



November 30th -
December 1st & 2nd 2023

The National Press Club
Washington DC

CVCT *turns* 20

SCIENTIFIC PROGRAM

**20th Global Cardio Vascular
Clinical Trialists Forum**

FACULTY

ACADEMY

1. Kirkwood Adams (Chapel Hill, USA)
2. Alberto Aimo (Pisa, ITA)
3. John Alexander (Durham, NC, USA)
4. Christopher Almond (Stanford, CA, USA)
5. Stefan Anker (Berlin, GER)
6. Lou Aronne (New York, NY, USA)
7. Julie Aultman (Rootstown, OH, USA)
8. Elizabeth Austin (Seattle, WA, USA)
9. Michel Azizi (Paris, FRA)
10. Emilia Bagiella (New York, NY, USA)
11. George Bakris (Chicago, IL, USA)
12. Archana Bajaj (Philadelphia, PA, USA)
13. Deborah Barnbaum (Kent, OH, USA)
14. Sanjeev Bhavnani (San Diego, CA, USA)
15. Mohamed Salah Ben Ammar (Paris, FRA)
16. Tor Biering-Sørensen (Copenhagen, DEN)
17. Vera Bittner (Birmingham, AL, USA)
18. Erin Bohula (Boston, MA, USA, Women as One CLIMB Awardee)
19. Biykem Bozkurt (Houston, TX, USA)
20. Khadijah Breathett (Indianapolis, IN, USA)
21. Javed Butler (Dallas, TX, USA)
22. Jawad Butt (Copenhaguen, DEN)
23. Barry Byrne (Gainesville, FL, USA)
24. David Callans (Philadelphia, PA, USA)
25. Glenn Chertow (Palo Alto, CA, USA)
26. Julio Chirinos (Philadelphia, PA, USA)
27. Brian Claggett (Boston, MA, USA)
28. Leslie Cho (Cleveland, OH, USA)
29. Caroline J Coats (Glasgow, UK, Women as One CLIMB Awardee)
30. Sean Coffey (Dunedin, NZ)
31. David Cohen (New York, NY, USA)
32. Jan Hein Cornel (Nijmegen, NED)
33. Maria Rosa Costanzo (Naperville, IL, USA)
34. Don Cutlip (Boston, MA, USA)
35. Aruna Das Pradhan (Boston, MA, USA)
36. Thomas Deering (Atlanta, GA, USA)
37. David DeMets (Madison, WI, USA)
38. Akshay Desai (Boston, MA, USA)
39. Milind Desai (Cleveland, OH, USA)
40. Laura Desveaux (Toronto, CAN)
41. Ron Do (New York, NY, USA)
42. Kieran Docherty (Glasgow, UK)
43. Mark Dweck (Edinburgh, UK)
44. Joao Ferreira (Porto, POR)
45. Enrico Ferro (Boston, MA, USA)
46. Naomi Fisher (Boston, MA, USA)
47. Mona Fiuzat (Washington, DC, USA)
48. Tim Friede (Göttingen, GER)
49. Annetine Gelijns (New York, NY, USA)
50. Bernard Gersh (Rochester, MN, USA)
51. Michael Gibson (Boston, MA, USA)
52. Nicolas Girerd (Nancy, FRA)
53. Robert Giugliano (Boston, MA, USA)
54. Sonali Gnanenthiran (Sydney, AUS, Women as One CLIMB Awardee)
55. Anne Goldberg (St Louis, MO, USA)
56. Mardi Gomberg-Maitland (Washington, USA)
57. Sascha Goonewardena (Ann Arbor, MI, USA)
58. Christopher Granger (Durham, NC, USA)
59. Barry Greenberg (San Diego, CA, USA)
60. John Gregson (London, UK)
61. Kendra Grubb (Atlanta, GA, USA)
62. M. Edip Gurol (Boston, MA, USA)
63. Robert Hawkins (Ann Arbor, MI, USA)
64. Hiddo Lambers Heerspink (Groningen, NED)
65. Adrian Hernandez (Durham, NC, USA)
66. Felix Hohendanner (Berlin, GER)
67. Kimberly Hong (San Diego, CA, USA)
68. Daphne Hsu (New York, NY, USA)
69. Marc Humbert (Paris, FRA)
70. Borja Ibanez (Madrid, ESP)
71. Lesley Inker (Boston, MA, USA)
72. Jim Januzzi (Boston, MA, USA)
73. Jesper Jensen (Hellerup, DEN)
74. Mariell Jessup (Philadelphia, PA, USA)
75. Markus Kalliola (Helsinki, FIN)
76. David Kandzari (Atlanta, GA, USA)
77. Navin Kapur (Boston, MA, USA)
78. Juan Pablo Kaski (London, UK)
79. Sunjay Kaushal (Chicago, IL, USA)
80. Steven Kawut (Philadelphia, PA, USA)
81. Sander Kersten (Wageningen, NED)
82. Rohan Khera (New Haven, CT, USA)
83. Paulus Kirchhof (Hamburg, GER)
84. Masatake Kobayashi (Tokyo, JPN)

85. Wolfgang Koenig (Munich, GER)
86. Ahmed Kolkailah (Dallas, TX, USA)
87. Marvin Konstam (Boston, MA, USA)
88. Marlys Koschinsky (London, CA)
89. Mikhail Kosiborod (Kansas City, MO, USA)
90. Vijay Kunadian (Newcastle upon Tyne, UK)
91. Harlan Krumholz (New Haven, CT, USA)
92. Neal Lakdawala (Boston, MA, USA)
93. Carolyn Lam (Singapore, SIN)
94. Ulf Landmesser (Berlin, GER)
95. Matthew Lee (Glasgow, UK)
96. Paul Leeson (Oxford/Ultromics, UK)
97. Peter Libby (Boston, MA, USA)
98. Cecilia Linde (Stockholm, SWE)
99. Peter Liu (Toronto, CAN)
100. Angela Lorts (Cincinnati, OH, USA)
101. Lars Lund (Stockholm, SWE)
102. Angela Maas (Nijmegen, NED)
103. Iain MacDougall (London, UK)
104. Theresa McDonagh (London, UK)
105. Darren McGuire (Dallas, USA)
106. Vallerie McLaughlin (Ann Arbor, USA)
107. Martin Maron (Boston, MA, USA)
108. Pieter Martens (Hasselt, BEL)
109. Alexandre Mebazaa (Paris, FRA)
110. Felipe Martinez (Corduba, ARG)
111. Konrad Maruszczyk (Birmingham, UK)
112. Roxana Mehran (New York, NY, USA)
113. Guiomar Mendieta-Badimon (Barcelona, ESP)
114. Robert Mentz (Durham, NC, USA)
115. Steve Messe (Philadelphia, PA, USA)
116. Suneet Mittal (Ridgewood, NJ, USA)
117. Shelley Miyamoto (Denver, CO, USA)
118. Bobak Mortazavi (New Haven, CT, USA)
119. Amy Mottl (Chapel Hill, NC, USA)
120. Mary Mooney (Dublin, IR)
121. Wilfried Mullens (Hasselt, BEL)
122. Paul Muntner (CDC, Atlanta, GA, USA)
123. Firas Mussa (Houston, TX, USA)
124. Kiran Musunuru (Philadelphia, PA, USA)
125. Girish Nadkarni (New York, NY, USA)
126. Patrick Nataf (Paris, FRA)
127. Brendon Neuen (Sydney, AUS)
128. Borge Nordestgaard (Copenhagen, DEN)
129. Chris O'Connor (Washington DC, USA)
130. Michelle O'Donoghue (Boston MA, USA)
131. Stephanie Oestreich (Myeloma Investment Fund, USA)
132. Patrick O'Gara (Boston, MA, USA)
133. Evangelos Oikonomou (New Haven, CT, USA)
134. Iacopo Olivotto (Trieste, ITA)
135. Milton Packer (Dallas, TX, USA)
136. Elfriede Pahl (Chicago, IL, USA)
137. Sahil Parikh (Boston, MA, USA)
138. Elisabetta Patorno (Boston, MA, USA)
139. Emerson Perin (Houston, TX, USA)
140. Mark Petrie (Glasgow, UK)
141. Gregory Piazza (Boston, MA, USA)
142. Philippe Pibarot (Québec, CAN)
143. Jonathan Piccini (Durham, NC, USA)
144. Ileana Piña (Mt Pleasant, MI, USA)
145. Bertram Pitt (Ann Arbor, MI, USA)
146. Elke Platz (Boston, MA, USA)
147. Stuart Pocock (London, UK)
148. Thomas Povsic (Durham, NC, USA)
149. Nawab Qizilbash (OXON Epidemiology, UK)
150. Paolo Raggi (Alberta, CAN)
151. Franck Rahaghi (Weston, FL, USA)
152. Rita Redberg (San Francisco, CA, USA)
153. Yogesh Reddy (Rochester, MN, USA)
154. Paul Ridker (Boston, MA, USA)
155. Frank Rockhold (Durham, NC, USA)
156. Anthony Rodgers (Sydney, AUS)
157. Kenneth Rosenfield (Boston, MA, USA)
158. Robert S. Rosenson (New York, NY, USA)
159. Rachel Rosovsky (Boston, MA, USA)
160. Joseph Rossano (Philadelphia, PA, USA)
161. Xavier Rossello (Madrid, ESP)
162. Lewis J. Rubin (New York, NY, USA)
163. Christian Ruff (Boston, MA, USA)
164. Jennifer Anne Rymer (Durham, NC, USA)
165. Sandeep Sahay (Houston, TX, USA)
166. Naveed Sattar (Glasgow, UK)
167. Gianluigi Savarese (Stockholm, SWE)
168. Heribert Schunkert (Munich, GER)
169. Gregory Schwartz (Denver, CO, USA)
170. Benjamin Scirica (Boston, MA, USA)
171. Eric Secemsky (Boston, MA, USA)
172. Eduard Shantsila (Liverpool, UK)
173. Svati Shah (Durham, NC, USA)
174. Abhinav Sharma (Montreal, CAN)
175. Michael Sharma (Hamilton, CAN)
176. Tabassome Simon (Paris, FRA)
177. Gérald Simonneau (Paris, FRA)
178. Olivier Sitbon (Paris, FRA)
179. Lynn Sleeper (Boston, MA, USA)
180. Scott Solomon (Boston, MA, USA)
181. Claire Snyder (Baltimore, MA, USA)
182. John Spertus (Kansas City, MO, USA)
183. Gregg Stone (New York, NY, USA)
184. Rami Tadros (New York, NY, USA)
185. Pam Taub (San Diego, CA, USA)

186. Jozine Ter Maaten (Groningen, NED)
187. Phyllis Thangaraj (New Haven, CT, USA)
188. Holger Thiele (Leipzig, GER)
189. Paul Thompson (Hartford, CT, USA)
190. Mintu Turakhia (Stanford, CA, USA)
191. Anne Tybjærg-Hansen (Copenhagen, DEN)
192. Jean-Luc Vachiéry (Brussels, BEL)
193. Muthiah Vaduganathan (Boston, MA, USA)
194. Harriette Van Spall (Hamilton, CAN)
195. Orly Vardeny (Minneapolis, MN, USA)
196. Francois Venter (Johannesburg, ZAF)
197. Birgit Vogel (New York, NY, USA)
198. Mary N. Walsh (St Vincent, IN, USA)
199. Nelson Wang (Newtown, AUS)
200. Karol Watson (Los Angeles, CA, USA)
201. Jason Weatherald (Edmonton, CA)
202. Bryan Weiner (Seattle, WA, USA)
203. Cindy Westerhout (Edmonton, CAN)
204. Bryan Williams (London, UK)
205. Lijing L. Yan (Jiangsu, CN)
206. Robert Yeh (Boston, MA, USA)
207. Faiez Zannad (Paris, FRA)
208. Wei Zhou (Tucson, AZ, USA)
209. Wolfram Zimmermann (Göttingen, GER)
210. Carmine Zoccali (Reggio Calabria, ITA)

JOURNAL/MEDIA

211. Michael Basson (Nature Medicine, USA)
212. Robert Bonow (JAMA Cardiology, USA)
213. Filippo Crea (EHJ Editor, ITA)
214. Emile Daoud (JACC Electrophysiology, USA)
215. Joseph Hill (Circulation Editor, USA)
216. Jane Leopold (NEJM, USA)
217. Chana Sacks (NEJM, USA)
218. Jennifer Sargent (Nature, UK)
219. Stuart Spencer (The Lancet, UK)
220. Jan Tijssen (JACC, NED)

INDUSTRY

221. George Adams (Cordis, USA)
222. Philip Adamson (Abbott, USA)
223. Hafid Ait-Oufella (Polygon, FRA)
224. Shazia Ali (Regeneron, USA)
225. Dominic Allocco (Boston Scientific, USA)
226. Sangeetha Anand (CSL Vifor, CH)
227. Charalambos Antoniades (Oxford/Caristo Diagnostics, UK)
228. Puja Banka (Merck, USA)
229. Arnaud Bastien (BMS, USA)
230. Andrew Bellinger (Verve Therapeutics, USA)

231. Maria Borentain (Bayer, GER)
232. Michela Brambatti (Merck, USA)
233. Sandeep Brar (Medtronic, USA)
234. Wout Brusselaers (Deep6 AI, USA)
235. Kristine Buchholtz (Novonordisk, DEN)
236. Jim Carr (Stealth, USA)
237. Ansgar Conrad (Prothema, USA)
238. Gad Cotter (Momentum, USA)
239. Martin Cowie (AstraZeneca, UK)
240. Bjorn Dahlof (Cereno, SWE)
241. Beth Davison (Momentum, USA)
242. Larry Deckelbaum (CSL Behring, USA)
243. Anouk Déruaz-Luyet (Boehringer Ingelheim, GER)
244. Peter Dibattiste (Prolocor, USA)
245. Marc Ditmarsch (New Amsterdam Pharma, NED)
246. Nancy Dreyer (Dreyer strategies, USA)
247. Rich Dujmovic (Boston Scientific, USA)
248. Jay Edelberg (Prolaio, USA)
249. Kevin Elgui (Owkin, FRA)
250. Matthias Fink (Akrateam, GER)
251. Tara Fish (Lemon Tree, USA)
252. Bruno Flamion (Idorsia, CH)
253. Mackenzie Ford (Merck, USA)
254. Leonard Ganz (Abbott, USA)
255. Tomasz Gasior (Boehringer Ingelheim, GER)
256. Jyothis George (Amgen, USA)
257. Sofia Gerward (NovoNordisk, DEN)
258. Hunter Gillies (Aerovate, USA)
259. Allison Goldfine (Novartis, USA)
260. Christine Gouillard (US2.AI, FRA)
261. Eric Green (Maze Therapeutics, USA)
262. Didier Haguenaer (Cellprothera, FRA)
263. James Hall (Betagenon/Cambrian, SWE)
264. Signe Harring (NovoNordisk, DEN)
265. Irene Hedelund Langbakke (NovoNordisk, DEN)
266. Therese Heinonen (Trialynx, USA)
267. Stephen Heitner (Cytokinetics, USA)
268. Robert Hillman (Celecor, USA)
269. Udo Hoffman (Cleverly, USA)
270. Bradley Horst (Boston Scientific, USA)
271. Anders Hvelplund (NovoNordisk, DEN)
272. Daniel Jacoby (Cytokinetics, USA)
273. Michael Jaff (Boston Scientific, USA)
274. Klaus Jensen (Vectura Fertin, CH)
275. Rebecca Juliano (Juliano Consulting, USA)
276. Takehiko Kaneko (Heartseed, JPN)
277. Amit Khera (Verve Therapeutics, Boston, MA, USA)
278. Robert Kroschwitz (Berlin Heart, USA)
279. Rebecca Kunder (IGM Biosciences, USA)
280. Stuart Kupfer (Cytokinetics, USA)

