

18th Global **C**ardio **V**ascular
Clinical **T**rialists Forum

CVCT

2-5 December 2021
The Live Virtual Experience

PRELIMINARY PROGRAM

FACULTY

(All tentative, to be confirmed)

ACADEMY

1. Alexandre Abizaid (Sao Paulo, BRA)
2. William Abraham (Columbus, USA)
3. Kirkwood Adams (Chapel Hill, USA)
4. Yousif Ahmad (Los Angeles, USA)
5. John Alexander (Durham, USA)
6. Dominick Angiolillo (Miami, USA)
7. Stefan Anker (Berlin, GER)
8. Michel Azizi (Paris, FRA)
9. Emilia Bagiella (New York, USA)
10. George Bakris (Chicago, USA)
11. Christina Eleanor Barkauskas (Durham, USA)
12. Julia Baron (Derby, GBR)
13. Suzanne Baron (Burlington, USA)
14. Ian Barrow (Washington, USA)
15. Supria Batra (Washington, USA)
16. Ori Ben-Yehuda (San Diego, USA)
17. Raymond Benza (Columbus, USA)
18. Deepak Bhatt (Boston, USA)
19. Sanjeev Bhavnani (La Jolla, USA)
20. Jan Biegus (Wroclaw, POL)
21. Roberto Bolli (Louisville, USA)
22. Athenais Boucly (Paris, FRA)
23. Jeffrey Borer (New York, USA)
24. Barry Borlaug (Rochester, USA)
25. Nadia Bouabdallaoui (Montreal, CAN)
26. Michael Bowdish (Los Angeles, USA)
27. Biykem Bozkurt (Houston, USA)
28. Javed Butler (Jackson, USA)
29. Dan Burkhoff (New York, USA)
30. Robert Byrne (Dublin, IRE)
31. Jun Cai (Fu Wai, CN)
32. David Callans (Philadelphia, USA)
33. Antonio Cannata (London, GBR)
34. Davide Capodanno (Catania, ITA)
35. Davide Cao (New York, USA)
36. Alaide Chieffo (Milano, ITA)
37. Daein Choi (New York, USA)
38. Joanna Chikwe (Los Angeles, USA)
39. Ashley Chin (Capetown, SA)
40. John Cleland (Glasgow, USA)
41. David J Cohen (New York, USA)
42. Joe Coresh (Baltimore, USA)
43. Maria Rosa Costanzo (Naperville, USA)
44. Martin Cowie (London, GBR)
45. Linda Cripe (Columbus, USA)
46. Blanche Cupido (Capetown, SA)
47. Donald Cutlip (Boston, USA)
48. Nikolaos Dages (Leipzig, GER)
49. George Dangas (New York, USA)
50. Thomas Deering (Atlanta, USA)
51. Victoria Delgado (Leiden, NED)
52. David DeMets (Madison, USA)
53. Ron Do (New York, USA)
54. Gregory Elliott (Salt Lake City, USA)
55. Lisa Emmens (Groningen, NED)
56. Murray Epstein (Miami, USA)
57. Derek Exner (Calgary, CAN)
58. Charles Fauvel (Columbus, USA)
59. Brian Ference (Oxford, GBR)
60. Joao Ferreira (Porto, POR)
61. Gerasimos Filippatos (Athens, GRE)
62. Gemma Figtree (Sydney, AUS)
63. Gregg C. Fonarow (San Francisco, USA)
64. Veronica Franco (Columbus, USA)
65. Marat Fudim (Durham, USA)
66. Nazzareno Galiè (Bologna, ITA)
67. Peter Ganz (San Francisco, USA)
68. Mario Gaudino (New York, USA)
69. Raul Angel A Garcia (Kansas City, USA)
70. Annetine Gelijns (New York, USA)
71. Bernard Gersh (Rochester, USA)
72. Simon Gibbs (London, GBR)
73. Michael Gibson (Boston, USA)
74. Wendy Gin-Sing (London, GBR)
75. Mardi Gomberg-Maitland (Washington, USA)
76. Sascha Goonewardena (Ann Arbor, USA)
77. Christopher Granger (Durham, USA)
78. Jennifer Green (Durham, USA)
79. Barry Greenberg (San Diego, USA)
80. John Gregson (London, GBR)
81. Mayra Guerrero (Rochester, USA)
82. Camilla Hage (Stockholm, SWE)
83. Rebecca Hahn (New York, USA)
84. Signe Hansen (Copenhagen, DEN)
85. Josephine Harrington (Durham, USA)
86. Robert Harrington (Stanford, USA)
87. Paul Hassoun (Baltimore, USA)

