Boston, MA, USA), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA) and other invited panelists

**Room : LONDON
Friday 02 December, 2022
10:30 -12:30**

**PRIMARY PREVENTION
HOW AND WHEN TO MOVE BEYOND EVENT DRIVEN TRIALS?**

Chairpersons : Patrice Desvigne-Nickens (NHLBI, USA) & Tom Gaziano (Boston, MA, USA)

How artificial intelligence may help targeting the right population
An Artificial Intelligence Investigator Perspective
Barry Greenberg (San Diego, CA, USA)

Risk enrichment and responder profiling to limit population sample size?

Proteomic biomarkers.
Reza Mohebi (Boston, MA, USA)

Bioimaging
James Min (Clearly, USA)

An Industry Perspective
Arnaud Bastien (BMS, USA)

Observational and Real-World Evidence. The role of causal inference
Issa Dahabreh (Boston, MA, USA)

The NIH viewpoint
Lawrence Fine (NHLBI, USA)

Regulatory viewpoint
Robert Temple (FDA, USA)

Industry viewpoints
Tomas Andersson (AstraZeneca, SWE), Steven Williams (Somalogic, USA), Karsten Strauss (Olink, SWE)

Patients' viewpoint and "Science of Patients inputs"
Philip Collis (British Heart Foundation, UK)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

PRIMARY PREVENTION. HOW AND WHEN TO MOVE BEYOND EVENT DRIVEN TRIALS?

Chairpersons : Patrice Desvigne-Nickens (NHLBI, USA) & Tom Gaziano (Boston, MA, USA)

Panelists: Tomas Andersson (AstraZeneca, SWE), Arnaud Bastien (BMS, USA), Philip Collis (British Heart Foundation, UK), Issa Dahabreh (Boston, MA, USA), Patrice Desvigne-Nickens (NHLBI, USA), Lawrence Fine (NHLBI, USA), Tom Gaziano (Boston, MA, USA), Barry Greenberg (San Diego, CA, USA), Evan Mills (Olink, SWE), James Min (Clearly, USA), Reza Mohebi (Boston, MA, USA), Karsten Strauss (Olink, SWE), Robert Temple (FDA, USA), Steven Williams (Somalogic, USA), and other invited panelists

**Room : LONDON
Friday 02 December, 2022
14:00 -16:00**

THE QUEST FOR WEIGHT LOSS INDICATION

Chairpersons : Laurie Friedman Donze (NHLBI, USA) & Benjamin Scirica (Boston, MA, USA)

**Is obesity a disease?
Naveed Sattar (Glasgow, UK)**

**The promising role of dietary weight loss trials. Beyond the DiRECT trial.
Matthew Lee (CVCT Future trialist, Glasgow, UK),**

**The evolving landscape of anti-obesity drug trials.
Benjamin Scirica (Boston, MA, USA)**

**Is it time for a head-to-head trial between drugs vs. bariatric surgery?
Paul Poirier (Quebec, CAN)**

**Can weight loss drugs interventions have QoL and functional capacity indication significance?
John Spertus (Kansas City, MO, USA)**

**Industry viewpoints
Siddique Abbasi (Amgen, USA), Kristine Buchholtz (NovoNordisk, DEN), Masahiro Murakami (Lilly, USA)**

**Regulatory viewpoints
Laura Higginbotham (FDA, USA)
John Sharretts (FDA, USA)**

**Payer viewpoint
Roger Longman (Real Endpoints, USA)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW MUCH WEIGHT TO PUT ON WEIGHT LOSS?

Chairpersons : Laurie Friedman Donze (NHLBI, USA) & Benjamin Scirica (Boston, MA, USA)

Panelists: Siddique Abbasi (Amgen, USA), Kristine Buchholtz (NovoNordisk, DEN), Laurie Friedman Donze (NHLBI, USA), Laura Higginbotham (FDA, USA), Matthew Lee (CVCT Future trialist, Glasgow, UK), Roger Longman (Real Endpoints, USA), Masahiro Murakami (Lilly, USA), Stuart Pocock (London, UK), Paul Poirier (Quebec, CAN), Hartmut Ruetten (Boehringer, GER), Arun Sanyal (Richmond, VA, USA), Naveed Sattar (Glasgow, UK), Benjamin Scirica (Boston, MA, USA), John Sharretts (FDA, USA), John Spertus (Kansas City, MO, USA), and other invited panelists

**Room : LONDON
Friday 02 December, 2022
16:30 -19:00**

PROGRESSING FROM WEIGHT LOSS TO CARDIOMETABOLIC ENDPOINTS
Chairpersons : Darren K McGuire (Dallas, TX, USA) & Naveed Sattar (Glasgow, UK)

Can weight loss drugs have diabetes prevention impact?
Naveed Sattar (Glasgow, UK)

Can weight loss drugs have a cardiovascular prevention impact?
Darren K McGuire (Dallas, TX, USA)

Can weight loss drugs have NASH impact?
Arun Sanyal (Richmond, VA, USA)

How multiple outcomes in a single trial may apply to obesity clinical trials?
Marc Buyse (IDDI, BEL)

Industry viewpoints

Masahiro Murakami (Lilly, USA), Hartmut Ruetten (Boehringer, GER) Maria Sejersten Ripa (NovoNordisk, DEN)

Regulatory perspective: What are the regulatory CV safety/benefits requirements to approve a drug for weight reduction ?