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281. Brendan Christopher Jones (NovoNordisk, DEN)
282. Alessandra Lafranconi (Boehringer, GER)
283. Andres Laguna (Novartis, CH)
284. Anna Maria Langkilde (AstraZeneca, SWE)
285. Francesca Lawson (Corteria Pharmaceuticals, FRA)
286. David Lebwohl (Intellia, USA)
287. Marty Lefkowitz (Novartis, USA)
288. Anastasia Lesogor (Novartis, CH)
289. Concetta Lipardi (Janssen, USA)
290. Dustin Little (AstraZeneca, UK)
291. Antonio Lopez (AMGEN, USA)
292. Hank Mansbach (89bio, USA)
293. Michele Mercuri (Alexion, USA)
294. Laura Michael (Lilly, USA)
295. Marie Mide Michelsen (NovoNordisk, DEN)
296. Pieter Muntendam (SQ Innovation, USA)
297. Masahiro Murakami (Eli Lilly, USA)
298. Gillian Murtagh (Abbott, USA)
299. Stefan Nilsson (Lipigon Pharmaceuticals, SWE)
300. Syed Numan (American Regent, USA)
301. Mahesh Patel (Merck, USA)
302. Shira Perl (AstraZeneca, SWE)
303. Garrett Pilcher (Medtronic, USA)
304. Ron Portman (Novartis, USA)
305. Jürgen Prochaska (Boehringer Ingelheim, GER)
306. Stacey Ruiz (Renibus, USA)
307. Adel Rizkala (Novartis, USA)
308. Laura Robertson (Tenaya, USA)
309. Matthew Roe (AstraZeneca, USA)
310. Lothar Roessig (Bayer, GER)
311. Harry Rowland (Endotronix, USA)
312. Giacomo Ruotolo (Lilly, USA)
313. Amr Salahieh (Supira, USA)
314. Jonathan Schwartz (RocketPharma, USA)
315. Amy Sehnert (BMS, USA)
316. Maria Sejersten Ripa (NovoNordisk, DEN)
317. Kimberly Selzman (Boston Scientific, USA)
318. Marc Semigran (Edgewise, USA),
319. Monica Shah (Rocket Pharma, USA)
320. Salim Shah (Sarfez, USA)
321. Alka Shaunik (CSL Behring, USA)
322. Charles Simonton (Abiomed, USA)
323. Jack Springer (Nectero Medical, USA)
324. Evan Stein (LIBTherapeutics, USA)
325. Kenneth Stein (Boston Scientific, USA)
326. Dominik Steubl (Boehringer Ingelheim, GER)
327. James Strait (Merck, USA),
328. Karsten Strauß (Olink, SWE)
329. Mikhail Sumin (Boehringer Ingelheim, GER)
330. Tadaaki Taniguchi (Astellas, USA)
331. Thomas Thum (Cardior, GER)
332. Pierluigi Tricoci (CSL Behring, USA)
333. Sam Tsimikas (Ionis, USA)
334. Martin van Eickels (Bayer, GER)
335. -Jessica Williams (Somalogic, USA)
336. Janet Wittes (Wittes LLC, USA)
337. Fred Yang (KBP, USA)
338. Nadim Yared (CVRx, USA)
339. Antoine Yver (Centessa, USA)
340. André Ziegler (Roche, CH)
341. Larry Zisman (Gossamer, USA)
342. Eapen Zubin (Element Science, USA)
- ## REGULATORY
343. Rosalyn Adigun (FDA, USA)
344. Stephen Browning (FDA, USA)
345. Rob Califf (FDA commissioner, USA)
346. Terri Cornelison (FDA, USA)
347. Aneesh Deoras (FDA, USA)
348. Ronald Fairman (FDA, USA)
349. Andrew Farb (FDA, USA)
350. Charu Gandotra (FDA, USA)
351. Nicole Gillette (FDA, USA)
352. Lydia Glaw (FDA, USA)
353. Matthew Hillebrenner (FDA, USA),
354. Nicole Ibrahim (FDA, USA)
355. Alar Irs (EMA, EST)
356. Rekha Kambhampati (FDA, USA)
357. Douglas Kelly (FDA, USA)
358. Maciej Kostrubiec (EMA, POL)
359. Steven Lossef (FDA, USA)
360. Peter Marks (FDA, USA)
361. Janet Maynard (FDA, USA)
362. Tom Melvin (Dublin, IRE)
363. Mauro Moscucci (FDA, USA)
364. Gregory O'Connell (FDA, USA)
365. Jordan Pomeroy (FDA, USA)
366. Mitch Psootka (FDA, USA)
367. Jaime Raben (FDA, USA)
368. Mark Rothman (FDA, USA)
369. Fortunato Senatore (FDA, USA)
370. John Sharretts (FDA, USA)
371. Norman Stockbridge (FDA, USA)
372. Piotr Szymanski (EU, POL)
373. Steffen Thirstrup (EMA, CMO, NED)
374. Aliza Thompson (FDA, USA)
375. Katherine Trivedi (FDA, USA)
376. George van Hare (FDA, USA)
377. Bernard Vasseur (FDA, USA)
378. Changfu Wu (FDA, USA)
379. Jialu Zhang (FDA, USA)

380. Bram Zuckerman (FDA, USA)

NIH / NHLBI

- 381. Kristin Burns (NHLBI, NIH, USA)
- 382. Kathleen Fenton (NIH, USA)
- 383. Tracy Finch (NIHR, UK)
- 384. Rebecca Gottesman (NIH/NINDS, USA)
- 385. Erin Iturriaga (NHLBI, NIH, USA)
- 386. Cara Lewis (NHLBI, NIH, USA),
- 387. George Mensah (NHLBI, NIH, USA)
- 388. Gail Pearson (NIH, USA)
- 389. Yves Rosenberg (NHLBI, NIH, USA)
- 390. Kavita Singh (Public Health Foundation, IND)

PATIENTS/PATIENTS REPRESENTATIVES

- 391. Jacqueline Alikhaani (Los Angeles, USA)
- 392. Sadegh Alikhaani (Los Angeles, USA)
- 393. Marc Bains (HeartLife Foundation, CAN)
- 394. Naomi Buntsma (Amsterdam, NED)
- 395. Philip Collis (British Heart Foundation, UK)
- 396. Robin Gage (Lakeland, FL, USA)
- 397. Patrick Gee (Chesterfield, MO, USA)
- 398. Penilla Gunther (Stockholm, SWE)
- 399. Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)
- 400. Martha Hill (Baltimore, MD, USA)
- 401. Greg Merritt (Patient is Partner, USA)
- 402. Rhonda Monroe (Baltimore, MD, USA)
- 403. Gina Peattie (Children's Cardiomyopathy Foundation, USA)
- 404. Juddson Rupp (Milestone Pharmaceuticals, USA)
- 405. Lisa Salberg (HCMA, USA)
- 406. Mellanie True Hills (StopAfib.org, USA)
- 407. Mariette Verbakel (Nijmegen, NED)

LAWYERS / ETHICS

- 408. Dave Clissold (HPM, USA)
- 409. Michael Ewer (Houston, TX, USA)
- 410. Evelyne Friedel (Paris, FRA)
- 411. Kayte Spector-Bagdady (Ann Arbor, MI, USA)
- 412. Frank Sasinowski (HPM, USA)
- 413. Ellis Unger (HPM, WA, USA)
- 414. Alex Varond (Goodwin, USA)

PAYER / ECONOMISTS / INVESTORS

- 415. Steven Farmer (CMS, USA)
- 416. Alan Fraser (CORE-MD, UK)

417. Peter Kolchinsky (RA Capital Management, USA)

- 418. Jason Gordon (HEOR, UK)
- 419. Marco Marchetti (Agenas and EU HTA, ITA)
- 420. Stuart Mealing (YHEC, UK)
- 421. Steve Stranne (Foley Hoag, USA)
- 422. Dan Ollendorf (Boston, MA, USA)

THURSDAY, NOVEMBER 30TH

LUNCH SERVED AT THE MEETING VENUE

BALLROOM

8:30 - 10:30

Cardiokidney drugs trials

[view details >>](#)

10:30

11:00



11:00 - 13:00

Innovation in device trials. FDA TAP

[view details >>](#)

13:00

14:00



14:00 - 16:00

Evidence generation in Electrophysiology

[view details >>](#)

16:00

16:30



16:30 - 19:00

Obesity CV trials 1

[view details >>](#)

CONFERENCE

8:30 - 10:30

Digital tools for clinical trials

[view details >>](#)

10:30

11:00



11:00 - 13:00

Master Class Statistical Design

[view details >>](#)

13:00

14:00



14:00 - 16:00

Master Class Statistical design & reporting 2

[view details >>](#)

16:00

16:30



16:30 - 19:00

Biologics and cell therapy

[view details >>](#)

HOLEMAN

8:30 - 10:30

Neurocardiology trials

[view details >>](#)

10:30

11:00



11:00 - 13:00

Lp(a) and inflammation athero trials

[view details >>](#)

13:00

14:00



14:00 - 16:00

Gene editing atherosclerosis trials

[view details >>](#)

16:00

16:30



16:30 - 19:00

Triglyceride athero trials

[view details >>](#)

FOURTH ESTATE

8:30 - 10:30

Diversity among trialists

[view details >>](#)

10:30

11:00



11:00 - 13:00

Aortic Stenosis trials

[view details >>](#)

13:00

14:00



14:00 - 16:00

Biotech trials

[view details >>](#)

16:00

16:30



16:30 - 19:00

Cardiomyopathies

[view details >>](#)

ROOM 5

16:30 - 19:30

iCVCT Device approval and reimbursement

[view details >>](#)

FRIDAY, DECEMBER 1ST

LUNCH SERVED AT THE MEETING VENUE

BALLROOM

8:30 - 10:30

Obesity CV trials 2

[view details >>](#)

10:30

11:00



11:00 - 13:00

**Industry_back_to_
CV_Innovation**

[view details >>](#)

13:00

14:00



14:00 - 17:00

AI for clinical trials

[view details >>](#)

CONFERENCE

8:30 - 10:30

**Implementation
lipid lowering
drugs**

[view details >>](#)

10:30

11:00



11:00 - 13:00

**iCVCT_surgical_
trials**

[view details >>](#)

13:00

14:00



14:00 - 17:00

Hypertension

[view details >>](#)

HOLEMAN

8:30 - 10:30

**Pulmonary arterial
hypertension 1**

[view details >>](#)

10:30

11:00



11:00 - 13:00

**Pulmonary arterial
hypertension 2**

[view details >>](#)

13:00

14:00



14:00 - 17:00

**Cholesterol athero
trials**

[view details >>](#)

FOURTH ESTATE

8:30 - 10:30

iCVCT Shock

[view details >>](#)

10:30

11:00



11:00 - 13:00

**Iron_in_heart_
failure**

[view details >>](#)

13:00

14:00



14:00 - 17:00

**Pediatric cell-gene
trials**

[view details >>](#)

18:00 - 19:00 Keynote lecture at the Ronald Reagan Building

19:00 CVCT 20TH ANNIVERSARY CELEBRATION

ATRIUM OF THE RONALD REAGAN CENTER

SATURDAY, DECEMBER 2ND

LUNCH SERVED AT THE MEETING VENUE

BALLROOM

8:30 - 10:30

iCVCT_Peripheral_artery_disease

[view details >>](#)

10:30
11:00



11:00 - 13:00

CV trials in ESKD

[view details >>](#)

13:00
14:00



14:00 - 16:00

Implementation of cardiokidney drugs

[view details >>](#)

16:00
16:30



16:30 - 19:00

Endpoints in cardiokidney trials

[view details >>](#)

CONFERENCE

8:30 - 10:30

Implementation science

[view details >>](#)

10:30
11:00



11:00 - 13:00

Real World Evidence

[view details >>](#)

13:00
14:00



14:00 - 16:00

SGLT2i MI trials

[view details >>](#)

16:00
16:30



16:30 - 19:00

iCVCT Thrombosis trials

[view details >>](#)

HOLEMAN

8:30 - 10:30

Trialists – Industry relationships

[view details >>](#)

10:30
11:00



11:00 - 13:00

Patient trialists

[view details >>](#)

13:00
14:00



14:00 - 16:00

Biomarkers

[view details >>](#)

16:00
16:30



16:30 - 19:00

Heart failure RWE for implementation

[view details >>](#)

FOURTH ESTATE

8:30 - 10:30

Women in clinical trials

[view details >>](#)

10:30
11:00



11:00 - 13:00

iCVCT Aortic and carotid disease

[view details >>](#)

13:00
14:00



14:00 - 16:00

Pediatric CV trials

[view details >>](#)

16:00
16:30



16:30 - 19:00

Law and Ethics in trials

[view details >>](#)

Ballroom
Thursday 30 November, 2023
8:30 -10:30

CHRONIC HEART KIDNEY DISORDER TRIALS.
HITTING TWO BIRDS WITH A SINGLE STONE. DRUGS WITH CARDIAC AND KIDNEY BENEFITS
Chairpersons : Amy Mottl (Chapel Hill, NC, USA), Carmine Zoccali (Reggio Calabria, ITA)

Towards a unified framework of Chronic Heart Kidney Disorder (CHKD)
Faiez Zannad (Paris, FRA)

Investigating common mechanistic pathways underlying the progression of CKD and CVD.
Milton Packer (Dallas, TX, USA)

GLP1RAs to prevent CV outcomes in T2D and CKD. The SOUL trial.
Darren McGuire (Dallas, USA)

MRAs for Chronic Heart Kidney Disorder
George Bakris (Chicago, IL, USA)

Meta-analytical insights from the SGLT-2 Meta-Analysis Cardio-Renal Trialists' Consortium (SMART-C)
Brendon Neuen (Sydney, AUS)

Exploring the inflammation pathway. From RESCUE to ZEUS
Paul Ridker (Boston, MA, USA)

The potential of myeloperoxidase inhibition for heart failure with preserved ejection fraction
Lars Lund (Stockholm, SWE)

Industry viewpoints
Kristine Buchholtz (NovoNordisk, DEN), Jürgen Prochaska (Boehringer, GER), Martin van Eickels (Bayer, GER)

THE CVCT Multi-Stakeholder Panel Debate

CHRONIC HEART KIDNEY DISORDER TRIALS
HOW TO PROGRESS THE AGENDA OF A COMMON CHRONIC HEART KIDNEY DISORDER ?
Chairpersons : Amy Mottl (Chapel Hill, NC, USA), Carmine Zoccali (Reggio Calabria, ITA)

Panelists : George Bakris (Chicago, IL, USA), Kristine Buchholtz (NovoNordisk, DEN), Tomasz Gasior (Boehringer, GER), Lars Lund (Stockholm, SWE), Darren McGuire (Dallas, USA), Amy Mottl (Chapel Hill, NC, USA), Brendon Neuen (Sydney, AUS), Milton Packer (Dallas, TX, USA), Jürgen Prochaska (Boehringer, GER), Paul Ridker (Boston, MA, USA), Martin van Eickels (Bayer, GER), Faiez Zannad (Paris, FRA), Carmine Zoccali (Reggio Calabria, ITA)

Conference
Thursday 30 November, 2023
8:30 -10:30

DIGITAL TOOLS FOR TRIAL DESIGN AND EXECUTION

Chairpersons: Harlan Krumholz (New Haven, CT, USA), Carolyn Lam (Singapore, SIN)

AI to help target relevant trial patient populations

ECG

Rohan Khera (New Haven, CT, USA)

Imaging : Atherosclerosis, Stenosis, Ischemia, Inflammation
Charalambos Antoniades (Oxford/Caristo Diagnostics, UK)

Ultrasound

Carolyn Lam (Singapore, SIN)

Industry viewpoints

Wout Brusselaers (Deep6 AI, USA), Paul Leeson (Oxford/Ultromics, UK), Suneet Mittal (Ridgewood, NJ, USA)

Adaptive Enrichment of Clinical trials with AI
Evangelos Oikonomou (New Haven, CT, USA)

Digital transformation of Patient Recruitment, Engagement and Retention.
Adrian Hernandez (Durham, NC, USA)

Wearable digital health technologies in the context of trial designs
Sanjeev Bhavnani (San Diego, CA, USA)

What will immersive technologies bring to health care?
Patrick Nataf (Paris, FRA)

NIH viewpoint

Erin Iturriaga (NHLBI, NIH, USA)

THE CVCT Multi-Stakeholder Panel Debate

DIGITAL TOOLS FOR TRIAL DESIGN AND EXECUTION

Chairpersons: Harlan Krumholz (New Haven, CT, USA), Carolyn Lam (Singapore, SIN)

Panelists: Charalambos Antoniades (Oxford/Caristo Diagnostics, UK), Sanjeev Bhavnani (San Diego, CA, USA), Wout Brusselaers (Deep6 AI, USA), Jay Edelberg (ProLiaio, USA), Aneesh Deoras (FDA, USA), Adrian Hernandez (Durhama, NC, USA), Erin Iturriaga (NHLBI, NIH, USA), Rohan Khera (New Haven, CT, USA), Harlan Krumholz (New Haven, CT, USA), Carolyn Lam (Singapore, SIN), Paul Leeson (Oxford/Ultromics, UK), Suneet Mittal (Ridgewood, NJ, USA), Evangelos Oikonomou (New Haven, CT, USA)

Holeman
Thursday 30 November, 2023
8:30 -10:30

NEUROCARDIOLOGY
RUNNING MULTIDISCIPLINARY TRIALS IN AN EMERGING SPECIALTY
Chairpersons : Rebecca Gottesman (NIH/NINDS, USA), Edip Gurol (Boston, MA, USA)

Neurocardiology: Ongoing trials and why do we need to collaborate?
Edip Gurol (Boston, MA, USA)

Not all strokes are equally serious. How to adjudicate and better quantify the long-term implications of “events”?
Akshay Desai (Boston, MA, USA)

Stroke Prevention in Atrial Fibrillation with Ablation and Left Atrial Appendage Closure
Paulus Kirchhof (Hamburg, GER)

Stroke in heart failure and no atrial fibrillation. The case for a randomized NOAC trial
Faiez Zannad (Paris, FRA)

The gut-brain -axis and the opportunity for pharmacological intervention to reduce cognitive decline in Heart Failure .
Bertram Pitt (Ann Arbor, MI, USA)

Should cognitive decline be part of CV prevention trials?
Rebecca Gottesman (NIH/NINDS, USA)

Industry viewpoints
Kenneth Stein (Boston Scientific, USA), James Strait (Merck, USA), Pierluigi Tricoci (CSL Behring, USA)

Regulatory viewpoints. Neurocardiology claims for CV therapies
Maciej Kostrubiec (EMA, POL)
Jordan Pomeroy (FDA, USA)

THE CVCT Multi-Stakeholder Panel Debate

NEUROCARDIOLOGY
RUNNING MULTIDISCIPLINARY TRIALS IN AN EMERGING SPECIALTY
Chairpersons : Rebecca Gottesman (NIH/NINDS, USA), Edip Gurol (Boston, MA, USA)

Panelists : Akshay Desai (Boston, MA, USA), Rebecca Gottesman (NIH/NINDS, USA), M. Edip Gurol (Boston, MA, USA), Paulus Kirchhof (Hamburg, GER), Maciej Kostrubiec (EMA, POL), Bertram Pitt (Ann Arbor, MI, USA), Jordan Pomeroy (FDA, USA), Kenneth Stein (Boston Scientific, USA) , James Strait (Merck, USA), Pierluigi Tricoci (CSL Behring, USA), Katherine Trivedi (FDA, USA), Faiez Zannad (Paris, FRA)

Fourth Estate
Thursday 30 November, 2023
8:30 -10:30

HOW TO PROMOTE DIVERSITY AMONG TRIALISTS LEADERSHIP

Chairpersons: Roxana Mehran (New York, NY, USA), Guiomar Mendieta-Badimon (Barcelona, ESP)

Why is trial leadership still lacking diversity and what changes need to be made?