88. Neil Hawkins (Glasgow, GBR)
89. Hidido Heerspink (Groningen, NED)
90. Adrian Hernandez (Durham, USA)
91. Gerhard Hindricks (Leipzig, GER)
92. Ziad Hijazi (Uppsala, SWE)
93. Marius Hoeper (Hannover, GER)
94. Marc Humbert (Paris, FRA)
95. Yong Huo (Peking University, CN)
96. Elaine Hylek (Boston, USA)
97. Alexander Iribarne (Lebanon, USA)
98. Stefan James (Uppsala, SWE)
99. Jim Januzzi (Boston, USA)
100. Ewa Jankowska (Wroclaw, POL)
101. Karola Jering (San Diego, USA)
102. Mariell Jessup (AHA, Hingham, USA)
103. Pia R Kamstrup (Copenhagen, DEN)
104. Navin Kapur (Boston, USA)
105. Saibal Kar (Los Angeles, USA)
106. Steve Kawut (Philadelphia, USA)
107. Rani Khatib (Leeds, GBR)
108. Paulus Kirchhof (Hamburg, GER)
109. Winfried Klausnitzer (Nürnberg, GER)
110. Panos Kanavos (London, GBR)
111. Susheel Kodali (New York, USA)
112. Wolfgang Koenig (Münich, GER)
113. Mikhail Kosiborod (Kansas City, USA)
114. Karl-Patrik Kresoja (Leipzig, GER)
115. Florian Kronenberg (Innsbruck, AUS)
116. Konstantin Krychtiuk (Durham, USA)
117. Linong Ji (Peking, CN)
118. Philip Joseph (Hamilton, CAN)
119. Carolyn Lam (Singapore, SIN)
120. David Lanfear (Detroit, USA)
121. Martin Landray (Oxford, GBR)
122. Martin Leon (New York, USA)
123. Jane Leopold (Boston, USA)
124. Adeera Levin (Vancouver, CAN)
125. Eldrin Lewis (Stanford, USA)
126. Peter Libby (Boston, USA)
127. Cecilia Linde (Stockholm, SWE)
128. Joann Lindenfeld (Nashville, USA)
129. Gregory Lip (Liverpool, GBR)
130. Renato Lopes (Durham, USA)
131. Jamie Mc Cabe (Washington, USA)
132. Finnian Mc Causland (Boston, USA)
133. Theresa McDonagh (London, GBR)
134. Michael Mack (Dallas, USA)
135. Darren McGuire (Dallas, USA)
136. Vallerie McLaughlin (Ann Arbor, USA)
137. John McMurray (Glasgow, GBR)
138. Akiko Maehara (New York, USA)
139. Francesco Maisano (Milano, ITA)
140. Waqas Malick (New York, USA)
141. Daniel Mark (Durham, USA)
142. Brad Maron (Boston, USA)
143. Ramesh Mazhari (Washington, USA)
144. Roxana Mehran (New York, USA)
145. Marco Metra (Brescia, ITA)
146. Erin Michos (Baltimore, USA)
147. Gary Mintz (Washington, USA)
148. Jaime J Miranda (Lima, PEN)
149. Alexandre Mebazaa (Paris, FRA)
150. Freny Mody (Los Angeles, USA)
151. David Montani (Paris, FRA)
152. Marie-Claude Morice (Paris, FRA)
153. Nick Morrell (Cambridge, USA)
154. Jagat Narula (New York, USA)
155. Bruce Neal (Sydney, AUS)
156. Dan Nguyen (Kansas City, USA)
157. Johnny Nicolas (New York, USA)
158. Christopher O'Connor (Washington, USA)
159. Michelle O'Donoghue (Boston, USA)
160. Patrick O'Gara (New York, USA)
161. Suzanne Oparil (Birmingham, USA)
162. Rebecca Ortega (North Carolina, USA)
163. John O'Sullivan (Sydney, AU)
164. Jessica Overbey (New York, USA)
165. Douglas Packer (Rochester, USA)
166. Milton Packer (Dallas, USA)
167. Richard Page (Burlington, USA)
168. Ambarish Pandey (Dallas, USA)
169. Manesh Patel (Durham, USA)
170. Vlado Perkovic (Sydney, AUS)
171. Anna Sonia Petronio (Pisa, ITA)
172. Frederik Persson (Copenhaguen, DEN)
173. Marc Pfeffer (Boston, USA)
174. Jonathan Piccini (Durham, USA)
175. Ileana Pina (Detroit, USA)
176. Duane Pinto (Boston, USA)
177. Bertram Pitt (Ann Arbor, USA)
178. Elke Platz (Boston, USA)
179. Stuart Pocock (London, GBR)
180. Piotr Ponikowski (Wroclaw, POL)
181. Aruna Pradhan (Boston, USA)
182. Ioana Preston (Boston, USA)
183. Arshed Quyyumi (Atlanta, USA)
184. Daniel Rader (Philadelphia, USA)
185. Kazem Rahimi (Oxford, GBR)
186. Sanjay Rajagopalan (Cleveland, USA)
187. Stuart Rich (Chicago, USA)
188. Paul Ridker (Boston, USA)
189. Karl-Philipp Rommel (Leipzig, GER)