Maciej Kostrubiec (EMA, POL)

NIH viewpoint

Laurie Friedman Donze (NHLBI, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

PROGRESSING FROM WEIGHT LOSS TO CARDIOMETABOLIC INDICATIONS
Chairpersons : Darren K McGuire (Dallas, TX, USA) & Naveed Sattar (Glasgow, UK)

Panelists: Marc Buyse (IDDI, BEL), Laurie Friedman Donze (NHLBI, USA), Maciej Kostrubiec (EMA, POL), Darren K McGuire (Dallas, TX, USA), Caius Ovidiu Mersa (European Heart Network, ROM), Masahiro Murakami (Lilly, USA), Stuart Pocock (London, UK), Hartmut Ruetten (Boehringer, GER), Arun Sanyal (Richmond, VA, USA), Naveed Sattar (Glasgow, UK), Maria Sejersten Ripa (NovoNordisk, DEN), John Sharretts (FDA, USA), John Spertus (Kansas City, MO, USA) and other invited panelists

**Room : BALLROOM E
Friday 02 December, 2022
08:00 -10:00**

**ACUTE DECOMPENSATED HEART FAILURE DEVICE TRIALS
THE COMPETITIVE LANDSCAPE AND TRIAL DESIGN CHALLENGE**

Chairpersons : Maria Rosa Costanzo (Naperville IL, USA) & Biykem Bozkurt (Houston, TX, USA)

Overview: Devices to treat decompensated heart failure (DRI2P2S)
Hannah Rosenblum (New York, NY, USA)

Current competitive landscape.

Acute neuromodulation
William Abraham (Columbus, OH, USA)

“Removers”: Aquaphoresis and beyond
Maria Rosa Costanzo (Naperville IL, USA)

“Interstitial”: lymphatics as a target for decompensated heart failure
Marat Fudim (Durham, NC, USA)

“Pushers” and “Pullers”: devices to improve renal perfusion
Hannah Rosenblum (New York, NY, USA)

Challenges in Device trials in acute decompensated heart failure.

Defining target populations. Unmet needs vs. willingness to accept more risk for emerging technologies?
Alexandre Mebazaa (Paris, FRA)

Defining clinically meaningful endpoints. Decongestion, in-hospital WHF, patient reported outcomes, hemodynamics, length of stay, discharge on GDMT?
Biykem Bozkurt (Houston, TX, USA)

Industry viewpoints:
Steve Goedeke (Cardionomic, USA)

Regulatory Perspective: What is the most clinically meaningful approvable outcomes to establish Safety & Effectiveness in AHF?
Meir Shinnar (FDA, USA)

Patients’ viewpoint
Greg Merritt (Brighton, CO, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**ACUTE DECOMPENSATED HEART FAILURE DEVICE TRIALS
THE COMPETITIVE LANDSCAPE AND TRIAL DESIGN CHALLENGE**

Chairpersons : Maria Rosa Costanzo (Naperville IL, USA) & Biykem Bozkurt (Houston, TX, USA)

Panelists: William Abraham (Columbus, OH, USA), Biykem Bozkurt (Houston, TX, USA), Daniel Burkhoff (New York, NY, USA), Maria Rosa Costanzo (Naperville IL, USA), Andrew Farb (FDA, USA), Marat Fudim (Durham, NC, USA), Steve Goedeke (Cardionomic, USA), Alexandre Mebazaa (Paris, FRA), Greg Merritt (Brighton, CO, USA), Hannah Rosenblum (New York, NY, USA), Meir Shinnar (FDA, USA), Shelley Zieroth (Manitoba, CAN), and other invited panelists

**Room : BALLROOM E
Friday 02 December, 2022
10:30 -12:30**

**HOW TO GET HEART FAILURE PATIENTS FAST ON GDMT.
RESULTS AND CONSEQUENCES OF THE STRONG-HF TRIAL**
Chairpersons : Alexandre Mebazaa (Paris, FRA) & Ileana Pina (Detroit, MI, USA)

Rapid up-titration of evidence-based guideline-recommended therapies. Design and features of the STRONG-HF trial.
Gad Cotter (Paris, FRA)

Main results
Alexandre Mebazaa (Paris, FRA)

What HF docs did better than usual care?
Alain Cohen Solal (Paris, FRA)

Statistical perspective
Beth Davison (Paris, FRA)

Generalizability issues.

Validity of the STRONG-HF strategy across HF_rEF and HF_pEF, and with updated GDMT.
Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

Is the STRONG-HF strategy easily implementable across various healthcare systems?

US perspective:
Ileana Pina (Detroit, MI, USA)

EU perspective
Lars Lund (Stockholm, SWE)

May remote monitoring be an option for HF specialist driven rapid up-titration of evidence-based guideline-recommended therapies?
Alexandre Mebazaa (Paris, FRA)*

Industry viewpoints
Martin Cowie (AstraZeneca, UK)
Markus Schwertfeger (Roche, CHE)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

SHOULD HEART FAILURE GDMT NOW INCLUDE RAPID UPTITRATION STRATEGY?
Chairpersons : Alexandre Mebazaa (Paris, FRA) & Ileana Pina (Detroit, MI, USA)

Panelists: Tariq Ahmad (New Haven, CT, USA), Javed Butler (Jackson, TX, USA), Alain Cohen Solal (Paris, FRA), Gad Cotter (INSERM UMR-S 942, Paris, FRA), Martin Cowie (AstraZeneca, USA), Beth Davison (Paris, FRA), Justin Ezekowitz (Edmonton, CAN), Robin Gage (Lakeland, FL, USA), Francesca Lawson (Corteria, FRA), Lars Lund (Stockholm, SWE), Alexandre Mebazaa (Paris, FRA), Ileana Pina (Detroit, MI, USA), Piotr Ponikowski (Wroclaw, POL), Markus Schwertfeger (Roche, CHE), Shelley Zieroth (Manitoba, CAN), André Ziegler (Roche, GER), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA) and other invited panelists

**Room : BALLROOM CD
Friday 02 December, 2022
14:00 -16:00**

**THROMBOSIS TRIALS
SOLVING THE EQUATION OF MAXIMIZING THE NET BENEFIT OF ANTI-THROMBOTIC THERAPY
Chairpersons : Vijay Kunadian (Newcastle, UK) & Roxana Mehran (New York, NY, USA)**

Can anti-thrombotic therapy net benefit be improved? The promise with Xla inhibitors and other novel agents.