Escalator Award experience and perspective

Jennifer Anne Rymer (Durham, NC, USA)

Khadijah Breathett (Indianapolis, IN, USA)

Pro-active solutions for diversifying clinical trialists leadership

ACC Upping Your Game

Mary N. Walsh (St Vincent, IN, USA)

ESC initiative

Cecilia Linde (Stockholm, SWE)

Women as One solutions

Roxana Mehran (New York, NY, USA)

How industry sponsors may promote diversity among trialists leadership

Jyothis George (Amgen, USA)

CVCT Future trialists fellowship

Guiomar Mendieta-Badimon (Barcelona, ESP)

Geographical diversity. CVCT Asia and CVCT Africa Middle East

Faiez Zannad (Paris, FRA)

Geographical diversity. LATAM countries

Felipe Martinez (Corduba, ARG)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO PROMOTE DIVERSITY AMONG TRIALISTS LEADERSHIP RUNNING MULTIDISCIPLINARY TRIALS IN AN EMERGING SPECIALTY

Chairpersons: Roxana Mehran (New York, NY, USA), Guiomar Mendieta-Badimon (Barcelona, ESP)

Panelists : Khadijah Breathett (Indianapolis, IN, USA), Jyothis George (Amgen, USA), Lydia Glaw (FDA, USA), Cecilia Linde (Stockholm, SWE), Felipe Martinez (Corduba, ARG), Roxana Mehran (New York, NY, USA), Guiomar Mendieta-Badimon (Barcelona, ESP), Anne Rymer (Durham, NC, USA), Alka Shaunik (GSL Behring, USA), Tabassome Simon (Paris, FRA), Harriette Van Spall (Hamilton, CAN), Mary N. Walsh (St Vincent, IN, USA), Faiez Zannad (Paris, FRA)

Ballroom
Thursday 30 November, 2023
11:00 - 13:00

**ACCELERATING ADOPTION OF INNOVATIVE CARDIOVASCULAR DEVICES
THE TOTAL PRODUCT LIFE CYCLE ADVISORY PROGRAM (TAP)**

Chairpersons: Jonathan Piccini (Durham, NC, USA), Ileana Piña (Mt Pleasant, MI, USA)

The FDA total Product Life Cycle Advisory program (TAP)
Douglas Kelly (FDA, USA)

Rapid fire use cases: (5min presentations)

LUX-HL Experience in the TAP Program Pilot
Rich Dujmovic (Boston Scientific, USA)

TAVR
Garrett Pilcher (Medtronic, USA)

Cardiomems
Philip Adamson (Abbott, USA)

Involving multiple stakeholders at the beginning of a program to accelerate adoption and access.

How is EU going to catch up? The promises of EU CORE-MD
Alan Fraser (CORE-MD, UK)

The new EU Health Technology Assessment Regulation and how it may impact innovation
Tom Melvin (Dublin, IRE)

Industry viewpoints
Matthias Fink (Akrateam, GER), Harry Rowland (Endotronix, USA), Nadim Yared (CVRx, USA)

THE CVCT Multi-Stakeholder Panel Debate

THE TOTAL PRODUCT LIFE CYCLE ADVISORY PROGRAM (TAP). READY FOR PRIMETIME?
Chairpersons: Jonathan Piccini (Durham, NC, USA), Ileana Piña (Mt Pleasant, MI, USA)

Panelists : Philip Adamson (Abbott, USA), Emile Daoud (JACC Electrophysiology, USA), Rich Dujmovic (Boston Scientific, USA), Matthias Fink (Akrateam, GER), Alan Fraser (CORE-MD, UK), Matthew Hillebrenner (FDA, USA), Douglas Kelly (FDA, USA), Tom Melvin (Dublin, IRE), Jonathan Piccini (Durham, NC, USA), Ileana Piña (Mt Pleasant, MI, USA), Garrett Pilcher (Medtronic, USA), Harry Rowland (Endotronix, USA), Nadim Yared (CVRx, USA)

Conference
Thursday 30 November, 2023
11:00 - 13:00

CVCT MasterClass Part 1
STATISTICAL DESIGN AND REPORTING OF PIVOTAL TRIALS:
HOW TO SUCCEED WITH REGULATORS AND JOURNALS

Chairpersons: Bernard Gersh (Rochester, MN, USA), Stuart Pocock (London, UK)

This MasterClass will cover those key aspects of clinical trial design and reporting that are particularly important for pivotal trials that are destined for regulatory approval and for publication. The four statistician speakers and seven discussants have a wealth of experience in cardiovascular trials and are keen to share their insights on what succeeds and what goes wrong in clinical trials, illustrated by specific trial examples.

How to succeed (and fail) with journals and regulators

How to irritate journal editors and regulators when reporting a randomized trial
Janet Wittes (Wittes LLC, USA)

Optimizing communications to key stakeholders: transparency is not always clear
Frank Rockhold (Durham, NC, USA)

Investigator viewpoint
Gregg Stone (New York, NY, USA)

Regulatory Discussant
Jialu Zhang (FDA, USA)

Editor Discussants
Michael Basson (Nature Medicine, USA)
Stuart Spencer (The Lancet, UK)

GENERAL DISCUSSION

Panelists : Michael Basson (Nature Medicine, USA), Bernard Gersh (Rochester, MN, USA), John Gregson (London, UK), Roxana Mehran (New York, NY, USA), Stuart Pocock (London, UK), Frank Rockhold (Durham, NC, USA), Stuart Spencer (The Lancet, UK), Gregg Stone (New York, NY, USA), Jan Tijssen (JACC, NED), Janet Wittes (Wittes LLC, USA), Jialu Zhang (FDA, USA)

Holeman
Thursday 30 November, 2023
11:00 - 13:00

CLINICAL TRIALS TARGETING LIPOPROTEIN(a) and INFLAMMATION FOR ATHEROSCLEROSIS THERAPY
Chairpersons: Marlys Koschinsky (London, CA), Robert Rosenson (New York, NY, USA)

Lp(a) Consensus Statements.
Marlys Koschinsky (London, CA)

What we know and what we don't know about Lp(a) associated risk
Sascha Goonewardena (Ann Arbor, MI, USA)

HORIZON Update
Leslie Cho (Cleveland, OH, USA)

OCEAN(a) Update
Michelle O'Donoghue (Boston, MA, USA)

Colchicine trials, update
US perspective
Paul Ridker (Boston, MA, USA)

EU perspective
Jan Hein Cornel (Nijmegen, NED)

Cytokine disruption, inflammasome and other targets
Peter Libby (Boston, MA, USA)

Regulatory viewpoints
Roselyn Adigun (FDA, USA)
Maciej Kostrubiec (EMA, POL)

Industry viewpoints
Sofia Gerward (NovoNordisk, DEN), Udo Hoffman (Clearly, USA), Antonio Lopez (AMGEN, USA), Laura Michael (Lilly, USA)

Patient viewpoint
Sadegh Alikhaani (Los Angeles, USA)

THE CVCT Multi-Stakeholder Panel Debate

CLINICAL TRIALS TARGETING LIPOPROTEIN(a) and INFLAMMATION FOR ATHEROSCLEROSIS THERAPY
Chairpersons : Marlys Koschinsky (London, CA), Robert Rosenson (New York, NY, USA)

Panelists : Roselyn Adigun (FDA, USA), Sadegh Alikhaani (Los Angeles, USA), Leslie Cho (Cleveland, OH, USA) , Jan Hein Cornel (Nijmegen, NED), Aruna Das Pradhan (Boston, MA, USA), Sofia Gerward (NovoNordisk, DEN), Sascha Goonewardena (Ann Arbor, MI, USA), Udo Hoffman (Clearly, USA), Sander Kersten (Wageningen, NED) , Marlys Koschinsky (London, CA), Maciej Kostrubiec (EMA, POL), Peter Libby (Boston, MA, USA), Antonio Lopez (AMGEN, USA), Hank Mansbach (89bio, USA), Laura Michael (Lilly, USA), Stefan Nilsson (Lipigon Pharmaceuticals, SWE), Borge Nordestgaard (Copenhagen, DEN), Michelle O'Donoghue (Boston, MA, USA), Paul Ridker (Boston, MA, USA), Robert Rosenson (New York, NY, USA), Giacomo Ruotolo (Lilly, USA), Anne Tybjærg-Hansen (Copenhagen, DEN)

Fourth Estate
Thursday 30 November, 2023
11:00 - 13:00

TRIALS OF PROGRESSION OF AORTIC VALVE STENOSIS

Chairpersons: Robert Bonow (JAMA Cardiology, USA), Philippe Pibarot (Québec, CAN)

The natural history of AS progression and why medical therapy for calcific aortic valve disease is an unmet need?
Sean Coffey (Dunedin, NZ)

Aortic valve stenosis as an atherosclerosis endpoint

Lipid Lowering for AS progression trials
Mark Dweck (Edinburgh, UK)

Targeting oxidized phospholipids: is this the link to Lp(a) -mediated aortic valve calcification?
Sam Tsimikas (Ionis, USA)

Imaging endpoints in aortic valve stenosis trials.
Mark Dweck (Edinburgh, UK)

How to progress toward feasible, affordable and clinically meaningful aortic valve stenosis trials?
Philippe Pibarot (Québec, CAN)

Ethical and DSMB viewpoint:
David Demets (Madison, WI, USA)

Industry viewpoints:
Larry Deckelbaum (CSL Behring, USA), Andres Laguna (Novartis, CH)

Regulatory viewpoint
Charu Gandotra (FDA, USA)

THE CVCT Multi-Stakeholder Panel Debate

TRIALS OF PROGRESSION OF AORTIC VALVE STENOSIS

Chairpersons: Robert Bonow (JAMA Cardiology, USA), Philippe Pibarot (Québec, CAN)

Panelists : Robert Bonow (JAMA Cardiology, USA), Sean Coffey (Dunedin, NZ), Larry Deckelbaum (CSL Behring, USA), David Demets (Madison, WI, USA), F Mark Dweck (Edinburgh, UK), Charu Gandotra (FDA, USA), Andres Laguna (Novartis, CH), Philippe Pibarot (Québec, CAN), Bertram Pitt (Ann Arbor, MI, USA), Sam Tsimikas (Ionis, USA)

Ballroom
Thursday 30 November, 2023
14:00 - 16:00

EVIDENCE GENERATION IN ELECTROPHYSIOLOGY AND ARRHYTHMIAS

Chairpersons : Thomas Deering (Atlanta, GA, USA), Mariell Jessup (Philadelphia, PA, USA)

Does the current evidence generation enterprise provide the scientific basis for interventional and device electrophysiology clinical practice

Electrophysiologists

USA: David Callans (Philadelphia, PA, USA)

EU: Felix Hohendanner (Berlin, GER)

HF specialist

Lars Lund (Stockholm, SWE)

Industry viewpoint

Kenneth Stein (Boston Scientific, USA)

Regulatory viewpoints

George van Hare (FDA, USA)

Piotr Szymanski (EU, POL)

HTAs viewpoint

Marco Marchetti (Agenas and EU HTA, ITA)

Early rhythm control strategies. Value and limitation of pragmatic trials.

Paulus Kirchhof (Hamburg, GER)

Jonathan Piccini (Durham, NC, USA)

What paradigm-shifting paper I would like to see, as a journal editor?

Emile Daoud (JACC Electrophysiology, USA)

Patient viewpoints

Mariette Verbakel (Nijmegen, NED)

Industry discussants:

Leonard Ganz (Abbott, USA), Kimberly Selzman (Boston Scientific, USA)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO IMPROVE EVIDENCE GENERATION IN ELECTROPHYSIOLOGY

Chairpersons : Thomas Deering (Atlanta, GA, USA), Mariell Jessup (Philadelphia, PA, USA)

Panelists : David Callans (Philadelphia, PA, USA), Emile Daoud (JACC Electrophysiology, USA), Thomas Deering (Atlanta, GA, USA), Leonard Ganz (Abbott, USA), Felix Hohendanner (Berlin, GER), Mariell Jessup (Philadelphia, PA, USA), Paulus Kirchhof (Hamburg, GER), Lars Lund (Stockholm, SWE), Marco Marchetti (Agenas and EU HTA, ITA), Jonathan Piccini (Durham, NC, USA), Kimberly Selzman (Boston Scientific, USA), Kenneth Stein (Boston Scientific, USA), Piotr Szymanski (EU, POL), George van Hare (FDA, USA), Mariette Verbakel (Nijmegen, NED)

Conference
Thursday 30 November, 2023
14:00 - 16:00

CVCT MasterClass Part 2
STATISTICAL DESIGN AND REPORTING OF PIVOTAL TRIALS:
HOW TO SUCCEED WITH REGULATORS AND JOURNALS
Chairpersons: Gregg Stone (New York, NY, USA), Jan Tijssen (JACC, NED)

This MasterClass will cover those key aspects of clinical trial design and reporting that are particularly important for pivotal trials that are destined for regulatory approval and for publication. The four statistician speakers and seven discussants have a wealth of experience in cardiovascular trials and are keen to share their insights on what succeeds and what goes wrong in clinical trials, illustrated by specific trial examples.