190. Hannah Rosenblum (New York, USA)
191. Robert S. Rosenson (New York, USA)
192. Joseph Ross (New Haven, USA)
193. Peter Rossing (Copenhagen, DEN)
194. Patrick Rossignol (Nancy, FRA)
195. Prabir Roy-Chaudhury (North Carolina, USA)
196. Raul Santos (São Paulo, USA)
197. Naveed Sattar (Glasgow, GBR)
198. Gregory Schwartz (Colorado, USA)
199. Frank Sellke (Providence, USA)
200. Kimberly Selzman (Salt Lake City, USA)
201. Sanjiv Shah (Chicago, USA)
202. Aleesha Shaik (New York, USA)
203. Gérald Simonneau (Paris, FRA)
204. Olivier Sitbon (Paris, FRA)
205. Peter Kent Smith (Durham, USA)
206. John Spertus (Kansas City, USA)
207. Paul Sobotka (Philadelphia, USA)
208. Scott Solomon (Boston, USA)
209. Giulio Stefanini (Milano, ITA)
210. Gabriel Steg (Paris, FRA)
211. Robert Storey (Sheffield, GBR)
212. Erik Stroes (Amsterdam, NED)
213. Gilbert Tang (New York, USA)
214. Wilson Tang (Cleveland, USA)
215. Jean Claude Tardif (Montreal, CAN)
216. John Teerlink (San Francisco, USA)
217. Thennapan Thennapan (Minneapolis, USA)
218. Holger Thiele (Leipzig, GER)
219. Jasper Tromp (Singapore, SG)
220. Mintu Turakhia (Stanford, USA)
221. Marcus Antony Urey (San Diego, USA)
222. Arnoud van't Hof (Maastricht, NED)
223. Harriette Van Spall (Hamilton, CAN)
224. Subodh Verma (Toronto, CAN)
225. Eric Vicaut (Paris, FRA)
226. Scott Visovatti (Columbus, USA)
227. Jha Vivekanand (New Delhi, IND)
228. Adriaan Voors (Groningen, NED)
229. Ori Waksman (New York, USA)
230. Jiguang Wang (Shanghai, CN)
231. Christoph Wanner (Wurzburg, GER)
232. Jason Weatherald (Calgary, CAN)
233. David Wheeler (London, GBR)
234. Christopher Wilcox (Washington, USA)
235. Stephan Windecker (Bern, CH)
236. Jianwei Xuan (Sun Yat-Sen University, CN)
237. Clyde Yancy (Chicago, USA)
238. Robert Yeh (Boston, USA)
239. Isabelle Durand-Zalesky (Paris, FRA)