Will Xla have differential benefit on MIs and Stroke, and DVTs?
Guillaume Pare (Hamilton, CAN)

Post MI and stroke prevention
Vijay Kunadian (Newcastle, UK)

Myocardial infarction following non cardiac surgery
Philip Devereaux (Hamilton, CAN)

In Interventional cardiology
Vijay Kunadian (Newcastle, UK)

For atrial fibrillation
Manesh Patel (Durham, NC, USA)

What real world evidence is acceptable for regulatory decision- making?
Alison Cave (MHRA, UK)
Nancy Dreyer (IQVIA, USA)

Statistical viewpoint
Dean Follmann (NIH, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**SOLVING THE EQUATION OF MAXIMIZING THE NET BENEFIT OF ANTI-THROMBOTIC THERAPY
Chairpersons : Michael Gibson (Boston, MA, USA) & Roxana Mehran (New York, NY, USA)**

Panelists: Angeles Alonso (MHRA, UK), Alison Cave (MHRA, UK), Elliot Barnathan (JnJ, USA), Björn Dahlof (Cereno, SWE), Philip Devereaux (Hamilton, CAN), Nancy Dreyer (IQVIA, USA), Dean Follmann (NIH, USA), Vijay Kunadian (Newcastle, UK), Roxana Mehran (New York, NY, USA), Hardi Mundl (Bayer, GER), Guillaume Pare (Hamilton, CAN), Manesh Patel (Durham, NC, USA), Nick West (Abbott, USA) and other invited panelists

**Room : BALLROOM CD
Friday 02 December, 2022
16:30 -19:00**

**THROMBOSIS TRIALS
INTEGRATING BENEFIT AND RISK IN CLINICAL TRIALS**

Chairpersons : Scott Evans (Washington DC, USA) & Paul Ridker (Boston, MA, USA)

Antithrombotic Therapy in Pulmonary embolism
Tabassome Simon (Paris, FRA)

Antithrombotic Therapy in Older Adults
Darae Ko (CVCT Future trialist, Boston, MA, USA)

Antithrombotic therapy in COVID-19
Marc Bonaca (Denver, CO, USA)

Why integrate benefit and risk?
Frank Rockhold (Durham, NC, USA)

Net clinical benefit in trials of antithrombotic therapy
Sachin Shah (Boston, MA, USA)
Daniel Singer (Boston, MA, USA)

The “desirability of outcome ranking” (DOOR) analysis
Scott Evans (Washington DC, USA)

Industry viewpoints
Tomas Andersson (AstraZeneca, SWE), Björn Dahlof (Cerenon, SWE), Stefan Hantel (Boehringer, GER), Puneet Mohan (BMS, USA), Hardi Mundl (Bayer, GER), Martin Unverdorben (Daiichi Sankyo, USA)

Regulatory viewpoint
Ann Farrell (FDA, USA)

Payers’ viewpoint
Roger Longman (Real Endpoints, USA)

Patients’ viewpoint
Steve Macari (Poitiers, FRA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**INTEGRATING BENEFIT AND RISK IN CLINICAL TRIALS. DO WE HAVE A ROADMAP?
Chairpersons : Scott Evans (Washington DC, USA) & Paul Ridker (Boston, MA, USA)**

Panelists: Angeles Alonso (MHRA, UK), Tomas Andersson (AstraZeneca, SWE), Elliot Barnathan (JnJ, USA), Marc Bonaca (Denver, CO, USA), Scott Evans (Washington DC, USA), Ann Farrell (FDA, USA), Stefan Hantel (Boehringer, GER), Darae Ko (CVCT Future trialist, Boston, MA, USA), Steve Macari (Poitiers, FRA), Puneet Mohan (BMS, USA), Hardi Mundl (Bayer, GER), Roger Longman (Real Endpoints, USA), Paul Ridker (Boston, MA, USA), Frank Rockhold (Durham, NC, USA), Sachin Shah (Boston, MA, USA), Daniel Singer (Boston, MA, USA), Tabassome Simon (Paris, FRA), Martin Unverdorben (Daiichi Sankyo, USA), Nick West (Abbott, USA) and other invited panelists



Keynote
THE BROKEN MIRACLE The Paul Cardall story
with Aditya “AK” Kaza (Boston, MA, USA)

Piano Performance
“Music for the Heart” with Paul Cardall

ON SITE DINNER and RECEPTION

Friday 2 December, 2022
19.00-21.00

Meet Paul Cardall, an award-winning pianist who turned his hardships into harmonies. Born with half a heart and facing life-threatening circumstances, Paul grew up having to endure numerous critical surgeries. Against all odds, after living years with a congenital heart defect (CHD), he received a successful heart transplant in 2009. Ever since, he’s used his emotional experience as an opportunity to spread joy and help others. Known for his uplifting melodies and with more than 3 billion streams worldwide and multiple Billboard #1 albums, Paul is one of today’s most inspiring and sought after guest speakers. He’s performed all over the world including the White House, and now it’s our honor to welcome him to CVCT.

Please join us for a can’t-miss keynote event featuring Paul and his physician (who performed his life-saving surgery), Dr. AK Kaza, followed directly by a very special performance by Paul himself.

**Room : LONDON
Saturday 03 December, 2022
08:00 -10:00**

**WHEN IS EVIDENCE GENERATION OTHER THAN USING RANDOMIZED CLINICAL TRIALS ACCEPTABLE?
PART 1 : CASE STUDIES**

Chairpersons : Milton Packer (Dallas,TX, USA) & Antoine Yver (Centessa, USA)

Introduction

Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

**A case for drug development NOT anchored on RCT and the 6-point blueprint for first approval
Antoine Yver (Centessa, USA)**

**Regulator's agility. A case study Trastuzumab deruxtecan in breast cancer.
Asma Dilawari (OCE Oncology, FDA, USA)**

**The need for high certainty: A Case study. Sotatercept in Pulmonary Arterial Hypertension
Janethe de Oliveira Pena (Merck, USA)**

**Peri-approval use of Real World Data. Case study for remote monitoring in PAH studies
Philip Adamson (Abbott, USA)
Alexander Rothman (Sheffield, UK)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**WHEN IS EVIDENCE GENERATION OTHER THAN USING RANDOMIZED CLINICAL TRIALS ACCEPTABLE?
Chairpersons : Milton Packer (Dallas,TX, USA) & Antoine Yver (Centessa, USA)**