Choice of primary and secondary outcomes, testing strategies, subgroup analyses, journal guidelines, adaptive designs
Stuart Pocock (London, UK)

Competing risks, missing data, repeat event analyses, win ratio strategies
John Gregson (London, UK)

Investigator viewpoint
Gregg Stone (New York, NY, USA)

Regulatory Discussant
Jialu Zhang (FDA, USA)

Editor Discussant
Jan Tijssen (JACC, NED)

GENERAL DISCUSSION

Panelists : Michael Basson (Nature Medicine, USA), John Gregson (London, UK), Roxana Mehran (New York, NY, USA), Stuart Pocock (London, UK), Frank Rockhold (Durham, NC, USA), Stuart Spencer (The Lancet, UK), Gregg Stone (New York, NY, USA), Jan Tijssen (JACC, NED), Janet Wittes (Wittes LLC, USA), Jialu Zhang (FDA, USA)

HOLEMAN
Thursday 30 November, 2023
14:00 - 16:00

TRIALS TARGETING LIPOPROTEINS WITH NEW MOLECULAR TOOLS

Chairpersons: Kiran Musunuru (Philadelphia, PA, USA), Paul Ridker (Boston, MA, USA)

Genetic information in decision making for CV therapy
Heribert Schunkert (Munich, GER)

Machine learning-based estimation of coronary artery disease risk
Ron Do (New York, NY, USA)

Gene replacement for dyslipidemia
Archna Bajaj (Philadelphia, PA, USA)

Gene editing for dyslipidemias
Kiran Musunuru (Philadelphia, PA, USA)

Developing 'once-and-done' gene editing medicines to treat cardiovascular disease
Andrew Bellinger (Verve Therapeutics, USA)

In vivo base editing of ANGPTL3 to lower LDL-C and TG to treat atherosclerotic cardiovascular disease
Amit Khera (Verve Therapeutics, Boston, MA, USA)

Industry viewpoints:
Andrew Bellinger (Verve Therapeutics, USA)

Regulatory viewpoints. The way to Approval for sRNA therapies
Rosalyn Adigun (FDA, USA)

Patient viewpoint
Greg Merritt (Patient is Partner, USA)

THE CVCT Multi-Stakeholder Panel Debate

TRIALS TARGETING LIPOPROTEINS WITH NEW MOLECULAR TOOLS

Clinical trials challenges with biotechnological lipid therapies

Chairpersons: Kiran Musunuru (Philadelphia, PA, USA), Paul Ridker (Boston, MA, USA)

Panelists : Rosalyn Adigun (FDA, USA), Archna Bajaj (Philadelphia, PA, USA), Andrew Bellinger (Verve Therapeutics, USA), Ron Do (New York, NY, USA), Amit Khera (Verve Therapeutics, Boston, MA, USA), Greg Merritt (Patient is Partner, USA), Kiran Musunuru (Philadelphia, PA, USA), Paul Ridker (Boston, MA, USA), Heribert Schunkert (Munich, GER)

Fourth Estate
Thursday 30 November, 2023
14:00 - 16:00

WHAT CLINICAL TRIALISTS MAY LEARN FROM BIOTECH PIONEERS?

Chairpersons: Peter Libby (Boston, MA, USA), Stephanie Oestreich (Myeloma Investment Fund, USA)

How to bring a Biotech concept to clinical trial. The example of RNA therapeutics becoming a CV reality
Thomas Thum (Cardior, GER)

Practitioner & Founder - paradox or possibility
Hafid Ait-Oufella (Polygon, FRA)

Large Biotech-Small Biotech: lessons learned
Rebecca Kunder (IGM Biosciences, USA)

Conducting quality trials for a start up
Therese Heinonen (Trialyx, USA)

How to be an intrapreneur in Pharma
Allison Goldfine (Novartis, USA)

Managing an imaging startup
Charalambos Antoniades (Oxford/Caristo Diagnostics, UK)

Going all the way from bench to drug
Eric Green (Maze Therapeutics, USA)

What it takes for a smaller company applying for approval at the FDA
Rebecca Juliano (Juliano Consulting, USA)

Biotech attacks Heart Failure
James Hall (Betagenon/Cambrian, SWE)

THE CVCT Multi-Stakeholder Panel Debate

WHAT CLINICAL TRIALISTS MAY LEARN FROM BIOTECH PIONEERS?

Chairpersons: Peter Libby (Boston, MA, USA), Stephanie Oestreich (Myeloma Investment Fund, USA)

Panelists : Hafid Ait-Oufella (Polygon, FRA), Charalambos Antoniades (Oxford/Caristo Diagnostics, UK), Allison Goldfine (Novartis, USA), Eric Green (Maze Therapeutics, USA), James Hall (Betagenon/Cambrian, SWE), Therese Heinonen (Trialyx, USA), Rebecca Juliano (Juliano Consulting, USA), Rebecca Kunder (IGM Biosciences, USA), Peter Libby (Boston, MA, USA), Stephanie Oestreich (Myeloma Investment Fund, USA), Thomas Thum (Cardior, GER)

Ballroom
Thursday 30 November, 2023
16:30 - 19:00

IS HEART OBESITY DRUG THERAPY NO LONGER A MINEFIELD?
Chairpersons: Naveed Sattar (Glasgow, UK), Pam Taub (San Diego, CA, USA)

The semaglutide obesity STEP-by-STEP program. Paving the way to SELECT
Mark Petrie (Glasgow, UK)

The SELECT trial. A game changer?

Main findings from the SELECT trial
Benjamin Scirica (Boston, MA, USA)

Important subgroup findings from the SELECT trial. BMI, T2 diabetes and co-morbidities
Guiomar Mendieta-Badimon (CVCT Future Trialist, Barcelona, ESP)

Statistical significance of SELECT findings
Frank Rockhold (Durham, NC, USA)

The SELECT Trial: Lessons and perspectives from the Data Monitoring Committee
Christopher Granger (Durham, NC, USA)

Are all GLP1RA alike? Discussing the class effect.
Pam Taub (San Diego, CA, USA)

Industry viewpoints:
Jyothis George (Amgen, USA), Signe Harring (NovoNordisk, DEN), Masahiro Murakami (Eli Lilly, USA)

Regulatory viewpoint: What evidence for what cardiometabolic claims?
John Sharretts (FDA, USA)

Patient viewpoint
Patrick Gee (Chesterfield, MO, USA)

THE CVCT Multi-Stakeholder Panel Debate

PREVENTING OBESITY-RELATED CV DISEASE. IMPLEMENTING THE SELECT TRIAL RESULTS
Chairpersons: Naveed Sattar (Glasgow, UK), Pam Taub (San Diego, CA, USA)

Panelists : Patrick Gee (Chesterfield, MO, USA), Jyothis George (Amgen, USA), Christopher Granger (Durham, NC, USA), Signe Harring (NovoNordisk, DEN), Guiomar Mendieta-Badimon (CVCT Future Trialist, Barcelona, ESP), Masahiro Murakami (Eli Lilly, USA), Mark Petrie (Glasgow, UK), Matthew Roe (AstraZeneca, USA), Frank Rockhold (Durham, NC, USA), Benjamin Scirica (Boston, MA, USA), John Sharretts (FDA, USA), Pam Taub (San Diego, CA, USA)

Conference
Thursday 30 November, 2023
16:30 - 19:00

**CV CELL AND GENE THERAPY TRIAL DESIGN:
KEY ISSUES AND FUTURE DIRECTIONS**

Chairpersons: Barry Greenberg (San Diego, CA, USA), Monica Shah (RocketPharma, USA)

How natural history studies can help inform trial design
Kimberly Hong (San Diego, CA, USA)

How prior knowledge on pathophysiology may orient clinical development?
Wolfram Zimmermann (Göttingen, GER)

Challenges in clinical trial design for therapies for rare diseases.
Barry Greenberg (San Diego, CA, USA)

Gene therapy for ischemic heart disease
Thomas Povsic (Durham, NC, USA)

Efficacy and safety endpoints. How imperative and workable are surrogate endpoints?
Emerson Perin (Houston, TX, USA)

How useful are single arm trials, and other innovative trial designs?
Jan Tijssen (JACC, NED)

Industry viewpoints
Brendan Christopher Jones (NovoNordisk, DEN), Takehiko Kaneko, (Heartseed, JPN), Laura Robertson (Tenaya, USA),
Monica Shah (RocketPharma, USA)

Regulatory viewpoints: How to facilitate rather than stifle development, yet not setting the bar too low?
Peter Marks (FDA, USA)

Payers' viewpoint: What data to satisfy the post-approval commercial/payor interface
Dan Ollendorf (Boston, MA, USA)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO ACCELERATE CV BIOLOGICS AND CELL THERAPY TRIALS.

Chairpersons: Barry Greenberg (San Diego, CA, USA), Monica Shah (RocketPharma, USA)

Panelists : Barry Greenberg (San Diego, CA, USA), Didier Haguenaer (Cellprothera, FRA),
Kimberly Hong (San Diego, CA, USA), Takehiko Kaneko (Heartseed, JPN), Brendan Christopher Jones (NovoNordisk,
DEN), Peter Marks (FDA, USA), Dan Ollendorf (Boston, MA, USA), Emerson Perin (Houston, TX, USA), Thomas Povsic
(Durham, NC, USA), Laura Robertson (Tenaya, USA), Monica Shah (RocketPharma, USA), Jan Tijssen (JACC, NED), Wolfram
Zimmermann (Göttingen, GER)

Holeman
Thursday 30 November, 2023
16:30 - 19:00

TRIGLYCERIDE RICH LIPOPROTEINS TRIALS

Chairpersons: Aruna Das Pradhan (Boston, MA, USA), Borge Nordestgaard (Copenhagen, DEN)

Classical and genetic epidemiology
Borge Nordestgaard (Copenhagen, DEN)

PPAR Alpha Agonists
Aruna Das Pradhan (Boston, MA, USA)

Apolipoprotein C3 inhibitors
Anne Tybjærg-Hansen (Copenhagen, DEN)

ANGPTL3 inhibitors
Robert Rosenson (New York, NY, NY USA)

ANGPTL4 inhibitors
Sander Kersten (Wageningen, NED)

FGF-21 therapies
Hank Mansbach (89bio, USA)

Industry viewpoints:
Hank Mansbach (89bio, USA), Stefan Nilsson (Lipigon Pharmaceuticals, SWE), Giacomo Ruotolo (Lilly, USA), Sam Tsimikas (Ionis, USA)

Regulatory viewpoint
Maciej Kostrubiec (EMA, POL)

Patient viewpoint
Jacqueline Alikhaani (Los Angeles, USA)

THE CVCT Multi-Stakeholder Panel Debate

TRIGLYCERIDE RICH LIPOPROTEINS TRIALS

Chairpersons: Aruna Das Pradhan (Boston, MA, USA), Borge Nordestgaard (Copenhagen, DEN)

Panelists : Jacqueline Alikhaani (Los Angeles, USA), Leslie Cho (Cleveland, OH, USA) , Jan Hein Cornel (Nijmegen, NED), Aruna Das Pradhan (Boston, MA, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Irene Hedelund Langbakke (NovoNordisk, DEN), Udo Hoffman (Cleerly, USA), Sander Kersten (Wageningen, NED) , Maciej Kostrubiec (EMA, POL), Peter Libby (Boston, MA, USA), Antonio Lopez (AMGEN, USA), Hank Mansbach (89bio, USA), Stefan Nilsson (Lipigon Pharmaceuticals, SWE), Borge Nordestgaard (Copenhagen, DEN), Michelle O'Donoghue (Boston, MA, USA), Robert Rosenson (New York, NY, USA), Giacomo Ruotolo (Lilly, USA), Sam Tsimikas (Ionis, USA), Anne Tybjærg-Hansen (Copenhagen, DEN)

Fourth Estate
Thursday 30 November, 2023
16:30 - 19:00

PROGRESS IN DESIGNING HYPERTROPHIC CARDIOMYOPATHY TRIALS
Chairpersons: Mona Fiuzat (Washington, DC, USA), Martin Maron (Boston, MA, USA)

Amyloid cardiomyopathy trials update
Alberto Aimo (Pisa, ITA)

Cardiac myosin inhibitor and other hypertrophic cardiomyopathy trials. The competitive landscape
Neal Lakdawala (Boston, MA, USA)

Endpoint related issues in hypertrophic cardiomyopathies

Endpoints in Phase 2 trials to inform progression to phase 3 in Obstructive hypertrophic cardiomyopathy trials
Martin Maron (Boston, MA, USA)

Progression to septal reduction therapy. An acceptable endpoint in Obstructive Hypertrophic Cardiomyopathy drug trials?
Milind Desai (Cleveland, OH, USA)

Arrhythmias endpoints in hypertrophic cardiomyopathy
Cecilia Linde (Stockholm, SWE)

Using AI approaches to optimize clinical trial design
Kevin Elgui (Owkin, FRA)

Industry viewpoints

Arnaud Bastien (BMS, USA), Jim Carr (Stealth, USA), Ansgar Conrad (Prothena, USA), Stephen Heitner (Cytokinetics, USA), Daniel Jacoby (Cytokinetics, USA), David Lebwohl (Intellia, USA), Michele Mercuri (Alexion, USA), Amy Sehnert (BMS, USA), Maria Sejersten Ripa (NovoNordisk, DEN), Marc Semigran (Edgewise, USA)

Regulatory viewpoint
Janet Maynard (FDA, USA)

Patient viewpoints
Juddson Rupp (Milestone Pharmaceuticals, USA)
Lisa Salberg (HCMA, USA)

THE CVCT Multi-Stakeholder Panel Debate

PROGRESS IN DESIGNING HYPERTROPHIC CARDIOMYOPATHY TRIALS
Chairpersons: Mona Fiuzat (Washington, DC, USA), Martin Maron (Boston, MA, USA)

Panelists : Alberto Aimo (Pisa, ITA), Arnaud Bastien (BMS, USA), Jim Carr (Stealth, USA), Caroline J Coats (Glasgow, UK, Women as One CLIMB Awardee), Ansgar Conrad (Prothena, USA), Milind Desai (Cleveland, OH, USA), Kevin Elgui (Owkin, FRA), Mona Fiuzat (Washington, DC, USA), Stuart Kupfer (Cytokinetics, USA), Stephen Heitner (Cytokinetics, USA), Daniel Jacoby (Cytokinetics, USA), Neal Lakdawala (Boston, MA, USA), David Lebwohl (Intellia, USA), Cecilia Linde (Stockholm, SWE), Martin Maron (Boston, MA, USA), Janet Maynard (FDA, USA) Michele Mercuri (Alexion, USA), Juddson Rupp (Milestone Pharmaceuticals, USA), Lisa Salberg (HCMA, USA), Amy Sehnert (BMS, USA), Marc Semigran (Edgewise, USA), Maria Sejersten Ripa (NovoNordisk, DEN)

Room 5
Thursday 30 November, 2023
16:30 - 19:30

iCVCT

BRINGING NEW CARDIOVASCULAR DEVICES TO MARKET
MEETING THE EVIDENCE THRESHOLD FOR APPROVAL AND REIMBURSEMENT
Chaipersons: Don Cutlip (Boston, MA, USA), Robert Yeh (Boston, MA, USA)

Endpoint related issues:

Peri-procedural MI – Can we define it ?
Lydia Glaw (FDA, USA)

Composites- How to choose them, How to interpret them?
David Cohen (New York, NY, USA)

Patient viewpoint
Penilla Gunther (Stockholm, SWE)

Panel discussion

Pre vs. Post-market data requirements – striking the right balance
Bram Zuckerman (FDA, USA)

Pathways for accelerating access to device innovation

FDA's Breakthrough Device Program: Current status and Looking Ahead
Jaime Raben (FDA, USA)

Transitional Coverage for Emerging Technologies (TCET). How hospital and physician payment for breakthrough devices may accelerate innovation?
Steve Farmer (CMS, USA)

Can new EU HTA regulations help device innovations?
Marco Marchetti (Agenas and EU HTA, ITA)
Tom Melvin (Dublin, IRE)

Industry viewpoints
Bradley Horst (Boston Scientific, USA), Harry Rowland (Endotronix, USA), Charles Simonton (Abiomed, USA), Nadim Yared (CVRx, USA)

THE iCVCT Multi-Stakeholder Panel Debate

BRINGING NEW CARDIOVASCULAR DEVICES TO MARKET
MEETING THE EVIDENCE THRESHOLD FOR APPROVAL AND REIMBURSEMENT
Chaipersons: Don Cutlip (Boston, MA, USA), Robert Yeh (Boston, MA, USA)

Panelists : David Cohen (New York, NY, USA), Don Cutlip (Boston, MA, USA), Andrew Farb (FDA, USA), Steven Farmer (CMS, USA), Lydia Glaw (FDA, USA), Penilla Gunther (Stockholm, SWE), Bradley Horst (Boston Scientific, USA), Marco Marchetti (Agenas and EU HTA, ITA) , Tom Melvin (Dublin, IRE), Jaime Raben (FDA, USA), Harry Rowland (Endotronix, USA), Charles Simonton (Abiomed, USA), Nadim Yared (CVRx, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

**Ballroom
Friday 01 December, 2023
8:30 - 10:30**

**DISRUPTING CARDIOMETABOLIC DRUG DEVELOPMENT BY TARGETING
OBESITY-RELATED CV DISEASE PROGRESSION Part 2**

Chairpersons: Mikhail Kosiborod (Kansas City, MO, USA), Mark Petrie (Glasgow, UK),

Obesity – HFpEF trials

STEP-HFpEF and STEP-HFpEF-DM: Semaglutide in patients living with HFpEF and Obesity
Mark Petrie (Glasgow, UK)

Synergizing agonism of GIP and GLP-1 receptors with Terzepatide from SURMOUNT to the SUMMIT trial
Milton Packer (Dallas, TX, USA)

Obesity drugs and HFrEF
Javed Butler (Dallas, TX, USA)

Next generation obesity treatments
Matthew Roe (AstraZeneca, USA)

What other weight loss trials in the CV space would be valuable
Naveed Sattar (Glasgow, UK)

Implementing SELECT findings. Who is to take action?