240. Roham Zamanian (Stanford, USA)
241. Faiez Zannad (Paris, FRA)
242. Wojciech Zareba (Rochester, USA)
243. Hong Zhang (Peking, CN)
244. Rayan El-Zein (Kansas City, USA)
245. Shelley Zieroth (Manitoba, CAN)
246. Mike Zile (Charleston, USA)

JOURNAL/MEDIA

247. Filippo Crea (EHJ, Rome, ITA)
248. Robert Golub (JAMA, Chicago, USA)
249. Joseph Hill (Circulation, Dallas, USA)
250. Larry Husten (CVCTCardiobrief, New York, USA)
251. John Keaney (NEJM, Boston, USA)
252. Rob Mentz (JCF, Durham, USA)
253. Rita Redberg (JAMA Internal Medicine, USA)
254. Chana Sacks (NEJM Evidence, USA)
255. Rupa Sarkar (The Lancet Digital Health, GBR)
256. Stuart Spencer (The Lancet, London, GBR)
257. Ron Winslow (Ex Wall Street Journal, Portland, USA)

INDUSTRY

258. Siddique Abbasi (Amgen, USA)
259. Philip Adamson (Abbott, USA)
260. Rahul Agrawal (Cardior Pharmaceuticals, GER)
261. Shazia Ali (Regeneron, USA)
262. Dominic Allocco (Boston Scientific, USA)
263. Tomas Andersson (AstraZeneca, SWE)
264. James Hamilton (Arrowhead, USA)
265. Andrea Ballagi (Olink, SWE)
266. Dawn Bardot (AbioMed, USA)
267. Maurice Berenger (Cardio Renal, FRA)
268. Corine Bernaud (Idorsia, CH)
269. Agim Beshiri (Abbott Dx, USA)
270. Sandeep Brar (Medtronic, USA)
271. Martina Brueckmann (Boehringer Ingelheim, GER)
272. Kristine Buchholtz (NovoNordisk, DEN)
273. Jim Carr (Stealth, USA)
274. Kelly Jean Craig (IBM, USA)
275. Björn Dahlof (Cereno, SWE)
276. Ben Dake (Aerovate Therapeutics, USA)
277. Irene Dankwa-Mullan (IBM, USA)
278. Efthymios Deliarhyris (Cytosorbents, USA)
279. Janethe de Oliveira Pena (Acceleron Pharma, Inc., USA)
280. Pete DiBattiste (Prolocor, USA)
281. Declan Doogan (Juvenescence, USA)
282. Irina Elyubaeva (Servier, FRA)
283. Marino Fernandez (Boehringer Ingelheim, GER)
284. Anders Gabrielse (AstraZeneca, SWE)