Panelists: Philip Adamson (Abbott, USA), Catherine Arnold (Centerview, USA), Ziad Bakri (T Rowe, USA), Marc Buyse (IDDI, BEL), Asma Dilawari (OCE Oncology, FDA, USA), Janethe de Oliveira Pena (Merck, USA), Francesco deRubertis (Medicxi, CH), Ramin Farzaneh-Far (RA Capital Aventure, USA), Michael Gibson (Boston, MA, USA), Craig Gordon (GordonMD Global Investment LP, Beverly Hills CA, USA), Phil McEwan (HEOR, UK), Milton Packer (Dallas,TX, USA), Alexander Rothman (Sheffield, UK), Chana Sacks (NEJM Evidence, USA), Steffen Thirstrup (Amsterdam, NED), Antoine Yver (Centessa, USA), Ron Winslow (Wall Street Journal, Ret. No. Conway NH USA), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA) and other invited panelists

**Room : LONDON
Saturday 03 December, 2022
10:30 -12:30**

**WHEN IS EVIDENCE GENERATION OTHER THAN USING RANDOMIZED CLINICAL TRIALS ACCEPTABLE?
PART 2 STAKEHOLDERS AND INVESTORS' VIEWPOINTS**

Chairpersons : Milton Packer (Dallas,TX, USA) & Antoine Yver (Centessa, USA)

Regulatory perspectives from EMA and FDA
Steffen Thirstrup (Amsterdam, NED)

Patient's viewpoint
Philip Collis (British Heart Foundation, UK)

The investors funding of innovation and development Where is innovation coming from and how is it funded? The role of pharmacology for derisking investments?

US perspective
Craig Gordon (GordonMD Global Investment LP, Beverly Hills CA, USA)


EU perspective
Francesco deRubertis (Medicxi, CH)

How is large cost committed, and what it means?
Catherine Arnold (Centerview, USA)
Phil McEwan (HEOR, UK)
Alex Strasser (RA Capital Aventure, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**WHEN IS EVIDENCE GENERATION OTHER THAN USING RANDOMIZED CLINICAL TRIALS ACCEPTABLE?
Chairpersons : Milton Packer (Dallas,TX, USA) & Antoine Yver (Centessa, USA)**

Panelists: Philip Adamson (Abbott, USA), Catherine Arnold (Centerview, USA), Marc Buyse (IDDI, BEL), Asma Dilawari (OCE Oncology, FDA, USA), Janethe de Oliveira Pena (Merck, USA), Francesco deRubertis (Medicxi, CH), Ramin Farzaneh-Far (RA Capital Aventure, USA), Michael Gibson (Boston, MA, USA), Craig Gordon (GordonMD Global Investment LP, Beverly Hills CA, USA), Phil McEwan (HEOR, UK), Milton Packer (Dallas,TX, USA), Alexander Rothman (Sheffield, UK), Chana Sacks (NEJM Evidence, USA), Steffen Thirstrup (Amsterdam, NED), Antoine Yver (Centessa, USA), Ron Winslow (Wall Street Journal, Ret. No. Conway NH USA), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA) and other invited panelists



KEYNOTE LECTURE
Robert Califf
(FDA, USA)

Room: Ballroom ABCD
Saturday 03 December, 2022
12:40 -13:00



**Celebration of the life of John Jarcho,
Deputy Editor, NEJM**

**Room: Ballroom ABCD
Friday 02 December, 2022
13.00-13.15**

Room : LONDON
Saturday 03 December, 2022
14:00 -16:00

ARE TRIALS AND TRIALISTS MEETING THE SOCIETY'S NEEDS?

Chairpersons : Salim Yusuf (Hamilton, CAN) & Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

Trialist perspective
Salim Yusuf (Hamilton, CAN)

Journal Editors perspective
Chana Sacks (NEJM Evidence, USA)
Jennifer Sargent (Nature Medicine, USA)
Stuart Spencer (The Lancet, UK)

FDA commissioner perspective
Robert Califf (FDA, USA)

EMA Chief Medical Officer perspective
Steffen Thirstrup (Amsterdam, NED)

Journalist perspective
Ron Winslow (Wall Street Journal, Ret. No. Conway NH USA)

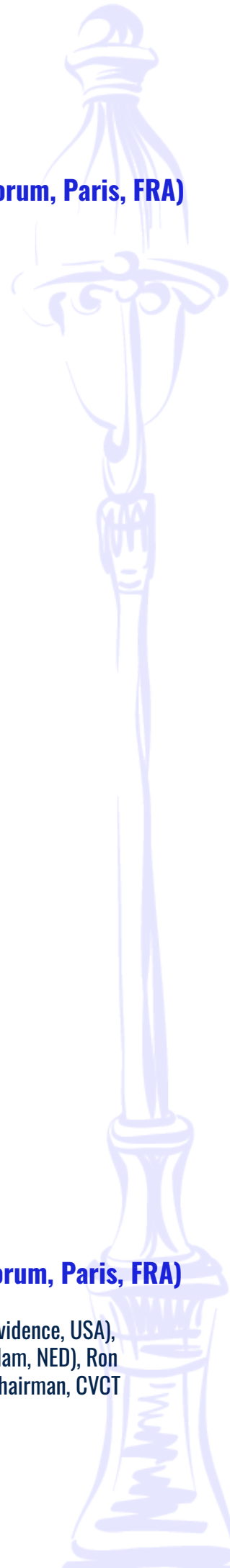
Patient's viewpoint
Philip Collis (British Heart Foundation, UK)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

ARE TRIALS AND TRIALISTS MEETING THE SOCIETY'S NEEDS?