The Cardiometabolic viewpoint
Mikhail Kosiborod (Kansas City, MO, USA)

The Endocrinologist viewpoint
Lou Aronne (New York, NY, USA)

Industry viewpoints
Alessandra Lafranconi (Boehringer, GER), Marie Mide Michelsen (Novonordisk, DEN), Masahiro Murakami (Eli Lilly, USA)

Patient viewpoint
Jacqueline Alikhaani (Los Angeles, USA)

THE FORUM Multi-Stakeholder Panel Debate

OBESITY TRIALS FROM WEIGHT LOSS TO HARD OUTCOME TRIALS

Chairpersons: Mikhail Kosiborod (Kansas City, MO, USA), Mark Petrie (Glasgow, UK),

Panelists : Jacqueline Alikhaani (Los Angeles, USA), Lou Aronne (New York, NY, USA), Javed Butler (Dallas, TX, USA),
Jyothis George (Amgen, USA), Mikhail Kosiborod (Kansas City, MO, USA), Alessandra Lafranconi (Boehringer, GER),
Guiomar Mendieta-Badimon (CVCT Future Trialist, Barcelona, ESP), Marie Mide Michelsen (NovoNordisk, DEN), Masahiro
Murakami (Eli Lilly, USA), Milton Packer (Dallas, TX, USA), Mark Petrie (Glasgow, UK), Matthew Roe (AstraZeneca, USA),
Frank Rockhold (Durham, NC, USA), Benjamin Scirica (Boston, MA, USA)

Conference
Friday 01 December, 2023
8:30 - 10:30

GAPS IN IMPLEMENTATION OF EVIDENCE-BASED LIPID LOWERING THERAPIES
Chairpersons: Vera Bittner (Birmingham, AL, USA), Gregory Schwartz (Denver, CO, USA)

Keynote Lecture

Why do we need new lipid lowering therapies?
Robert S. Rosenson (New York, NY, USA)

How far have we come and how far to go?
Vera Bittner (Birmingham, AL, USA)

International Guidelines

Borge Nordestgaard (Copenhagen, DEN)

Equity in Guidelines. Evidence based care of minorities.
Karol Watson (Los Angeles, CA, USA)

Fixed dose combination opportunities for polypharmacy.
Lijing Yan (Jiangsu, CN)

Insight from real world data
Paul Muntner (CDC, Atlanta, GA, USA)

Patient viewpoint
Mariette Verbakel (Nijmegen, NED)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO MAKE THE BEST USE OF AVAILABLE LIPID LOWERING THERAPIES?

Chairpersons: Vera Bittner (Birmingham, AL, USA), Gregory Schwartz (Denver, CO, USA)

Panelists : Shazia Ali (Regeneron, USA), Puja Banka (Merck, USA), Vera Bittner (Birmingham, AL, USA), Marc Ditmarsch (New Amsterdam Pharma, NED), Robert Giugliano (Boston, MA, USA), Irene Hedelund Langbakke (NovoNordisk, DEN), Wolfgang Koenig (Munich, GER), Anastasia Lesogor (Novartis, CH), Paul Muntner (CDC, Atlanta, GA, USA), Borge Nordestgaard (Copenhagen, DEN), Robert S. Rosenson (New York, NY, USA), Gregory Schwartz (Denver, CO, USA), Evan Stein (LIBTherapeutics, USA), Paul Thompson (Hartford, CT, USA), Mariette Verbakel (Nijmegen, NED), Karol Watson (Los Angeles, CA, USA), Lijing Yan (Jiangsu, CN)

Holeman
Friday 01 December, 2023
8:30 - 10:30

**A ROADMAP TO THE 7TH WORLD SYMPOSIUM ON PULMONARY HYPERTENSION:
GAPS IN EVIDENCE TO BE ADDRESSED.**

Chairpersons: Mardi Gomberg-Maitland (Washington, DC, USA), Gérald Simonneau (Paris, FRA)

Patients with cardiopulmonary comorbidities:

A need for clarification
Mardi Gomberg-Maitland (Washington, DC, USA)
Jean-Luc Vachiéry (Brussels, BEL)

Hemodynamic considerations for clinical trials of PAH with risk factors for HFpEF - How do we improve phenotyping for 'atypical' PAH
Yogesh Reddy (Rochester, MN, USA)

Investigator viewpoint
Lewis Rubin (New York, NY, USA)

Industry viewpoints
Hunter Gillies (Aerovate, USA), Mahesh Patel (Merck, USA), Antoine Yver (Centessa, USA), Larry Zisman (Gossamer, USA)

FDA Pediatric PAH regulatory framework
Mitch Psocka (FDA, USA)

Patient viewpoint
Martha Hill (Baltimore, MD, USA)

THE CVCT Multi-Stakeholder Panel Debate

**A ROADMAP TO THE 7TH WORLD SYMPOSIUM ON PULMONARY HYPERTENSION:
GAPS IN EVIDENCE TO BE ADDRESSED.**

Chairpersons: Mardi Gomberg-Maitland (Washington, DC, USA), Gérald Simonneau (Paris, FRA)

Panelists : Hunter Gillies (Aerovate, USA), Mardi Gomberg-Maitland (Washington, DC, USA), Marc Humbert (Paris, FRA), Steven Kawut (Philadelphia, PA, USA), Martha Hill (Baltimore, MD, USA), Vallerie McLaughlin (Ann Arbor, MI, USA), Mahesh Patel (Merck, USA), Mitch Psocka (FDA, USA), Franck Rahaghi (Weston, FL, USA), Yogesh Reddy (Rochester, MN, USA), Lewis J. Rubin (New York, NY, USA), Gérald Simonneau (Paris, FRA), Olivier Sitbon (Paris, FRA), Jean-Luc Vachiéry (Brussels, BEL), Antoine Yver (Centessa, USA), Jason Weatherald (Edmonton, CA), Antoine Yver (Centessa, USA), Larry Zisman (Gossamer, USA)

**Fourth Estate
Friday 01 December, 2023
08:30 - 10:30**

iCVCT

CARDIOGENIC SHOCK: TRIALS AND EVIDENCE

Chairpersons: Vijay Kunadian (Newcastle, UK), Nicole Gillette (FDA, USA),

Current state of evidence for mechanical circulatory support devices in cardiogenic shock
Holger Thiele (Leipzig, GER)

Observational evidence to evaluate mechanical circulatory support devices
Robert Yeh (Boston, MA, USA)

Is mortality the right endpoint for shock trials?
Navin Kapur (Boston, MA, USA)

Challenges for randomized clinical trials for mechanical circulatory support devices (equipose, cross-over, consent)
Vijay Kunadian (Newcastle, UK)

Methodological progress in mechanical circulatory support for cardiogenic shock trials. RECOVER IV
Gregg Stone (New York, NY, USA)

Regulatory perspectives on Device Approval for Cardiogenic Shock
Nicole Gillette (FDA, USA),

Established Industry viewpoints
Dominic Allocco (Boston Scientific, USA), Charles Simonton (Abiomed, USA)

Startup Industry viewpoint
Amr Salahieh (Supira, USA)

Clinician's viewpoint
Erin Bohula (Boston, MA, USA, Women as One CLIMB Awardee)

Patient viewpoint
Rhonda Monroe (Baltimore, MD, USA)

THE iCVCT Multi-Stakeholder Panel Debate

CARDIOGENIC SHOCK: TRIALS AND EVIDENCE

Chairpersons: Vijay Kunadian (Newcastle, UK), Nicole Gillette (FDA, USA)

Panelists : Dominic Allocco (Boston Scientific, USA), Erin Bohula (Boston, MA, USA, Women as One CLIMB Awardee), Nicole Gillette (FDA, USA), Navin Kapur (Boston, MA, USA), Vijay Kunadian (Newcastle, UK), Roxana Mehran (New York, NY, USA), Rhonda Monroe (Baltimore, MD, USA), Mauro Moscucci (FDA, USA), Amr Salahieh (Supira, USA), Charles Simonton (Abiomed, USA), Gregg Stone (New York, NY, USA), Holger Thiele (Leipzig, GER), Robert Yeh (Boston, MA, USA)

Ballroom
Friday 01 December, 2023
11:00 - 13:00

HOW TO ENTHUSE INDUSTRY BACK INTO CARDIOVASCULAR INNOVATION
Chairpersons: Filippo Crea (EHJ Editor, ITA), Joseph Hill (Circulation Editor, USA)

Why is industry moving away from cardiovascular?
Javed Butler (Dallas, TX, USA)

How challenging/rewarding is publication of innovation? Cardiovascular vs. other disciplines.
Robert Bonow (JAMA Cardiology, USA), Stuart Spencer (The Lancet, UK)

How mixed reality and teleporting may foster innovation in medicine and remote surgery.
Patrik Nataf (Paris, FRA)

Industry viewpoint
Martin Cowie (AstraZeneca, UK)

The role of learned societies. How to lobby industry back to cardiovascular innovation?
Mariell Jessup (AHA, USA)
Alan Fraser (CORE-MD, UK)

Are pricing policies the issue?
Salim Shah (Sarfez, USA)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO ENTHUSE INDUSTRY BACK INTO CARDIOVASCULAR INNOVATION
Chairpersons: Filippo Crea (EHJ Editor, ITA), Joseph Hill (Circulation Editor, USA)

Panelists : Robert Bonow (JAMA Cardiology, USA), Javed Butler (Dallas, TX, USA), Robert Califf (FDA commissioner, USA), Martin Cowie (AstraZeneca, UK), Filippo Crea (EHJ Editor, ITA), Alan Fraser (CORE-MD, UK), Joseph Hill (Circulation Editor, USA), Mariell Jessup (AHA, USA), Marvin Konstam (Boston, MA, USA), Patrik Nataf (Paris, FRA), Dan Ollendorf (Boston, MA, USA), Milton Packer (Dallas, TX, USA), Salim Shah (Sarfez, USA), Stuart Spencer (The Lancet, UK)

Conference
Friday 01 December, 2023
11:00 - 13:00

iCVCT-CTSN Joint session

THE EVOLVING RESEARCH AGENDA OF THE NHLBI CARDIOTHORACIC SURGICAL TRIALS NETWORK

Chairpersons: Annetine Gelijns (New York, NY, USA), Kendra Grubb (Atlanta, GA, USA)

Overview of CTSN research
Annetine Gelijns (New York, NY, USA)
Kathleen Fenton (NHLBI, NIH, USA)

Preventing and treating post operative atrial fibrillation
Anticoagulation for new onset post-operative atrial fibrillation after CABG: PACeS Trial
John Alexander (Durham, NC, USA)

Trials at the intersection of surgery and interventional cardiology

Comparing Effectiveness of mitral valve surgery and transcatheter edge-to-edge repair in degenerative mitral regurgitation: PRIMARY Trial
Patrick O'Gara (Boston, MA, USA)

Analyzing Multiple Events in Clinical Trials
Emilia Bagiella (New York, NY, USA)

Transcatheter Aortic Valve-in-Valve Procedure vs. Redo Surgical Aortic Valve Replacement for Failed Aortic Bioprosthesis
Robert Hawkins (Ann Arbor, MI, USA)

Embolic protection devices following high-risk valve surgery
Steve Messe (Philadelphia, PA, USA)

Regulatory viewpoint:
Bernard Vasseur (FDA, USA)

Industry viewpoints
Philip Adamson (Abbott, USA), Stacey Ruiz (Renibus, USA), Eapen Zubin (Element Science, USA)

THE iCVCT Multi-Stakeholder Panel Debate

THE EVOLVING RESEARCH AGENDA OF THE NHLBI CARDIOTHORACIC SURGICAL TRIALS NETWORK

Chairpersons: Annetine Gelijns (New York, NY, USA), Kendra Grubb (Atlanta, GA, USA)

Panelists: Philip Adamson (Abbott, USA), John Alexander (Durham, NC, USA), Emilia Bagiella (New York, NY, USA), Kathleen Fenton (NHLBI, NIH, USA), Annetine Gelijns (New York, NY, USA), Kendra Grubb (Atlanta, GA, USA), Robert Hawkins (Ann Arbor, MI, USA), Ahmed Kolkailah (Dallas, TX, USA), Steve Messe (Philadelphia, PA, USA), Patrick O'Gara (Boston, MA, USA), Stacey Ruiz (Renibus, USA), Bernard Vasseur (FDA, USA), Changfu Wu (FDA, USA), Eapen Zubin (Element Science, USA)

Holeman
Friday 01 December, 2023
11:00 - 13:00

DISEASE MODIFICATION IN PULMONARY ARTERIAL HYPERTENSION

Chairpersons: Marc Humbert (Paris, FRA), Vallerie McLaughlin (Ann Arbor, MI, USA)

Disease modification in PAH: proposed definitions
Vall rie McLaughlin (Ann Arbor, MI, USA)

Are calcium channel blockers disease modifying in acute vasodilator responders?
Olivier Sitbon (Paris, FRA)

Are currently approved PAH therapies disease modifying in PAH?
Sandeep Sahay (Houston, TX, USA)

Is sotatercept therapy disease modifying in PAH?
Marc Humbert (Paris, FRA)

Investigator viewpoints:
Steven Kawut (Philadelphia, PA, USA)
Franck Rahaghi (Weston, FL, USA)
Jason Weatherald (Edmonton, CA)

Industry viewpoints:
Michela Brambatti (Merck, USA), Hunter Gillies (Aerovate, USA), Antoine Yver (Centessa, USA), Larry Zisman (Gossamer, USA)

Regulator viewpoint
Mitch Psocka (FDA, USA)

Patient viewpoint
Martha Hill (Baltimore, MD, USA)

THE CVCT Multi-Stakeholder Panel Debate

DISEASE MODIFICATION IN PULMONARY ARTERIAL HYPERTENSION

Chairpersons: Marc Humbert (Paris, FRA), Vallerie McLaughlin (Ann Arbor, MI, USA)

Panelists : Michela Brambatti (Merck, USA), Hunter Gillies (Aerovate, USA), Mardi Gomberg-Maitland (Washington, USA); Martha Hill (Baltimore, MD, USA), Marc Humbert (Paris, FRA), Steven Kawut (Philadelphia, PA, USA), Vallerie McLaughlin (Ann Arbor, USA), Mitch Psocka (FDA, USA), Franck Rahaghi (Weston, FL, USA), Sandeep Sahay (Houston, TX, USA), G rald Simonneau (Paris, FRA), Olivier Sitbon (Paris, FRA), Jason Weatherald (Edmonton, CA), Antoine Yver (Centessa, USA), Larry Zisman (Gossamer, USA)

**Fourth Estate
Friday 01 December, 2023
11:00 - 13:00**

IV IRON IN HEART FAILURE. IRONCLAD EVIDENCE?