285. Ibon Garitaonandia (Cellprothera, FRA)
 286. Jyothis Thomas George (Novonordisk, DEN)
 287. Al Gianchetti (Xylocor, USA)
 288. Hunter Gillies (Aerovate Therapeutics, USA)
 289. Chris Giordano (TenaxThera, USA)
 290. Ruchira Glaser (Moderna, USA)
 291. Craig Granowitz (Alexion, USA)
 292. Sibylle Hauske (Boehringer Ingelheim, GER)
 293. Philippe Henon (Cellprothera, FRA)
 294. Robert Hillman (Celecor, USA)
 295. Narimon Honarpour (Amgen, USA)
 296. Neil Hounslow (Kowa, GBR)
 297. Silviu Itescu (Mesoblast, USA)
 298. Klaus Jensen (Vifor, CH)
 299. Nardev Khurmi (Sanofi, USA)
 300. Gerard Kornelis Hovingh (Novonordisk, DEN)
 301. Helina Kassahun (Amgen, USA)
 302. Jorg Koglin (Merck, USA)
 303. Rob Kowal (Medtronic, USA)
 304. Mikael Kubista (TATAA Biocenter, SWE)
 305. Anna Maria Langkilde (AstraZeneca, SWE)
 306. Robert Lawatscheck (Bayer, GER)
 307. Howard M. Lazarus (Altavant Sciences, Inc., USA)
 308. Victoria Lee (Cytosorbents, USA)
 309. Maria Leonsson-Zachrisson (AstraZeneca, SWE)
 310. Larry Liu (Merck, USA)
 311. Jill Loftiss (RedbudMed, CN)
 312. Santica Marcovina (MedPace, USA)
 313. Serge Masson (Roche, CH)
 314. Devan Mehrotra (Merck, USA)
 315. Kim So-Young (Bayer, USA)
 316. Peter Muntendam (G3Pharmaceuticals, USA)
 317. Masahiro Murakami (Eli Lilly, USA)
 318. Richard Nkulikiyinka (Bayer, GER)
 319. Mahesh Patel (Merck, USA)
 320. David Platt (Novartis, USA)
 321. Robert Pordy (Regeneron, USA)
 322. Emma Raderschadt (Boehringer Ingelheim, GER)
 323. Lothar Roessig (Bayer, GER)
 324. Jérôme Rossert (AstraZeneca, USA)
 325. Sébastien Roux (Idorsia, CH)
 326. Giacomo Ruotolo (Eli Lilly, USA)
 327. Dan Schaber (Medtronic, USA)
 328. AnnaLotta Schiller (TATAA, SWE)
 329. Marc Semigran (Renovacor, USA)
 330. Monica Shah (IQVIA, USA)
 331. Salim Shah (Sarfez, USA)
 332. Chuck Simonton (Abiomed, USA)
 333. David Soergel (Novartis, USA)
 334. Derek Solum (United Therapeutics, USA)
 335. Craig Sponseller (Kowa, USA)
 336. Kenneth Stein (Boston Scientific, USA)
 337. James Strait (Merck, USA)
 338. Fernando Suarez (IBM, USA)
 339. Mikhail Sumin (Boehringer Ingelheim, GER)
 340. Bill Symonds (Altavant Sciences, Inc., USA)
 341. Thomas Thum (Cardior Pharmaceuticals, GER)
 342. Thomas Thuren (Novartis, USA)
 343. Paul Trichelair (Owkin, FRA)
 344. Sotirios Tsimikas (Ionis, USA)
 345. Claudia Ulbrich (Cardior, GER)
 346. Martin Unverdorben (Daiichi Sankyo, USA)
 347. Christos Varounis (Abbott Dx, USA)
 348. Stephanie Weber (Idorsia, CH)
 349. Jaime Wheeler (Edwards, USA)
 350. Steve Williams (Somalogic, USA)
 351. Janet Wittes (StatCollaborative, USA)
 352. Fred Yang (KBP, USA)
 353. Shuo Yang (Sanofi China, CN)
 354. Nadim Yared (CVRx, USA)
 355. Antoine Yver (Centessa Pharmaceuticals, USA)
 356. Kezhou Zhang (NovoNordisk, CN)
 357. André Ziegler (Roche, CH)
 358. Lawrence S. Zisman (Gossamer Bio Inc, USA)
- ## REGULATORY
359. Angeles Alonso (MHRA, GBR)
 360. Kristina Dunder (EMA, SWE)
 361. Andrew Farb (FDA, USA)
 362. Alan Fraser (Cardiff, GBR)
 363. ChangFu Wu (FDA, USA)
 364. Charu Gandotra (FDA, USA)
 365. Nicole Ibrahim (FDA, USA)
 366. Armin Koch (EMA, GER)
 367. Adrian Magee (FDA, USA)
 368. Peter Mol (EMA, NED)
 369. Dan O'Connor (MHRA, GBR)
 370. Narumi Okura (PMDA, JAP)
 371. Bakul Patel (FDA, USA)
 372. Mitch Psootka (FDA, USA)
 373. Krishna Prasad (MHRA, GBR)
 374. Fred Senatore (FDA, USA)
 375. John Sharretts (FDA, USA)
 376. Meir Shinnar (FDA, USA)
 377. Jeff Siegel (FDA, USA)
 378. Norman Stockbridge (FDA, USA)
 379. Bob Temple (FDA, USA)
 380. Mary Thanh-Hai (FDA, USA)
 381. Aliza Thompson (FDA, USA)

- 382. Ellis Unger (Former FDA experience, USA)
- 383. George Van Hare (FDA, USA)
- 384. Bernard Vasseur (FDA, USA)
- 385. Bram Zuckerman (FDA, USA)