Chairpersons : Salim Yusuf (Hamilton, CAN) & Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

Panelists: Robert Califf (FDA, USA), Philip Collis (British Heart Foundation, UK), Chana Sacks (NEJM Evidence, USA), Jennifer Sargent (Nature Medicine, USA), Stuart Spencer (The Lancet, UK), Steffen Thirstrup (Amsterdam, NED), Ron Winslow (Wall Street Journal, Ret. No. Conway NH USA), Salim Yusuf (Hamilton CAN), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA) and other invited panelists



**Room : LONDON
Saturday 03 December, 2022
16:30 -19:00**

**IS HEART FAILURE WITH PRESERVED EJECTION FRACTION NO LONGER A MINEFIELD?
DELIVER TRIAL AND BEYOND.**

Chairpersons : Stefan Anker (Berlin, GER) & Scott Solomon (Boston, MA, USA)

Main results from the DELIVER trial
Scott Solomon (Boston, MA, USA)

Important subgroup findings from the DELIVER trial: Age, Frailty, Obesity.
Jawad Butt (CVCT Future Trialist, Glasgow, UK)

Clinical significance of dapagliflozin effect on electrolyte, uric acid and Iron metabolism biomarkers
Kieran Docherty (CVCT Future Trialist, Glasgow, UK)

EMPEROR preserved and DELIVER

The totality of evidence
Stefan Anker (Berlin, GER)

Important subgroup findings from SGLT2i HFpEF trials
Muthiah Vaduganathan (Boston, MA, USA)

Statistical perspective
Stuart Pocock (London, UK)

Are all SGLT inhibitors alike? Discussing the class effect.
Bertram Pitt (Ann Arbor, MI, USA)

Mechanism of the clinical benefits of SGLT2i. Insights from clinical proteomics.
Faiez Zannad (Chairman, CVCT Forum, Paris, FRA)

Industry viewpoints:
Martin Cowie (AstraZeneca, UK), Craig Granowitz (Lexicon, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

THE FUTURE OF HFPEF THERAPY AND HFPEF TRIALS

Chairpersons : Stefan Anker (Berlin, GER) & Scott Solomon (Boston, MA, USA)

Panelists: Angeles Alonso (MHRA, UK), Stefan Anker (Berlin, GER), Jawad Butt (CVCT Future Trialist, Glasgow, UK), Martin Cowie (AstraZeneca, UK), Kieran Docherty (CVCT Future Trialist, Glasgow, UK), Craig Granowitz (Lexicon, USA), Bertram Pitt (Ann Arbor, MI, USA), Stuart Pocock (London, UK), Scott Solomon (Boston, MA, USA), Muthiah Vaduganathan (Boston, MA, USA), Faiez Zannad (Chairman, CVCT Forum, Paris, FRA), Kristine Buchholtz (NovoNordisk, DEN), and other invited panelists

**Room : BALLROOM AB
Saturday 03 December, 2022
08:00 -10:00**

**HEART FAILURE POLYPHARMACY IMPLEMENTATION
PART 1: HOW CLINICAL TRIAL RESULTS MAY INFORM SEQUENCING STRATEGIES
Chairpersons : Marc Pfeffer (Boston, MA, USA) & Ileana Pina (Detroit, MI, USA)**

How to improve optimal use of HF therapies. Shall we conduct trials of implementation strategies?
Ileana Pina (Detroit, MI, USA)

Worsening heart failure treated in the outpatient setting: Will this strategy improve optimal use of HF therapies?
Lars Lund (Stockholm, SWE)

Optimization of chronic HF therapy after a worsening episode.
Justin Ezekowitz (Edmonton, CAN)

Initiation of chronic HF therapy in post MI patients.
Marc Pfeffer (Boston, MA, USA)

What IV Iron therapy and where to fit? Re-examining the evidence and mechanisms of IV iron.
Piotr Ponikowski (Wroclaw, POL)

New diuretic therapy strategies in the acute setting.
The ADVOR trial
Jeroen Dauw (Gent, BEL)

New diuretic therapy strategies in the chronic setting.
The TRANSFORM trial
Robert Mentz (Durham, NC, USA)

Congestion phenotypes and biomarker-based decongestive strategies.
John Cleland (Glasgow, UK)

Patients' viewpoint
Robin Gage (Lakeland, FL, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**HOW CLINICAL TRIAL RESULTS MAY INFORM SEQUENCING STRATEGIES
Chairpersons : Marc Pfeffer (Boston, MA, USA) & Ileana Pina (Detroit, MI, USA)**

Panelists: Tariq Ahmad (New Haven, CT, USA), Angeles Alonso (MHRA, UK), Javed Butler (Jackson, TX, USA), John Cleland (Glasgow, UK), Martin Cowie (AstraZeneca, USA), Jeroen Dauw (Gent, BEL), Justin Ezekowitz (Edmonton, CAN), Robin Gage (Lakeland, FL, USA), Francesca Lawson (Corteria, FRA), Lars Lund (Stockholm, SWE), Alexandre Mebazaa (Paris, FRA), Robert Mentz (Durham, NC, USA), Marc Pfeffer (Boston, MA, USA), Ileana Pina (Detroit, MI, USA), Piotr Ponikowski (Wroclaw, POL), Harriette Van Spall (Hamilton, CAN), and other invited panelists

**Room : BALLROOM AB
Saturday 03 December, 2022
10:30 -12:30**

**HEART FAILURE POLYPHARMACY IMPLEMENTATION
PART 2: THE ROLE OF THERAPY ENABLERS, DISEASE MANAGEMENT AND COVERAGE
Chairpersons : John Cleland (Glasgow, UK) & Harriette Van Spall (Hamilton, CAN)**

Therapy enablement

Decision support systems

Messaging to providers (PROMPT-HF)
Tariq Ahmad (New Haven, CT, USA)

Artificial intelligence and digital solutions
Harriette Van Spall (Hamilton, CAN)

Potassium binders. Lessons from DIAMOND
Javed Butler (Jackson, TX, USA)

The role of disease management programs
Ileana Pina (Detroit, MI, USA)

Could expanding the scope of the «polypill» and fixed dose combination to heart failure improve care?
Javed Butler (Jackson, TX, USA)

Shall it be the payers who decide? Is pricing evidence based?