Chairpersons: Theresa McDonagh (London, UK), Robert Mentz (Durham, NC, USA)

Iron for heart failure. The evidence so far
Stefan Anker (Berlin, GER)

IV-Iron in HFrEF. HEART-FID main results
Robert Mentz (Durham, NC, USA)

Does HEART-FID close the gap in evidence?
Stefan Anker (Berlin, GER)

New steps and implementation issues
Adrian Hernandez (Durham, NC, USA)

IV Iron in the time of SGLT2 inhibitor therapy
Kieran Docherty (Glasgow, UK)

Which patients might benefit from intravenous iron supplementation?
Pieter Martens (Hasselt, BEL)

Statistical viewpoint
Tim Friede (Göttingen, GER)

Industry viewpoints:
Sangeetha Anand (CSL Vifor, CH), Syed Numan (American Regent, USA)

Regulatory viewpoint
Charu Gandotra (FDA, USA)

Patient viewpoint
Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)

THE CVCT Multi-Stakeholder Panel Debate

WHERE DOES IRON NOW FIT IN HEART FAILURE GUIDELINES

Chairpersons: Theresa McDonagh (London, UK), Robert Mentz (Durham, NC, USA)

Panelists : Sangeetha Anand (CSL Vifor, CH), Stefan Anker (Berlin, GER), Kieran Docherty (Glasgow, UK), Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), Tim Friede (Göttingen, GER), Charu Gandotra (FDA, USA), Nicolas Girerd (Nancy, FRA), Adrian Hernandez (Durham, NC, USA), Pieter Martens (Hasselt, BEL), Theresa McDonagh (London, UK), Robert Mentz (Durham, NC, USA), Syed Numan (American Regent, USA), Gianluigi Savarese (Stockholm, SWE)

Conference
Friday 01 December, 2023
14:00 - 17:30

STRATEGIES FOR DIFFICULT TO TREAT HYPERTENSION TRIALS.
Chairpersons: Michel Azizi (Paris, FRA), Anthony Rodgers (Sydney, AUS)

Renal denervation. The evidence so far and implementation perspectives
Gregg Stone (New York, NY, USA)

Possible resurrection of renal artery denervation
Bernard Gersh (Rochester, MN, USA)

The future of device hypertension trials: Progress in clinical design principles and outcomes definitions
Naomi Fisher (Boston, MA, USA)

New long-acting drugs.
Angiotensinogen Suppression with Antisense Inhibition
George Bakris (Chicago, USA)

Baxdrostat and other aldosterone synthase inhibitors
Michel Azizi (Paris, FRA)

XXB750 monoclonal antibody targeting NPR1, also for heart failure?
Bryan Williams (London, UK)

Triple combination and polypills.
Anthony Rodgers (Sydney, AUS)

Industry viewpoints
Sandeep Brar (Medtronic, USA), Shira Perl (AstraZeneca, SWE), Adel Rizkala (Novartis, USA), Sam Tsimikas (Ionis, USA),
Fred Yang (KBP, USA)

DISCUSSION: NEW THERAPIES FOR DIFFICULT TO TREAT HYPERTENSION

What is needed for approval? Endpoint related issues
Is BP still a validated surrogate for difficult to treat hypertension trials, and what is the optimal BP measurement
method in 2023?
Sonali Gnanenthiran (Sydney, AUS, Women as One CLIMB Awardee)

What should be the duration of the trials and exposure to a placebo/sham?
Nelson Wang (Newtown, AUS)

Are outcome trials needed for new drugs and for device-based treatments?
David Kandzari (Atlanta, GA, USA)

Should we run systematically a non-inferiority trial vs. spironolactone?
Bertram Pitt (Ann Arbor, MI, USA)

Regulatory viewpoint
Rekha Kambhampati (FDA, USA)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO STRATEGIZE DRUG VS., DENERVATION FOR DIFFICULT TO TREAT HYPERTENSION
Chairpersons: Michel Azizi (Paris, FRA), Anthony Rodgers (Sydney, AUS)

Panelists : Michel Azizi (Paris, FRA), George Bakris (Chicago, USA), Sandeep Brar (Medtronic, USA), Andrew Farb (FDA, USA), Naomi Fisher (Boston, MA, USA), Bruno Flamion (Idorsia, CH), Bernard Gersh (Rochester, MN, USA), Sonali Gnanenthiran (Sydney, AUS, Women as One CLIMB Awardee), Rekha Kambhampati (FDA, USA), David Kandzari (Atlanta, GA, USA), Shira Perl (AstraZeneca, SWE), Bertram Pitt (Ann Arbor, MI, USA), Adel Rizkala (Novartis, USA), Anthony Rodgers (Sydney, AUS), Gregg Stone (New York, NY, USA), Sam Tsimikas (Ionis, USA), Nelson Wang (Newtown, AUS), Bryan Williams (London, UK), Fred Yang (KBP, USA)

Ballroom
Friday 01 December, 2023
14:00 - 17:00

DEMYSTIFYING ARTIFICIAL INTELLIGENCE STUDIES
A PRACTICAL GUIDE TO EVALUATING CUTTING-EDGE STUDIES FOR THE CLINICIAN SCIENTIST
Chairpersons: Rohan Khera (New Haven, CT, USA), Girish Nadkarni (New York, NY, USA)

AI in Clinical Trials. Current breakthrough
Rohan Khera (New Haven, CT, USA)

AI in Clinical Trials. Reasonable expectations
Harlan Krumholz (New Haven, USA)

Enriching clinical trials with genomic approaches
Girish Nadkarni (New York, NY, USA)

Using AI for clinical endpoints
Bobak Mortazavi (New Haven, CT, USA)

AI for Enriching Trial Populations and Predicting Outcomes . Use cases
Udo Hoffmann (Cleerly, USA)
Bobak Mortazavi (New Haven, CT, USA)

Digital and AI industry use-cases and viewpoints:
Christine Gouillard (US2.AI, USA), Mintu Turakhia (Stanford, CA, USA)

Healthcare industry viewpoints
Michael Jaff (Boston Scientific, USA), Matthew Roe (AstraZeneca, USA)

Statistician viewpoint
Janet Wittes (Wittes LLC, USA)

Generative AI to improve trial dissemination and summarization: a hands-on exercise
Phyllis Thangaraj (New Haven, CT, USA)

Regulatory viewpoints.

The FDA Mobile Digital Health Guidance
Aneesh Deoras (FDA, USA)

Regulatory aspects of AI in EU
Piotr Szymański (EMA, POL)

THE CVCT Multi-Stakeholder Panel Debate

AI IS HERE TO STAY. LET US MAKE THE BEST USE OF IT IN CLINICAL TRIALS.
Chairpersons: Rohan Khera (New Haven, CT, USA), Girish Nadkarni (New York, NY, USA)

Panelists : Stephen Browning (FDA, USA), Aneesh Deoras (FDA, USA), Christine Gouillard (US2.AI, FRA), Udo Hoffmann (Cleerly, USA), Michael Jaff (Boston Scientific, USA), Rohan Khera (New Haven, CT, USA), Harlan Krumholz (New Haven, CT, USA), Bobak Mortazavi (New Haven, CT, USA), Girish Nadkarni (New York, NY, USA), Matthew Roe (AstraZeneca, USA), Piotr Szymański (EMA, POL), Phyllis Thangaraj (New Haven, CT, USA), Mintu Turakhia (Stanford, CA, USA), , Janet Wittes (Wittes LLC, USA)

Holeman
Friday 01 December, 2023
14:00 - 17:00

CHOLESTEROL LOWERING THERAPIES TRIALS

Chairpersons : Wolfgang Koenig (Munich, GER), Gregory Schwartz (Denver, CO, USA)

PCSK9 mAbs – Update on VESALIUS
Robert Giugliano (Boston, MA, USA)

ASO/siRNA therapies for PCSK9. Inclisiran update. ORION 4, VICTORION-2Prevent, VICTORION- Plaque
Wolfgang Koenig (Munich, GER)

Lerodalcibep (LIB003) small binding protein
Evan Stein (LIBTherapeutics, USA)

Oral PCSK9 inhibitors
Benjamin Scirica (Boston, MA, USA)

Statin intolerance and Acyl citrate lyase inhibitor – CLEAR Outcomes

Main results
Paul Thompson (Hartford, CT, USA)

Statistical viewpoint
Stuart Pocock (London, UK)

CETP inhibition
Anne Goldberg (St Louis, MO, USA)

Industry viewpoints:
Shazia Ali (Regeneron, USA), Puja Banka (Merck, USA), Marc Ditmarsch (New Amsterdam Pharma, NED), Irene Hedelund Langbakke (NovoNordisk, DEN), Anastasia Lesogor (Novartis, CH), Evan Stein (LIBTherapeutics, USA)

Regulatory viewpoint:
John Sharretts (FDA, USA)

Patient viewpoint:
Greg Merritt (Patient is Partner, USA)

THE CVCT Multi-Stakeholder Panel Debate

CHOLESTEROL LOWERING THERAPIES TRIALS ON THE WAY TOWARDS PERSONALIZED LIPID THERAPY

Chairpersons : Wolfgang Koenig (Munich, GER), Gregory Schwartz (Denver, CO, USA)

Panelists : Shazia Ali (Regeneron, USA), Puja Banka (Merck, USA), Vera Bittner (Birmingham, AL, USA), Marc Ditmarsch (New Amsterdam Pharma, NED), Robert Giugliano (Boston, MA, USA), Anne Goldberg (St Louis, MO, USA), Irene Hedelund Langbakke (NovoNordisk, DEN), Wolfgang Koenig (Munich, GER), Anastasia Lesogor (Novartis, CH), Francois Mach (Geneva, CH), Greg Merritt (Patient is Partner, USA), Paul Muntner (CDC, Atlanta, GA, USA), Stuart Pocock (London, UK), Robert S. Rosenson (New York, NY, USA), Gregory Schwartz (Denver, CO, USA), Benjamin Scirica (Boston, MA, USA), John Sharretts (FDA, USA), Evan Stein (LIBTherapeutics, USA), Paul Thompson (Hartford, CT, USA), Lijing Yan (Jiangsu, CN)

Fourth Estate
Friday 01 December, 2023
14:00 - 17:00

PEDIATRIC CELL AND GENE THERAPY TRIALS

Chairpersons: Daphne Hsu (New York, NY, USA), Juan Pablo Kaski (London, UK)

Finding the ideal device for the smallest patients and measuring outcomes through ACTION registry
Angela Lorts (Cincinnati, OH, USA)

The need for better identification of genetic diseases and the importance of natural history and registry data
Juan Pablo Kaski (London, UK)

Stem Cell trial for Hypoplastic Left Heart Syndrome
Sunjay Kaushal (Chicago, IL, USA)

Gene therapy trials. Overview and challenges
Barry Byrne (Gainesville, FL, USA)

Trial design in genetic cardiology.
Barry Byrne (Gainesville, FL, USA)

Gene Therapy Trials in Genetic Cardiomyopathies: A Clinician's viewpoint
Joseph Rossano (Philadelphia, PA, USA)

Biomarkers in pediatric cardiovascular trials
Shelley Miyamoto (Denver, CO, USA)

General discussion

Industry viewpoints

Laura Robertson (Tenaya, USA), Jonathan Schwartz (RocketPharma, USA), Tadaaki Taniguchi (Astellas, USA)

The parent perspective: Patient advocate viewpoint
Gina Peattie (Children's Cardiomyopathy Foundation, USA)

The regulatory viewpoint
Peter Marks (FDA, USA)

Health economy viewpoint
Dan Ollendorf (Boston, MA, USA)

The NIH viewpoint
Kristin Burns (NHLBI, NIH, USA)

THE CVCT Multi-Stakeholder Panel Debate

PEDIATRIC CELL AND GENE THERAPY TRIALS

Chairpersons: Daphne Hsu (New York, NY, USA), Juan Pablo Kaski (London, UK)

Panelists : Christopher Almond (Stanford, CA, USA), Kristin Burns (NIH, USA), Barry Byrne (Gainesville, FL, USA), Mackenzie Ford (Merck, USA), Daphne Hsu (New York, NY, USA), Nicole Ibrahim (FDA, USA), Juan Pablo Kaski (London, UK), Sunjay Kaushal (Chicago, IL, USA), Robert Kroschwitz (Berlin Heart, USA), Angela Lorts (Cincinnati, OH, USA), Peter Marks (FDA, USA), Shelley Miyamoto (Denver, CO, USA), Dan Ollendorf (Boston, MA, USA), Elfriede Pahl (Chicago, IL, USA), Gail Pearson (NIH, USA), Gina Peattie (Children's Cardiomyopathy Foundation, USA), Ron Portman (Novartis, USA), Laura Robertson (Tenaya, USA), Joseph Rossano (Philadelphia, PA, USA), Jonathan Schwartz (RocketPharma, USA), Lynn Sleeper (Boston, MA, USA) Tadaaki Taniguchi (Astellas, USA)

**Off-site Keynote lecture at the Ronald Reagan Building
(walking distance from The National Press Club)
Friday Dec 1st
18.00-19.00**

**DO FISH KNOW ABOUT WATER?
(Do innovators appreciate what's vital for affordable innovation?)
Peter Kolchinsky, PhD**

**RA Capital Management, LP
Commentary: @PeterKolchinsky
Author: The Great American Drug Deal
Founder: No Patient Left Behind**

**CVCT 20th Anniversary Celebration
Friday Dec 1st 19.00-22.30
Atrium of the Ronald Reagan Center
Limited seating is available, access is limited to those who received a printed invitation along
with their badge.**

**Welcome, CVCT past and milestones
Faiez Zannad (Paris, FRA)**

**“Do cardiovascular clinical trialists know where they started? 1000-year journal of
physicians who ignite our fire”
Milton Packer (Dallas, TX, USA)**

Dinner service

**CVCT stakeholders, team and future
Faiez Zannad (Paris, FRA) and Bertram Pitt (Ann Arbor, MI, USA)**

**Closing remarks
Faiez Zannad (Paris, FRA) and Bertram Pitt (Ann Arbor, MI, USA)**

Ballroom
Saturday 02 December, 2023
8:30 - 10:30

iCVCT

PERIPHERAL ARTERY DISEASE AND PULMONARY EMBOLISM TRIALS

Chairpersons: Jennifer Rymer (Durham NC USA), Eric Secemsky (Boston, MA, USA)

Controversies in Peripheral Artery Disease Intervention
Lessons Learned from the Paclitaxel Meta-analysis

Lessons learned by the Vascular community
Sahil Parikh (Boston, MA, USA)

Lessons learned by Industry
Michael Jaff (Boston Scientific, USA)

Lessons learned by the FDA
Gregory O'Connell (FDA, USA)

Navigating Multidisciplinary Care With Opposing Trial Results: The BEST-CLI and BASIL-2 trials
Kenneth Rosenfield (Boston, MA, USA)

Intervention for intermediate- and high-risk pulmonary embolism: Do we have the data to support catheter-based treatment?

Interventionalist's Viewpoint
Gregory Piazza (Boston, MA, USA)

Non-Interventionalist's Viewpoint
Rachel Rosovsky (Boston, MA, USA)

Industry Viewpoints
Michael Jaff (Boston Scientific, USA), Jack Springer (Nectero Medical, USA)

Regulatory viewpoint
Steven Lossef (FDA, USA)

Patient viewpoint
Philip Collis (British Heart Foundation, UK)

THE iCVCT Multi-Stakeholder Panel Debate

PERIPHERAL ARTERY DISEASE AND PULMONARY EMBOLISM TRIALS

Chairpersons: Jennifer Rymer (Durham NC USA) , Eric Secemsky (Boston, MA, USA)

Panelists : George Adams (Cordis, USA), Philip Collis (British Heart Foundation, UK), Andrew Farb (FDA, USA), Michael Jaff (Boston Scientific, USA), Steven Lossef (FDA, USA), Gregory O'Connell (FDA, USA), Sahil Parikh (Boston, MA, USA), Gregory Piazza (Boston, MA, USA), Kenneth Rosenfield (Boston, MA, USA), Rachel Rosovsky (Boston, MA, USA), Jennifer Rymer (Durham NC USA) , Eric Secemsky (Boston, MA, USA), Jack Springer (Nectero Medical, USA)

Conference
Saturday 02 December, 2023
08:30 - 10:30

CVCT-NHLBI joint session
IMPLEMENTATION SCIENCE

OPTIMIZING CV CLINICAL TRIAL DESIGN AND EVIDENCE INTEGRATION

Chairpersons : George Mensah (NHLBI, NIH, USA), Yves Rosenberg (NHLBI, NIH, USA)

Introduction – Setting the stage to optimize CV Clinical Trial Design and evidence integration
Cara Lewis (NHLBI, NIH, USA)

Lessons from implementation science to inform translation of evidence

Making implementation science theory, principles, and methods practical And
Overcoming barriers to successful implementation
Bryan Weiner (Seattle, WA, USA)

Measuring and maximizing intervention fidelity in clinical trials
Laura Desveaux (Toronto, CAN)

Tailoring implementation strategies to diverse settings
Tracy Finch (NIHR, UK)

Optimizing CV clinical trials to advance implementation science

Strategies to optimize implementation success
Harriette Van Spall (Hamilton, CAN)

Learning from clinical trials with process evaluation
Kavita Singh (Public Health Foundation, IND)

Scaling and spreading evidence across systems and geographic regions
Mohamed Salah Ben Ammar (Paris, FRA)

Scaling and spreading evidence across systems and geographic regions
Francois Venter (Johannesburg, ZAF)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO BUILD AND SUSTAIN IMPLEMENTATION SCIENCE CAPACITY

Chairpersons : George Mensah (NHLBI, NIH, USA), Yves Rosenberg (NHLBI, NIH, USA)

Panelists : Mohamed Salah Ben Ammar (Paris, FRA), Laura Desveaux (Toronto, CAN), Tracy Finch (NIHR, UK), Cara Lewis (NHLBI, USA), George Mensah (NHLBI, USA), Yves Rosenberg (NHLBI, NIH, USA), Kavita Singh (Public Health Foundation, IND), Harriette Van Spall (Hamilton, CAN), Francois Venter (Johannesburg, ZAF), Bryan Weiner (Seattle, WA, USA)

Holeman
Saturday 02 December, 2023
08:30 - 10:30

TRIALISTS - INDUSTRY RELATIONSHIPS.
PROMOTING EFFICIENCY AND TRANSPARENCY

Chairpersons: Robert Califf (FDA, USA), Kenneth Stein (Boston Scientific, USA)

Survey of the state of industry-trialists collaboration.
Rita Redberg (San Francisco, CA, USA)

Values and issues with academic industry clinical trials oversight committees

Industry viewpoints
Martin Cowie (AstraZeneca, UK)
Kenneth Stein (Boston Scientific, USA)

Academic viewpoint
Milton Packer (Dallas, TX, USA)

Journal editors' viewpoints
Jane Leopold (NEJM, USA)
Stuart Spencer (The Lancet, UK)

Regulatory viewpoint
Robert Califf (FDA, USA)

Patient viewpoint
Rhonda Monroe (Baltimore, MD, USA)

Can Investigators "vouch" for the data? Investigator Access to clinical Trial Data

Anders Hvelplund (NovoNordisk, DEN)
Anna Maria Langkilde (AstraZeneca, SWE)
Marty Lefkowitz (Novartis, USA)
Lothar Roessig (Bayer, GER)
Scott Solomon (Boston, MA, USA)

The industry – CRO – academics interface
Mahesh Patel (Merck, USA)
Janet Wittes (Wittes LLC, USA)

THE CVCT Multi-Stakeholder Panel Debate

STREAMLINING TRIALISTS-INDUSTRY RELATIONSHIPS.