NIH

- 386. Patrice Desvigne-Nickens (NIH, USA)
- 387. Lawrence Fine (NHLBI, USA)
- 388. Erin Iturriaga (NIH, NHLBI, USA)
- 389. Jonathan Kaltman (NIH, USA)
- 390. Saul Malozowski (NIDDK, USA)
- 391. Yves Rosenberg (NIH, USA)
- 392. Ivonne Schulman (NIH, USA)
- 393. Wendy Weber (NIH, NCCIH, USA)

PATIENTS/PATIENTS REPRESENTATIVES

- 394. Bill Adams (Erhard, USA)
- 395. Jacqueline Alikhaani (Los Angeles, USA)
- 396. Sadeqh Alikhaani (Los Angeles, USA)
- 397. Luis Bras Rosario (European Heart Network, POR)
- 398. Cynthia Chauhan (Wichita, USA)
- 399. Jillianne Code (Vancouver, CAN)
- 400. Patrick Gee (Chesterfield, USA)
- 401. Nick Hartshorne-Evans (London, GBR)
- 402. Denis Janssen (Amsterdam, NED)
- 403. Trudie Lobban (London, GBR)
- 404. Steven Macari (Poitiers, FRA)
- 405. Robin Martinez (Denver, USA)
- 406. Greg Merritt (Brighton, USA)
- 407. Caius Ovidiu Mersa (European Heart Network, ROM)
- 408. Emily Milligan (Barth Syndrome Foundation, USA)
- 409. Wanda F Moore (Arizona, USA)
- 410. Collis Phil (European Heart Network, GBR)
- 411. Mellanie True Hills (StopAfib.org, Greenwood, USA)
- 412. Marietta Verbakel (Nijmegen, NED)
- 413. Marilena Vrana (European Heart Network, BEL)

LAWYERS & ETHICISTS

- 414. Paul M Rudolph (Arnold&Porter, USA)

PAYER / ECONOMISTS

- 415. Steven Farmer (CMS, USA)
- 416. Louis Jacques (ADVI, USA)
- 417. Mantovani Lorenzo (Milano, ITA)
- 418. Phil McEwan (HEOR, GBR)
- 419. Piotr Szymanski (Warsaw, POL)

THURSDAY, DECEMBER 2ND

GUSTAVE COURBET

13:00 - 15:00 CET
07:00 - 09:00 EST

HEART FAILURE WITH PRESERVED EJECTION FRACTION LIGHT AT THE END OF THE TUNNEL?

Part I. Understanding and Interpreting the results of EMPEROR-PRESERVED

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

HEART FAILURE WITH PRESERVED EJECTION FRACTION. LIGHT AT THE END OF THE TUNNEL?

Part II. Implementing the results of EMPEROR-PRESERVED

[view details >>](#)

18:00 - 20:30 CET
12:00 - 14:30 EST

TAILORING MEDICAL THERAPY TO HEART FAILURE CLINICAL PROFILES

[view details >>](#)

JEAN-AUGUSTE-DOMINIQUE INGRES

13:00 - 15:00 CET
07:00 - 09:00 EST

THE RAPIDLY CHANGING LANDSCAPE OF CARDIO KIDNEY TRIALS Part 1

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY Part 2

[view details >>](#)

18:00 - 20:30 CET
12:00 - 14:30 EST

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY Part 3

[view details >>](#)

EUGÈNE DELACROIX

13:00 - 15:00 CET
07:00 - 09:00 EST

PUBLISHING AND AUTHORSHIP OF MAJOR TRIALS RESULTS

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

MAXIMIZING SCIENTIFIC KNOWLEDGE PRODUCTION FROM TRIAL DATA

[view details >>](#)

18:00 - 20:30 CET
12:00 - 14:30 EST

THE INNOVATION LANDSCAPE Part 1: BIOTECH RAPID FIRE AND READINESS FOR TRANSLATION

[view details >>](#)