US experience
Javed Butler (Jackson, TX, USA)

EU experience
John Cleland (Glasgow, UK)

Industry viewpoint
Martin Cowie (AstraZeneca, USA), Fredrik Erlandsson (CSL Behring, GER)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**PART 2: HOW TO DO A BETTER JOB WITH EXISTING AND NOVEL THERAPIES
Chairpersons : John Cleland (Glasgow, UK) & Harriette Van Spall (Hamilton, CAN)**

Panelists: Tariq Ahmad (New Haven, CT, USA), Angeles Alonso (MHRA, UK), Javed Butler (Jackson, TX, USA), John Cleland (Glasgow, UK), Martin Cowie (AstraZeneca, USA), Fredrik Erlandsson (CSL Behring, GER), Justin Ezekowitz (Edmonton, CAN), Alexandre Mebazaa (Paris, FRA), Marc Pfeffer (Boston, MA, USA), Ileana Pina (Detroit, MI, USA), Piotr Ponikowski (Wroclaw, POL), Harriette Van Spall (Hamilton, CAN), and other invited panelists

**Room : BALLROOM AB
Saturday 03 December, 2022
14:00 -16:00**

**iCVCT
INTERVENTIONAL APPROACHES TO CORONARY ARTERY DISEASE 2022
Chairpersons : Rasha Al-Lamee (London, UK) & Roxana Mehran (New York, NY, USA)**

**Complex PCI: from Registries to RCTs
David Cohen (Roslyn, NY, USA)**

**Pragmatic Trials in PCI The only way forward is with RCT!
8'Speaker : Usman Baber (Oklahoma City, OK, USA)
2 Discussant: Adrian Hernandez (Durham,NC, USA)**

**How have the world of biomarkers changed the definition of myocardial infarction?
8'Speaker : Donald Cutlip (Boston, MA, USA)
2 Discussant: Davide Cao (New York, USA)**

**Trials of bleeding avoidance strategies in percutaneous coronary intervention: De-Escalation and P2Y12 monotherapy
(acute and chronic Maintenance)
8'Speaker : Dominick Angiolillo (Jacksonville, FL, USA)
2 Discussant: Christopher Granger (Durham, NC, USA)**

**Trials in Coronary Imaging: From Orbita to Now, What's Next
8'Speaker : Rasha Al-Lamee (London, UK)**

**Cardiogenic Shock Trials with Devices: What have we learned?
8'Speaker : Daniel Burkhoff (New York, NY, USA)**

**Trials in STEMI: Thrombus Aspiration, and more
8'Speaker : Roxana Mehran (New York, NY, USA)
2 Discussant: Vijay Kunadian (Newcastle, UK)**

**Statistician perspective
Cindy Westerhout (Edmonton, CAN)**

**NIH perspective
Yves Rosenberg (NIH, USA)**

**FDA perspective
Lydia Glaw (FDA, USA)**

**THE CVCT FORUM Multi-Stakeholder Moderated Debate
INTERVENTIONAL APPROACHES TO CORONARY ARTERY DISEASE 2022**

Chaipersons: Rasha Al-Lamee (London, UK) & Roxana Mehran (New York, NY, USA)

Panelists: Rasha Al-Lamee (London, UK), Dominick Angiolillo (Jacksonville, FL, USA), Usman Baber (Oklahoma City, OK, USA), Daniel Burkhoff (New York, NY, USA), Davide Cao (New York, USA), David Cohen (Roslyn, NY, USA), Donald Cutlip (Boston, MA, USA), Prakriti Gaba (Boston, MA, USA), Lydia Glaw (FDA, USA), Christopher Granger (Durham, NC, USA), Adrian Hernandez (Durham,NC, USA), Vijay Kunadian (Newcastle, UK), Adrian Magee (FDA, USA), Roxana Mehran (New York, NY, USA), Yves Rosenberg (NIH, USA), Bernard Vasseur (FDA, USA), Nick West (Abbott, USA), Cindy Westerhout (Edmonton, CAN)

**Room : BALLROOM AB
Saturday 03 December, 2022
16:30 -19:00**

**ACCELERATING CV CLINICAL TRIALS
PART 2: HOW RESEARCH ORGANISATIONS ARE HELPING CLINICAL TRIALS?
Chairpersons : Adrian Hernandez (Durham, NC, USA) & Milton Packer (Dallas, TX, USA)**

Academic trialist perspective
Milton Packer (Dallas, TX, USA)

ARO perspectives:

Investigator initiated ARO
Vijay Kunadian (Newcastle, UK)

The DUKE Clinical Research Initiative
Adrian Hernandez (Durham, NC, USA)

The George Institute
Hiddo Heerspink (Groningen, NED)

The Population Health Research Institute
Salim Yusuf (Hamilton, CAN)

The TIMI group
Stephen Wiviott (Boston, MA, USA)

DISCUSSION

CRO perspective
Ken Ouriel (NAMSA, USA)

Conducting trials in-house
So-Young Kim (Bayer, GER)

Statistician perspective
Janet Wittes (Wittes LLC, USA)

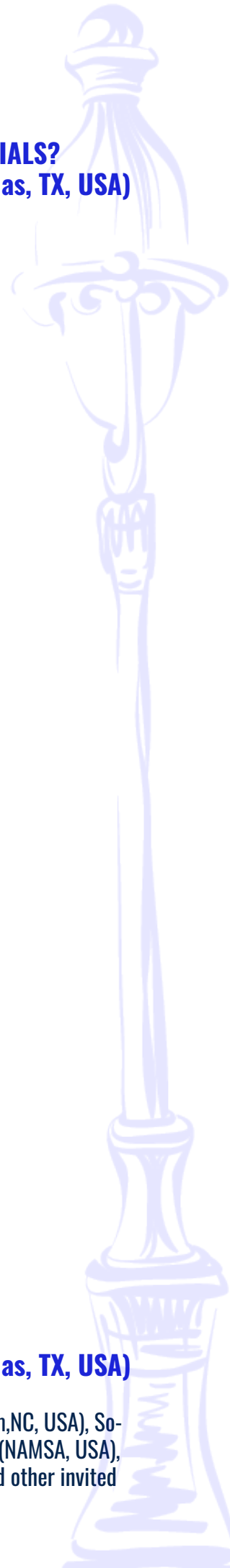
Industry perspective
Robert Blaustein (MSD, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW TO STREAMLINE TRIAL EXECUTION