Chairpersons: Robert Califf (FDA, USA), Kenneth Stein (Boston Scientific, USA)

Panelists : Robert Califf (FDA, USA), Martin Cowie (AstraZeneca, UK), Tara Fish (Lemon Tree, USA), Christine Gouillard (US2.AI, FRA), Anders Hvelplund (NovoNordisk, DEN), Rhonda Monroe (Baltimore, MD, USA), Anna Maria Langkilde (AstraZeneca, SWE), Marty Lefkowitz (Novartis, USA), Jane Leopold (NEJM, USA), Milton Packer (Dallas, TX, USA), Mahesh Patel (Merck, USA), Rita Redberg (San Francisco, CA, USA), Lothar Roessig (Bayer, GER), Stuart Spencer (The Lancet, UK), Scott Solomon (Boston, MA, USA), Kenneth Stein (Boston Scientific, USA), Janet Wittes (Wittes LLC, USA)

**Fourth Estate
Saturday 02 December, 2023
08:30 - 10:30**

**CVCT-WOMEN-AS-ONE JOINT SESSION
WOMEN PARTICIPANTS IN CARDIO-RENAL-METABOLISM TRIALS.
ACTIONABLE STEPS TO DRIVE LASTING CHANGE**

Chairpersons: Mary N. Walsh (St Vincent, IN, USA), Cindy Westerhout (Edmonton, CAN)

Women participation in drug/device clinical trials
Birgit Vogel (New York, NY, USA)

Exclusion by design: the role of eligibility criteria in under-representation of women in clinical trials
Harriette Van Spall (Hamilton, Canada)

Biological plausibility of sex differences in CV trials. Is a difference expected?
Angela Maas (Nijmegen, NED)

Meta-analysis of sex-based subgroup analyses in CV trials.
Vijay Kunadian (Newcastle upon Tyne, UK)

Differences between men and women. When, and how to demonstrate? How and when explore differences using subgroup analysis?
Cindy Westerhout (Edmonton, CAN)

What sex related difference is clinically meaningful? Dosing, efficacy or safety differences?
Orly Vardeny (Minneapolis, MN, USA)

Are Sex – gender differences accounted for in regulatory approval?
Terri Cornelison (FDA, USA)

Patient viewpoint
Lisa Salberg (HCMA, USA)

THE CVCT Multi-Stakeholder Panel Debate

**WOMEN PARTICIPANTS IN CARDIO-RENAL-METABOLISM TRIALS.
ACTIONABLE STEPS TO DRIVE LASTING CHANGE**

Chairpersons: Mary N. Walsh (St Vincent, IN, USA), Cindy Westerhout (Edmonton, CAN)

Panelists : Terri Cornelison (FDA, USA), Vijay Kunadian (Newcastle upon Tyne, UK), Angela Maas (Nijmegen, NED), Jaime Raben (FDA, USA), Lisa Salberg (HCMA, USA), Harriette Van Spall (Hamilton, Canada), Orly Vardeny (Minneapolis, MN, USA), Birgit Vogel (New York, NY, USA), Mary N. Walsh (St Vincent, IN, USA), Cindy Westerhout (Edmonton, CAN)

Ballroom
Saturday 02 December, 2023
11:00 - 13:00

THE NEGLECTED CASE OF CHRONIC HEMODIALYSIS PATIENTS. TIME FOR ACTION!
Chairpersons: Christopher Granger (Durham, NC, USA), Faiez Zannad (Paris, FRA)

Intravenous Iron in Patients Undergoing Maintenance Hemodialysis. Are the PIVOTAL trial results influencing clinical practice?

Iain MacDougall (London, UK)

Exploring the inflammation hypothesis with anti-L6 therapy (Clazakizumab)

Glenn Chertow (Palo Alto, CA, USA)

Anticoagulation therapy in hemodialysis patients. Unmet need, ongoing FX and FXI trials

Christopher Granger (Durham, NC, USA)

The role of cardiovascular calcification, and the ongoing CALIPSO trial

Paolo Raggi (Alberta, CAN)

Mineralocorticoid receptor antagonist in ESRD. The ALCHEMIST trial

Faiez Zannad (Paris, FRA)

Angiotensinogen as a novel target for RAAS intolerant heart failure

Sam Tsimikas (Ionis, USA)

Industry viewpoints:

Maria Borentain (Bayer, GER), Concetta Lipardi (Janssen, USA), Pierluigi Tricoci (CSL Behring, USA)

Regulatory viewpoints

Alar Irs (EMA, EST)

Aliza Thompson (FDA, USA)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO MAKE CV TRIALS IN ESKD ATTRACTIVE AND EFFICIENT.

Chairpersons: Christopher Granger (Durham, NC, USA), Faiez Zannad (Paris, FRA)

Panelists : Maria Borentain (Bayer, GER), Glenn Chertow (Palo Alto, CA, USA), Alar Irs (EMA, EST), Christopher Granger (Durham, NC, USA), Concetta Lipardi (Janssen, USA), Iain MacDougall (London, UK), Paolo Raggi (Alberta, CAN), Sam Tsimikas (Ionis, USA), Aliza Thompson (FDA, USA), Pierluigi Tricoci (CSL Behring, USA), Faiez Zannad (Paris, FRA)

Conference
Saturday 02 December, 2023
11:00 - 13:00

THE ROLE OF REAL-WORLD EVIDENCE ALONGSIDE RCTS IN ASSESSING THE EFFECTIVENESS AND SAFETY OF CARDIOLOGICAL INTERVENTIONS: A DEBATE.

Chairpersons: Bernard Gersh (Rochester, MN, USA), Nawab Qizilbash (OXON Epidemiology, UK)

Real world evidence (RWE) is being increasingly used to assess the effectiveness and safety of medications and devices. A panel of leading epidemiologists and trialists will debate to what extent and where RWE can be trusted to provide robust evidence alongside randomized trials, with discussants from FDA, EMA, NICE and others.

We plan to centre the debate around the following three main aspects:

1. Why randomised evidence can or cannot be complemented or replaced by comparative observational studies
2. How RCTs can be made easier and more relevant to clinical practice
3. What is the place and reliability of non-randomised evidence when randomisation is not feasible?

Introduction Nawab Qizilbash (OXON Epidemiology, UK) and Bernard Gersh (Rochester, MN, USA)

Speakers:

Elisabetta Patorno (Boston, MA, USA)
Gregg Stone (New York, NY, USA)
Stuart Pocock (London, UK)

Discussants:

Regulatory
Mark Rothman (FDA, USA)
Steffen Thirstrup (EMA, CMO, NED)

Payers

Alan Fraser (Cardif, UK)

NIH-NHLBI

Yves Rosenberg (NHLBI, NIH, USA)

EU health data space (EHDS)

Markus Kalliola (Helsinki, FIN)

Industry

Sangeetha Anand (CSL Vifor, CH), Anouk Déruaz-Luyet (Boehringer Ingelheim, GER)

CRO

Nancy Dreyer (Dreyer strategies, USA)

Journal Editor

Chana Sacks (NEJM, USA)

Patient viewpoint

Philip Collis (British Heart Foundation, UK)

THE CVCT Multi-Stakeholder Panel Debate

THE ROLE OF REAL-WORLD EVIDENCE ALONGSIDE RCTS IN ASSESSING THE EFFECTIVENESS AND SAFETY OF CARDIOLOGICAL INTERVENTIONS.

Chairpersons: Bernard Gersh (Rochester, MN, USA), Nawab Qizilbash (OXON Epidemiology, UK)

Panelists : Felipe Aguel (FDA, USA), Sangeetha Anand (CSL Vifor, CH), Philip Collis ((British Heart Foundation, UK), Anouk Déruaz-Luyet (Boehringer Ingelheim, GER), Nancy Dreyer (Dreyer strategies, USA), Enrico Ferro (Boston, MA, USA), Alan Fraser (Cardif, UK), Bernard Gersh (Rochester, MN, USA), Markus Kalliola (Helsinki, FIN), Elisabetta Patorno , Stuart Pocock (London, UK), Nawab Qizilbash (OXON Epidemiology, UK), Yves Rosenberg (NHLBI, NIH, USA), Mark Rothman (FDA, USA), Chana Sacks (NEJM, USA), Alka Shaunik (CSL Behring, USA), Gregg Stone (New York, NY, USA) , Steffen Thirstrup (EMA, CMO, NED)

Holeman
Saturday 02 December, 2023
11:00 - 13:00

ISOQOL-CVCT joint session

APPROVAL AND VALUING OF “LIVING WELL” AS A CRITICAL OUTCOME IN CV TRIALS

Chairpersons : Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), John Spertus (Kansas City, MO, USA)

Navigating the Use of Patient-Reported Outcomes in clinical trials. Tools and Resources from the PROTEUS Consortium
Claire Snyder (Baltimore, MD, USA)

Should “Living well” become mandatory as an outcome in cardiovascular trials?
Nick Hartshorne-Evans (Pumping Marvellous Foundation , UK)

Accelerating the uptake of QOL into clinical practice. Translating the evidence from the ISCHEMIA trial to the bedside.
John Spertus (Kansas City, MO, USA)

How to intergrate QOL measuments in decision sharing involving patients?
Marc Bains (HeartLife Foundation, CAN)

Using health information technology to advance patient-reported outcome measurement in research and practice settings
Elizabeth Austin (Seattle, WA, USA)

Should QOL become pivotal in Health technology assessment bodies?
Marco Marchetti (Agenas and EU HTA, ITA)

How health technology assessment bodies analyze cost effectiveness of QOL outcomes?
Stuart Mealing (YHEC, UK)

PROs in real-world evidence to support regulation, reimbursement and health policy
Konrad Maruszczyk (Birmingham, UK)

ISOQOL-CVCT joint session

THE CVCT Multi-Stakeholder Panel Debate

APPROVAL AND VALUING OF “LIVING WELL” AS A CRITICAL OUTCOME IN CV TRIALS

Chairpersons : Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), John Spertus (Kansas City, MO, USA)

Panelists : Elizabeth Austin (Seattle, WA, USA) , Jacqueline Alikhaani (Los Angeles, USA), Sadegh Alikhaani (Los Angeles, USA) , Marc Bains (HeartLife Foundation, CAN), Patrick Gee (Chesterfield, MO, USA), Penilla Gunther (Stockholm, SWE), Nick Hartshorne-Evans (Pumping Marvellous Foundation , UK), Konrad Maruszczyk (Birmingham, UK), Stuart Mealing (YHEC, UK), Marco Marchetti (Agenas and EU HTA, ITA), Greg Merritt (Patient is Partner, USA), Rhonda Monroe (Baltimore, MD, USA), Mauro Moscucci (FDA, USA), Gina Peattie (Children’s Cardiomyopathy Foundation, USA), Juddson Rupp (Milestone Pharmaceuticals, USA), Claire Snyder (Baltimore, MA, USA), John Spertus (Kansas City, MO, USA), Mellanie True Hills (StopAfib.org, USA), Mariette Verbakel (Nijmegen, NED)

**Fourth Estate
Saturday 02 December, 2023
11:00 - 13:00**

iCVCT

ABDOMINAL AORTIC ANEURYSM AND CAROTID DISEASE TRIALS

Chairpersons: Jennifer Rymer (Durham NC USA) , Eric Secemsky (Boston, MA, USA)

**The Role of Endovascular Treatment for Abdominal Aortic Aneurysm: Endoleaks, Ruptures and Long-term Follow-Up
Endovascular aortic aneurysm repair vs Open Repair: Have we swung too far in one direction?
Rami Tadros (New York, NY, USA)**

**Long term safety of endografts for abdominal aortic aneurysm repair. The SAFE-AAA Study
Eric Secemsky (Boston, MA, USA)**

**Thoracic Endovascular Aortic Repair for Aortic Dissection. The IMPROVE-AD trial
Firas Mussa (Houston, TX, USA)**

**Revisiting Endovascular Options for Extracranial Carotid Artery Disease
Wei Zhou (Tucson, AZ, USA)**

Industry viewpoints

Michael Jaff (Boston Scientific, USA), Jack Springer (Nectero Medical, USA)

Patient viewpoints

**Naomi Buntsma (Amsterdam, NED)
Robin Gage (Lakeland, FL, USA)**

Regulatory viewpoint

Ronald Fairman (FDA, USA)

THE iCVCT Multi-Stakeholder Panel Debate

ABDOMINAL AORTIC ANEURYSM AND CAROTID DISEASE TRIALS

Chairpersons: Jennifer Rymer (Durham NC USA), Eric Secemsky (Boston, MA, USA)

All speakers : Naomi Buntsma (Amsterdam, NED), Ronald Fairman (FDA, USA), Robin Gage (Lakeland, FL, USA), Michael Jaff (Boston Scientific, USA), Firas Mussa (Houston, TX, USA), Kenneth Rosenfield (Boston, MA, USA), Jennifer Rymer (Durham NC USA), Eric Secemsky (Boston, MA, USA), Jack Springer (Nectero Medical, USA), Rami Tadros (New York, NY, USA), Wei Zhou (Tucson, AZ, USA)

Ballroom
Saturday 02 December, 2023
14:00 - 16:00

CHRONIC HEART KIDNEY DISORDER TRIALS.
IMPLEMENTATION ISSUES
WHO IS TO ACT ON CARDIORENAL EVIDENCE?

Chairpersons: Lesley Inker (Boston, MA, USA), Amy Mottl (Chapel Hill, NC, USA)

Any further trial evidence and/or real-world data needed?
Hiddo Lambers Heerspink (Groningen, NED)

How and who to act on the evidence in Chronic Heart Kidney Disorder?
Carmine Zoccali (Reggio Calabria, ITA),

Why and how to get nephrologists screen for CVD and heart failure
George Bakris (Chicago, IL, USA)

How and whom to get CKD patients on an MRA and/or an SGLT2is.