TOULOUSE LAUTREC

13:00 - 15:00 CET
07:00 - 09:00 EST

DEVELOPMENTS IN ATHEROSCLEROSIS FAMILIAL HYPERCHOLESTEROLEMIA TRIALS

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

LIPOPROTEIN (a) INHIBITORS LOWERING DRUGS TRIALS

[view details >>](#)

18:00 - 20:30 CET
12:00 - 14:30 EST

ATHEROSCLEROSIS AND INFLAMMATION TRIALS

[view details >>](#)

FRIDAY, DECEMBER 3RD

ALFRED SISLEY

13:00 - 15:00 CET
07:00 - 09:00 EST

**NEW HFrEF GUIDELINES...
SO WHAT?**

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

**SHOULD NOT THE FUTURE
HFrEF TRIALS RATHER BE
IMPLEMENTATION TRIALS?**

[view details >>](#)

18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST

**THE INNOVATION LANDSCAPE
Part 2: RARE DISEASE
CARDIOMYOPATHIES
PATHWAYS FOR APPROVAL**

[view details >>](#)

PAUL GAUGUIN

13:00 - 15:00 CET
07:00 - 09:00 EST

**HOW CLOSE ARE WE TO
A "REASONABLY LIKELY"
AND "UNIVERSAL"
CARDIOVASCULAR
SURROGATE ENDPOINT?**

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

**PRIMARY PREVENTION.
RECENT AND ONGOING
TRIALS**

[view details >>](#)

18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST

**PROMOTING THE PRIMARY
PREVENTION TRIALS AGENDA**

[view details >>](#)

CAMILLE PISSARRO

13:00 - 15:00 CET
07:00 - 09:00 EST

**DEVELOPMENTS IN
HYPERTRIGLYCERIDEMIA
TRIALS**

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

**OBESITY TRIALS: WEIGHT
LOSS AND CARDIOVASCULAR
OUTCOME TRIALS WITH GIP
AND/OR GLP-1 RECEPTOR
AGONISTS**

[view details >>](#)

18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST

**SGLT2i and GLP1RA
CARDIOMETABOLIC TRIALS**

[view details >>](#)

AUGUSTE RODIN

13:00 - 15:00 CET
07:00 - 09:00 EST

**IMPLANTABLE DEVICES AND
MONITORING HEART FAILURE
TRIALS**

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

**HEMODYNAMIC SUPPORT
DEVICES TRIALS (ICVCT) 1**

[view details >>](#)

18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST

**VALUATION OF DEVICE
CLINICAL EVIDENCE FOR
COVERAGE PURPOSES**

[view details >>](#)

SATURDAY, DECEMBER 4TH

PIERRE-AUGUSTE RENOIR

13:00 - 15:00 CET
07:00 - 09:00 EST

ANTITHROMBOTIC THERAPY TRIALS (ICVCT) 2

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

PERIOPERATIVE MANAGEMENT OF ANTITHROMBOTIC THERAPY (ICVCT) 3

[view details >>](#)

18:00 - 20:00 CET
12:00 - 14:00 EST

TRIALS IN HIGH BLEEDING RISK PATIENTS (ICVCT) 4

[view details >>](#)

PAUL CEZANNE

13:00 - 15:00 CET
07:00 - 09:00 EST

ATRIAL FIBRILLATION PREVENTION OF PROGRESSION AND MORTALITY & MORBIDITY RISK REDUCTION TRIALS

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

THE EVOLVING LANDSCAPE OF PULMONARY ARTERIAL HYPERTENSION TRIALS Part 1- PROGRESS IN TRIAL DESIGN

[view details >>](#)

18:00 - 20:00 CET
12:00 - 14:00 EST

THE EVOLVING LANDSCAPE OF PULMONARY ARTERIAL HYPERTENSION PHASE 3 TRIALS Part 2- REDEFINING CLINICALLY MEANINGFUL ENDPOINTS

[view details >>](#)

EDGAR DEGAS

13:00 - 15:00 CET
07:00 - 09:00 EST

PATIENT REPORTED OUTCOMES

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

PATIENT VOICE IN CLINICAL TRIAL - GETTING BEYOND LIP SERVICE

[view details >>](#)