Chairpersons : Adrian Hernandez (Durham, NC, USA) & Milton Packer (Dallas, TX, USA)

Panelists: Robert Blaustein (MSD, USA), Hiddo Heerspink (Groningen, NED), Adrian Hernandez (Durham, NC, USA), So-Young Kim (Bayer, GER), Vijay Kunadian (Newcastle, UK), Milton Packer (Dallas, TX, USA), Ken Ouriel (NAMSA, USA), Janet Wittes (Wittes LLC, USA), Stephen Wiviott (Boston, MA, USA), Salim Yusuf (Hamilton, CAN), and other invited panelists



**Room : BALLROOM CD
Saturday 03 December, 2022
08:00 -10:00**

**PULMONARY ARTERIAL HYPERTENSION TRIALS (Part 1)
NEW PATHWAYS AND NEW BIOTARGETS INVESTIGATED IN NEW TRIALS**

Chairpersons : Mardi Gomberg-Maitland (Washington, DC, USA) & Marc Humbert (Paris, FRA)

Where do we stand? The evolving landscape of PAH randomized clinical trials (CVCT 2021 take home messages)
Jason Weatherald (Edmonton, CAN)

Targeting the PDGF pathway: randomized clinical trials
Olivier Sitbon (Paris, FRA)

Rebalancing the BMPR-II pathway with activin receptor type II ligands traps: sotatercept phase III program
Vallerie McLaughlin (Ann Arbor, MI, USA)

Rebalancing the BMPR-II dysfunctional pathway with BMP9
Nick Morrell (Centessa Pharmaceuticals, USA)

Rebalancing the BMPR-II pathway with FK506
Edda Spiekerkoetter (Stanford, CA, USA)

Histone Deacetylase inhibition (HDACi) for PAH?
Björn Dahlof (Cereno, SWE)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

DO WE NEED NEW MODES OF EVIDENCE GENERATION FOR NEWER DRUGS?

Chairpersons : Mardi Gomberg-Maitland (Washington, DC, USA) & Marc Humbert (Paris, FRA)

Panelists: Laurent Bertoletti (Saint Etienne, FRA), Björn Dahlof (Cereno, SWE), Ben Dake (Aerovate, USA), Pisana Ferrari (Milan, ITA), Mardi Gomberg-Maitland (Washington, DC, USA), Paul Hassoun (Baltimore, MA, USA), Marc Humbert (Paris, FRA), Vallerie McLaughlin (Ann Arbor, MI, USA), Bradley Maron (Boston, MA, USA), Nick Morrell (Centessa Pharmaceuticals, USA), Iona Preston (Boston, MA, USA), Mitch Psozka (FDA, USA), Carol Satler (Respira Therapeutics, USA), Gérald Simonneau (Paris, FRA), Olivier Sitbon (Paris, FRA), Edda Spiekerkoetter (Stanford, CA, USA), Thennapan Thennapan (Minneapolis, MN, USA), Jason Weatherald (Edmonton, CAN), and other invited panelists

**Room : BALLROOM CD
Saturday 03 December, 2022
10:30 -12:30**

**PULMONARY HYPERTENSION TRIALS (Part 2)
HOW TO ADAPT TRIAL DESIGN AND ENDPOINTS TO PAH GROUPS
GROUP 2 (LEFT HEART DISEASE), GROUP 3 (CHRONIC LUNG DISEASE) AND GROUP 4 (CTEPH)
Chairpersons : Vallerie McLaughlin (Ann Arbor, MI, USA) & Gérald Simonneau (Paris, FRA)**

Group 2 PH due to heart disease: current knowledge
Bradley Maron (Boston, MA, USA)

Group 2 PH due to heart disease: current trials
Mardi Gomberg-Maitland (Washington, DC, USA)

Group 3 PH due to interstitial lung disease: ongoing RCT
Iona Preston (Boston, MA, USA)

Group 3 PH due to COPD: ongoing RCT
Paul Hassoun (Baltimore, MA, USA)

Group 4 PH (CTEPH): challenges and opportunities (multimodality strategy trials)
Gérald Simonneau (Paris, FRA)

Randomized controlled of anticoagulation in CTEPH
Laurent Bertoletti (Saint Etienne, FRA)

Investigator perspective:
Thenappan Thenappan (Minneapolis, MN, USA)

Industry Viewpoints
Alessandro Maresta (Janssen, USA), Mahesh Patel (Merck, USA)

Regulatory viewpoint
Mitch Psocka (FDA, USA)

Patient's viewpoints:
Pisana Ferrari (Milan, ITA)
Ilse Verstraaten (Amsterdam, NED)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**HOW TO ADAPT TRIAL DESIGN AND ENDPOINTS IN NON-PAH PH
Chairpersons : Vallerie McLaughlin (Ann Arbor, MI, USA) & Gérald Simonneau (Paris, FRA)**

Panelists: Laurent Bertoletti (Saint Etienne, FRA), Björn Dahlof (Cereno, SWE), Ben Dake (Aerovate, USA), Thao Duong-Verle (GossamerBio, USA), Pisana Ferrari (Milan, ITA), Mardi Gomberg-Maitland (Washington, DC, USA), Paul Hassoun (Baltimore, MA, USA), Marc Humbert (Paris, FRA), Vallerie McLaughlin (Ann Arbor, MI, USA), Alessandro Maresta (Janssen, USA), Bradley Maron (Boston, MA, USA), Nick Morrell (Centessa Pharmaceuticals, USA), Mahesh Patel (Merck, USA), Iona Preston (Boston, MA, USA), Mitch Psocka (FDA, USA), Carol Satler (Respira Therapeutics, USA), Gérald Simonneau (Paris, FRA), Edda Spiekerkoetter (Stanford, CA, USA), Thenappan Thenappan (Minneapolis, MN, USA), Ilse Verstraaten (Amsterdam, NED), Jason Weatherald (Edmonton, CAN), and other invited panelists