Nephrologist viewpoint
Amy Mottl (Chapel Hill, NC, USA)

Cardiologist viewpoint
Bertram Pitt (Ann Arbor, MI, USA)

General physician viewpoint
Eduard Shantsila (Liverpool, UK)

How to get general physicians to screen for undiagnosed heart failure and CKD
Kieran Docherty (Glasgow, UK)

The nationwide NUDGE-CKD trial – NUDGING general physician's and CKD patients to use guideline directed medical therapy.
Tor Biering-Sørensen (Copenhagen, DEN)

Industry viewpoints
Sofia Gerward (NovoNordisk, DEN), Mahesh Patel (Merck, USA), Jürgen Prochaska (Boehringer, GER), Martin van Eickels (Bayer, GER)

Patient viewpoint
Penilla Gunther (Stockholm, SWE)

THE CVCT Multi-Stakeholder Panel Debate

CHRONIC HEART KIDNEY DISORDER TRIALS
HOW AND WHO IS TO ACT ON THE ACCUMULATED CARDIORENAL EVIDENCE?
Chairpersons : Lesley Inker (Boston, MA, USA), Amy Mottl (Chapel Hill, NC, USA)

Panelists : George Bakris (Chicago, IL, USA), Tor Biering-Sørensen (Copenhagen, DEN), Kieran Docherty (Glasgow, UK), Sofia Gerward (NovoNordisk, DEN), Penilla Gunther (Stockholm, SWE), Hiddo Lambers Heerspink (Groningen, NED), Lesley Inker (Boston, MA, USA), Jesper Jensen (Hellerup, DEN), Amy Mottl (Chapel Hill, NC, USA), Mahesh Patel (Merck, USA), Bertram Pitt (Ann Arbor, MI, USA), Jürgen Prochaska (Boehringer, GER), Eduard Shantsila (Liverpool, UK), Martin van Eickels (Bayer, GER), Carmine Zoccali (Reggio Calabria, ITA)

Conference
Saturday 02 December, 2023
14:00 - 16:00

**SGLT2 INHIBITOR THERAPY POST MI
DEEP DIVE IN EMPACT-MI & DAPA-MI**

Chairpersons: Biykem Bozkurt (Houston, TX, USA), Javed Butler (Dallas, TX, USA)

Main results of DAPA MI
Darren McGuire (Dallas, USA)

Baseline Characteristics of EMPACT MI
Javed Butler (Dallas, TX, USA)

Comparing and contrasting DAPA MI and EMPACT MI. Study design and patient populations
Muthiah Vaduganathan (Boston, MA, USA)

How to interpret DAPA MI Win Ratio

Clinician viewpoint
Scott Solomon (Boston, MA, USA)

Statistical viewpoint
David DeMets (Madison, WI, USA)

Putting the results of SGLT2i in post MI patients in the context of clinical practice
Faiez Zannad (Paris, FRA)

Industry viewpoints
Martin Cowie (AstraZeneca, UK), Mikhail Sumin (Boehringer Ingelheim, GER)

Regulatory viewpoint
Jordan Pomeroy (FDA, USA)

THE CVCT Multi-Stakeholder Panel Debate

SGLT2 INHIBITOR THERAPY POST MI

Chairpersons: Biykem Bozkurt (Houston, TX, USA), Javed Butler (Dallas, TX, USA)

Panelists : Biykem Bozkurt (Houston, TX, USA), Javed Butler (Dallas, TX USA), Martin Cowie (AstraZeneca, UK), David DeMets (Madison, WI, USA), Darren McGuire (Dallas, USA), Jordan Pomeroy (FDA, USA), Scott Solomon (Boston, MA, USA), Mikhail Sumin (Boehringer Ingelheim, GER), Muthiah Vaduganathan (Boston, MA, USA), Faiez Zannad (Paris, FRA)

Holeman
Saturday 02 December, 2023
14:00 - 16:00

BIOMARKERS FOR CV TRIALS AND BIOMARKER TRIALS

Chairpersons: Jim Januzzi (Boston, MA, USA), Chris O'Connor (Washington DC, USA)

Biomarkers for defining patient population in CV trials. Natriuretic peptides as inclusion criteria in heart failure studies
Abhinav Sharma (Montreal, CAN)

Biomarkers for investigating mechanism of action in drug trials
Joao Ferreira (Porto, POR)

Debate: Are we ready for biomarkers as validated endpoints in later-stage drug trials? Biomarkers as endpoints in trials

Biomarkers do inform mechanisms of disease and can be trusted endpoints in trials.
Peter Liu (Toronto, CAN)

Biomarkers do not inform mechanism of disease and cannot be trusted endpoints in trials.
Milton Packer (Dallas, TX, USA)

Regulatory viewpoint: Establishing criteria for biomarker use as a validated endpoint for regulatory approvals in cardiovascular drug trials: what will it take?
Fortunato Senatore (FDA, USA)

Challenges in trial design for registrational studies of natriuretic peptides and troponin.
André Ziegler (Roche, CH)

Biomarkers for identifying biotargets
Julio Chirinos (Philadelphia, PA, USA)

The AMP HF/FNIH program.
Svati Shah (Durham, NC, USA)

Industry viewpoints:

Identifying new biomarkers: What are the challenges?

Tomasz Gasior (Boehringer, GER), Gillian Murtagh (Abbott, USA), Karsten Strauß (Olink, SWE), Jessica Williams (Somalogic, USA), André Ziegler (Roche, CH)

THE CVCT Multi-Stakeholder Panel Debate

HOW TO PROGRESS BIOMARKER SCIENCE FOR CLINICAL TRIALS

Chairpersons: Jim Januzzi (Boston, MA, USA), Chris O'Connor (Washington DC, USA)

Panelists: Kirkwood Adams (Chapel Hill, USA), Julio Chirinos (Philadelphia, PA, USA), Joao Ferreira (Porto, POR), Tomasz Gasior (Boehringer, GER), Peter Liu (Toronto, CAN), Masatake Kobayashi (Tokyo, JPN), Gillian Murtagh (Abbott, USA), Chris O'Connor (Washington DC, USA), Milton Packer (Dallas, TX, USA), Fortunato Senatore (FDA, USA), Svati Shah (Durham, NC, USA), Abhinav Sharma (Montreal, CAN), Karsten Strauß (Olink, SWE), Jessica Williams (Somalogic, USA), Faiez Zannad (Paris, FRA), André Ziegler (Roche, CH)

Fourth Estate
Saturday 02 December, 2023
14:00 - 16:00

PEDIATRIC CARDIOLOGY TRIALS

Chairpersons: Elfriede Pahl (Chicago, IL, USA), Gail Pearson (NIH, USA)

Pediatric Heart Registries as foundations and opportunities for clinical trials
Daphne Hsu (New York, NY, USA)

Examples of Pediatric Heart Registries available for research (rapid fire 5 mins presentations)

Pediatric Heart Network
Kristin Burns (NHLBI, NIH, USA)

The Pediatric Cardiomyopathy Registry and Heart Failure
Daphne Hsu (New York, NY, USA)

ACTION network - Mechanical support devices
Angela Lorts (Cincinnati, OH, USA)

Berlin Heart Trial
Robert Kroschwitz (Berlin Heart, USA)

ISHLT registry
Daphne Hsu (New York, NY, USA)

Endpoints in pediatric heart failure trials. The MATE SCORE
Christopher Almond (Stanford, CA, USA)

Designing the ideal Clinical Trial in Pediatric cardiology.
Christopher Almond (Stanford, CA, USA)

Challenges in statistics for smaller populations
Lynn Sleeper (Boston, MA, USA)

Industry viewpoints
Mackenzie Ford (Merck, USA), Ron Portman (Novartis, USA)

The parent perspective: Patient advocate viewpoint
Gina Peattie (Children's Cardiomyopathy Foundation, USA)

Regulatory viewpoint
Nicole Ibrahim (FDA, USA)

Patient viewpoint
Naomi Buntsma (Amsterdam, NED)

THE CVCT Multi-Stakeholder Panel Debate

HOW BEST TO FUND AND DO MULTICENTER PEDIATRIC CARDIOLOGY STUDIES

Chairpersons: Elfriede Pahl (Chicago, IL, USA), Gail Pearson (NIH, USA)

Panelists : Christopher Almond (Stanford, CA, USA), Naomi Buntsma (Amsterdam, NED), Kristin Burns (NIH, USA), Mackenzie Ford (Merck, USA), Daphne Hsu (New York, NY, USA), Nicole Ibrahim (FDA, USA), Sunjay Kaushal (Chicago, IL, USA), Robert Kroschwitz (Berlin Heart, USA), Angela Lorts (Cincinnati, OH, USA), Tom Melvin (Dublin, IRE), Shelley Miyamoto (Denver, CO, USA), Elfriede Pahl (Chicago, IL, USA), Gail Pearson (NIH, USA), Gina Peattie (Children's Cardiomyopathy Foundation, USA), Ron Portman (Novartis, USA), Laura Robertson (Tenaya, USA), Jonathan Schwartz (RocketPharma, USA), Lynn Sleeper (Boston, MA, USA), George Van Hare (FDA, USA)

Ballroom
Saturday 02 December, 2023
16:30 - 19:00

CHRONIC HEART KIDNEY DISORDER TRIALS.
PROGRESS IN ENDPOINTS DEFINITION

Chairpersons: Maria Rosa Costanzo (Naperville, IL, USA), Hiddo Lambers Heerspink (Groningen, NED)

Use of GFR slope as kidney endpoint in cardiovascular/heart failure trials
Lesley Inker (Boston, MA, USA)

Is albuminuria a reliable surrogate for kidney protection in CV trials?
Hiddo Lambers Heerspink (Groningen, NED)

New statistical approaches to the analysis of kidney function
Brian Claggett (Boston, MA, USA)

Combining kidney and cardiovascular endpoints in a hierarchical composite endpoint
Dustin Little (AstraZeneca, UK)

Regulatory viewpoints
Aliza Thompson (FDA, USA)

Industry viewpoints
Maria Borentain (Bayer, GER), Kristine Buchholtz (NovoNordisk, DEN), Concetta Lipardi (Janssen, USA), Dominik Steubl (Boehringer Ingelheim, GER), Fred Yang (KBP, USA)

Economist viewpoint
Jason Gordon (HEOR, UK)

THE CVCT Multi-Stakeholder Panel Debate

CHRONIC HEART KIDNEY DISORDER TRIALS
CAN WE REACH A CONSENSUS ON ENDPOINTS IN FUTURE CARDIORENAL TRIALS?

Chairpersons: Maria Rosa Costanzo (Naperville, IL, USA), Hiddo Lambers Heerspink (Groningen, NED)

Panelists : Maria Borentain (Bayer, GER), Kristine Buchholtz (NovoNordisk, DEN), Brian Claggett (Boston, MA, USA), Maria Rosa Costanzo (Naperville, IL, USA), Hiddo Lambers Heerspink (Groningen, NED), Lesley Inker (Boston, MA, USA), Concetta Lipardi (Janssen, USA), Dustin Little (AstraZeneca, UK), Jason Gordon (HEOR, UK), Dominik Steubl (Boehringer Ingelheim, GER), Aliza Thompson (FDA, USA), Fred Yang (KBP, USA)

Conference
Saturday 02 December, 2023
16:30 - 19:00

iCVCT

NEW TRIAL DESIGN AND OPPORTUNITIES WITH NEWER THROMBOSIS DRUGS

Chairpersons: Vijay Kunadian (Newcastle upon Tyne, UK), Roxana Mehran (New York, NY, USA)

Thrombotic risk post ACS, can we improve risk prediction and is it time for precision medicine?
Roxana Mehran (New York, NY, USA)

Can we Reduce Pathologic Thrombosis and Preserve Healthy Hemostasis with Factor Xi Inhibition?
C. Michael Gibson (Boston, MA, USA)

Can we further reduce the risk of bleeding with Factor Xi inhibition post stroke and what is the best efficacy endpoint:
Only symptomatic strokes, TIAs, or asymptomatic strokes as well?
Michael Sharma (Hamilton, CAN)

Are we going for both less bleeding and superior efficacy or just less bleeding in the setting of Factor Xi anticoagulation
for Atrial Fibrillation?
Christian Ruff (Boston, MA, USA)

Patients Self Injecting with P2Y12 Inhibition Before Hospitalization for ACS
Mary Mooney (Dublin, IR)

Early STEMI Care in the Home and Infarct Size as Part of a Win Ratio in Trials
C. Michael Gibson (Boston, MA, USA)

Industry viewpoints

Bjorn Dahlof (Cereno, SWE), Peter Dibattiste (Prolocor, USA), Bruno Flamion (Idorsia, CH), Robert Hillman (Celecor, USA), Klaus Jensen (Vectura Fertin, CH)

Patient viewpoints

Mellanie True Hills (StopAfib.org, USA)

Regulatory viewpoint

Jordan Pomeroy (FDA, USA)

THE iCVCT Multi-Stakeholder Panel Debate

NEW TRIAL DESIGN AND OPPORTUNITIES WITH NEWER THROMBOSIS DRUGS

Chairpersons: Vijay Kunadian (Newcastle upon Tyne, UK), Roxana Mehran (New York, NY, USA)

Panelists : Bjorn Dahlof (Cereno, SWE), Peter Dibattiste (Prolocor, USA), Bruno Flamion (Idorsia, CH), C. Michael Gibson (Boston, MA, USA), Robert Hillman (Celecor, USA), Klaus Jensen (Vectura Fertin, CH), Vijay Kunadian (Newcastle upon Tyne, UK), Mary Mooney (Dublin, IR), Jordan Pomeroy (FDA, USA), Christian Ruff (Boston, MA, USA), Michael Sharma (Hamilton, CAN), Mellanie True Hills (StopAfib.org, USA)

Holeman
Saturday 02 December, 2023
16:30 - 19:00

**ACTING ON THE EVIDENCE FROM WORSENING HEART FAILURE REAL WORLD DATA AND TRIALS.
GUIDELINES UPDATE AND IMPLEMENTATION STRATEGIES**

Chairpersons: Xavier Rossello (Madrid, ESP), Elke Platz (Boston, MA, USA)

Should new drug development in heart failure focus on patients discharged from an acute heart failure admission?
Gad Cotter (Momentum, USA)

Are Studies in Post-Acute Heart Failure Relevant to Chronic Heart Failure?
Milton Packer (Dallas, TX, USA)

Acute and worsening heart failure: How do SGLT2is, Sotagliflozin and Vericiguat fit?
Javed Butler (Dallas, TX, USA)
Bertram Pitt (Ann Arbor, MI, USA)

Decongestion strategies in acute heart failure:

Natriuresis guided therapy in acute heart failure
Jozine Ter Maaten (Groningen, NED)

How to maximize patient decongestion before discharge.
Wilfried Mullens (Hasselt, BEL)

How subcutaneous Furosemide help?
Marvin Konstam (Boston, MA, USA)

STRONG-HF in a box : How to use STRONG-HF tool kit in clinical practice.
Alexandre Mebazaa (Paris, FRA)

Guidelines update

The newest set of ESC guidelines
Borja Ibanez (Madrid, ESP)

Are US guidelines any different?
Biykem Bozkurt (Houston, USA)

Shouldn't heart failure guidelines of ICD prevention of sudden death be updated?
Jawad Butt (Copenhagen, DEN)

Patient viewpoint
Nick Hartshorne-Evans (Pumping Marvellous Foundation , UK)

THE CVCT Multi-Stakeholder Panel Debate
IMPLEMENTATION STRATEGIES FOR WORSENING HEART FAILURE
WHAT WORKS AND WHAT DOES NOT WORK?

Chairpersons: Xavier Rossello (Madrid, ESP), Elke Platz (Boston, MA, USA)

Panelists : Kirkwood Adams (Chapel Hill, USA), Biykem Bozkurt (Houston, USA), Javed Butler (Dallas, TX, USA), Jawad Butt (Copenhagen, DEN), Gad Cotter (Momentum, USA), Beth Davison (Momentum, USA), Nicolas Girerd (Nancy, FRA), Nick Hartshorne-Evans (Pumping Marvellous Foundation , UK), Borja Ibanez (Madrid, ESP), Marvin Konstam (Boston, MA, USA), Francesca Lawson (Corteria Pharmaceuticals, FRA), Matthew Lee (Glasgow, UK), Alexandre Mebazaa (Paris, FRA), Wilfried Mullens (Hasselt, BEL), Pieter Muntendam (SQ Innovation, USA), Milton Packer (Dallas, TX, USA), Bertram Pitt (Ann Arbor, MI, USA), Elke Platz (Boston, MA, USA), Xavier Rossello (Madrid, ESP), Jozine Ter Maaten (Groningen, NED), Harriette Van Spall (Hamilton, CAN), Faiez Zannad (Paris, FRA)

Fourth Estate
Saturday 02 December, 2023
16:30 - 19:00

LEGAL AND ETHICAL ISSUES ASSOCIATED WITH CLINICAL TRIALS
Chairpersons: Ellis Unger (HPM, WA, USA), Janet Wittes (Wittes LLC, USA)

Payment for patient recruitment in clinical trials: direct payment to investigators, access to health databases, competitive enrolment, and advertising for clinical research, waivers of informed consent

Legal: Alex Varond (Goodwin, USA)
Ethical: Deborah Barnbaum (Kent, OH, USA)

Liability of DSMB members and others involved in clinical trials

Legal: Michael Ewer (Houston, TX, USA)
Ethical: Julie Aultman (Rootstown, OH, USA)

Clinical trial data access and data sharing, biospecimens, data protection, electronic health records, AI

Legal: Dave Clissold (HPM, USA)
Ethical: Kayte Spector-Bagdady (Ann Arbor, MI, USA)

Legal framework and legal issues related to coverage of innovative technology

Steve Stranne (Foley Hoag, USA)

Journal Editor viewpoint

Jennifer Sargent (Nature, UK)

Patient viewpoint

Robin Gage (Lakeland, FL, USA)

THE CVCT Multi-Stakeholder Panel Debate

HOW TRIALISTS SHOULD NAVIGATE THE LEGAL AND ETHICAL FRAMEWORK

Chairpersons: Ellis Unger (HPM, WA, USA), Janet Wittes (Wittes LLC, USA)

Panelists: Julie Aultman (Rootstown, OH, USA), Deborah Barnbaum (Kent, OH, USA), Steve Stranne (Foley Hoag, USA), Dave Clissold (HPM, USA), Michael Ewer (Houston, TX, USA), Evelyne Friedel (Paris, FRA), Robin Gage (Lakeland, FL, USA), Jennifer Sargent (Nature, UK), Frank Sasinowski (HPM, USA), Kayte Spector-Bagdady (Ann Arbor, MI, USA), Ellis Unger (HPM, WA, USA), Alex Varond (Goodwin, USA), Mariette Verbakel (Nijmegen, NED), Janet Wittes (Wittes LLC, USA)