**Room : BALLROOM CD
Saturday 03 December, 2022
14:00 -16:00**

**CELL, GENE AND ORPHAN DISEASE THERAPY TRIALS
A CIRM-CVCT joint session**

Chairpersons : Dennis Buxton (NIH, USA) & Joseph Wu (Stanford, CA, USA)

Cell-based therapies for heart failure: Autopsy of failed trials.
Peter Johnston (Baltimore, MD, USA)

Stem cell therapy trials. What is next?
Josh Hare (Miami, FL, USA)

New strategies and designs for streamlining future cell therapy trials.
Emerson Perin (Houston, TX, USA)

Statistical methods for cell-gene and small sample therapy trials.
Janet Wittes (Wittes LLC, USA)

Pluripotent stem cell-derived cardiomyocytes for drug development and regenerative therapies
Joseph Wu (Stanford, CA, USA)

Gene Therapy for Treating Patients with Danon Disease
Barry Greenberg (San Diego CA, USA)

Cell therapy for cardiac diseases. Regulatory viewpoint
Elizabeth Hart (CBER, FDA, USA)

Journal Editor's viewpoint
Joe Hill (Circulation, USA)

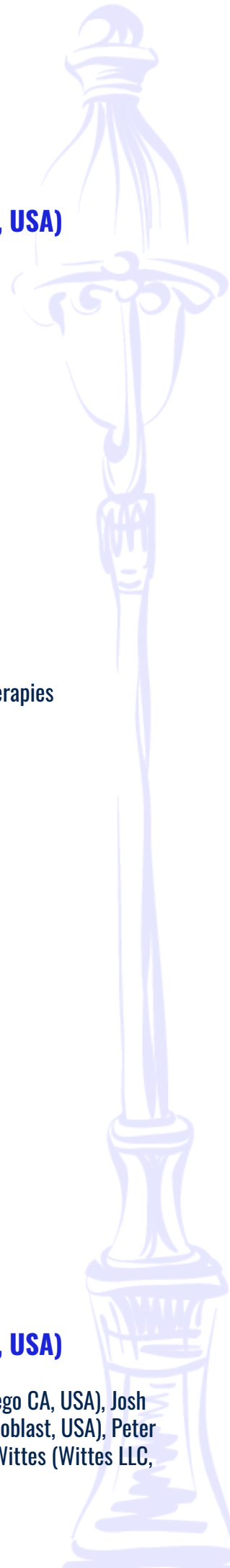
Industry and CRO viewpoints:
Richard Flaaten (NovoNordisk, DEN)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

GUIDANCE FOR FUTURE CV CELL THERAPY TRIALS

Chairpersons : Dennis Buxton (NIH, USA) & Joseph Wu (Stanford, CA, USA)

Panelists: Dennis Buxton (NIH, USA), Richard Flaaten (NovoNordisk, DEN), Barry Greenberg (San Diego CA, USA), Josh Hare (Miami, FL, USA), Elizabeth Hart (CBER, FDA, USA), Joe Hill (Circulation, USA), Silviu Itescu (Mesoblast, USA), Peter Johnston (Baltimore, MD, USA), Emerson Perin (Houston, TX, USA), David Strauss (FDA, USA), Janet Wittes (Wittes LLC, USA), Joseph Wu (Stanford, CA, USA), and other invited panelists



**Room : BALLROOM CD
Saturday 03 December, 2022
16:30 -19:00**

**CARDIOMYOPATHY TRIALS
HYPERTROPHIC CARDIOMYOPATHIES AND THE CONTEXT OF RARE DISEASES
Chairpersons : Carolyn Ho (Boston, MA, USA) & Martin Maron (Boston, MA, USA)**

Amyloid Transthyretin Cardiomyopathy (ATTR-CM). Current trials landscape.

TTR depleters
Martha Grogan (Rochester, MN, USA)

Eplontersen CARDIO-TTRansform trial
Mathew Maurer (New York, MA, USA)

Hypertrophic Cardiomyopathy. Competitive landscape and ongoing trials. Rapid fire.

Novel Myosin inhibitors trials

Aficamten REDWOOD and SEQUOIA-HCM trials
Ahmad Masri (Portland, OR, USA)

Myosin Inhibitors trials for Non-Obstructive HCM
Carolyn Ho (Boston, MA, USA)

Cardiac mitotrope (IMPROVE-HCM)
Martin Maron (Boston, MA, USA)

Non-traditional use of traditional medications for hypertrophic cardiomyopathy
Carolyn Ho (Boston, MA, USA)

Mitochondrial dysfunction cardiomyopathy, Barth Syndrome.
Hilary Vernon (Baltimore, MD, USA)

Industry viewpoints
Jim Carr (Stealth, USA), Stephen Heitner (Cytokinetics, USA), Amy Sehnert (BMS, USA)

Endpoint Considerations in Rare Diseases
Janet Maynard (FDA, USA)

Patient's viewpoints
Rhonda Monroe (Baltimore, MD, USA)
Lisa Salberg (HCMA, Denville, NJ, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**CARDIOMYOPATHY TRIALS
CARDIOMYOPATHY TRIALS. BUILDING EVIDENCE IN THE CONTEXT OF ORPHAN DISEASES
Chairpersons : Carolyn Ho (Boston, MA, USA) & Martin Maron (Boston, MA, USA)**

Panelists: Jim Carr (Stealth, USA), Mads David Engelmann (NovoNordisk, DEN), Martha Grogan (Rochester, MN, USA), Stephen Heitner (Cytokinetics, USA), Carolyn Ho (Boston, MA, USA), Ahmad Masri (Portland, OR, USA), Martin Maron (Boston, MA, USA), Mathew Maurer (New York, MA, USA), Janet Maynard (FDA, USA), Rhonda Monroe (Baltimore, MD, USA), Lisa Salberg (HCMA, Denville, NJ, USA), Eugene Schneider (Ionis, USA), Amy Sehnert (BMS, USA), Norman Stockbridge (FDA, USA), Hilary Vernon (Baltimore, MD, USA), and other invited panelists