18:00 - 20:00 CET
12:00 - 14:00 EST

INCREASING EQUITY AND DIVERSE REPRESENTATION AMONG PARTICIPANTS IN CARDIOVASCULAR CLINICAL TRIALS

[view details >>](#)

VINCENT VAN GOGH

13:00 - 15:00 CET
07:00 - 09:00 EST

DIGITAL HEALTH TRIALS

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY Part 1 : ONGOING TRIALS

[view details >>](#)

18:00 - 20:00 CET
12:00 - 14:00 EST

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY Part 2 : METHODOLOGICAL ISSUES

[view details >>](#)

SUNDAY, DECEMBER 5TH

ÉDOUARD MANET

13:00 - 15:00 CET
07:00 - 09:00 EST

REVASCULARIZATION TRIALS
(ICVCT)

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST

SURGICAL TRIALS IN
CARDIOVASCULAR DISEASE
(ICVCT) 6

[view details >>](#)

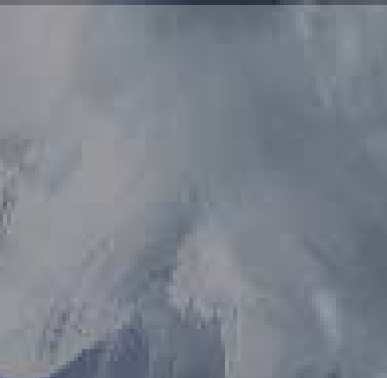
18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST

MITRAL AND TRICUSPID
VALVE TRIALS
(ICVCT) 7

[view details >>](#)

CLAUDE MONET

13:00 - 15:00 CET
07:00 - 09:00 EST

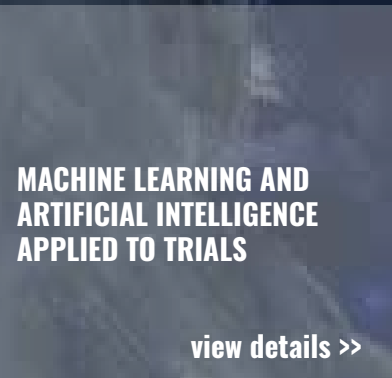


15:30 - 17:30 CET
09:30 - 11:30 EST

CHEAPER, FASTER AND
MORE EFFICIENT TRIALS. IS
PRAGMATIC THE SOLUTION?

[view details >>](#)

18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST



MACHINE LEARNING AND
ARTIFICIAL INTELLIGENCE
APPLIED TO TRIALS

[view details >>](#)

JEAN BAPTISTE COROT

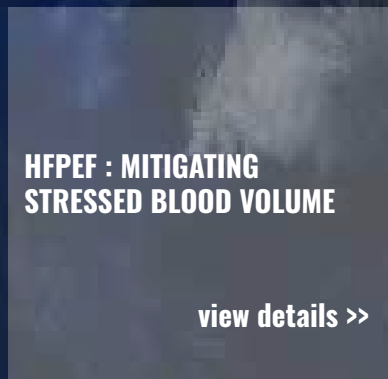
13:00 - 15:00 CET
07:00 - 09:00 EST



CVCT GLOBAL – CHINA

[view details >>](#)

15:30 - 17:30 CET
09:30 - 11:30 EST



HFPEF : MITIGATING
STRESSED BLOOD VOLUME

[view details >>](#)

18:00 - 20:00/20:30 CET
12:00 - 14:00/14:30 EST



LESSONS FROM COVID

[view details >>](#)

**Room: Gustave Courbet
Thursday 02 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST**

**HEART FAILURE WITH PRESERVED EJECTION FRACTION LIGHT AT THE END OF THE TUNNEL?
Part I. Understanding and Interpreting the results of EMPEROR-PRESERVED
Chairpersons : Carolyn Lam (Singapore, SIN) & Naveed Sattar (Glasgow, GBR)**

**EMPEROR-PRESERVED main CV results
Stefan Anker (Berlin, GER)**

**EMPEROR-PRESERVED main renal results
Joao Ferreira (Porto, POR)**

**Patient reported outcomes results
Javed Butler (Jackson, USA)**

**Safety considerations
Gerasimos Filippatos (Athens, GRE)**

**Statistical viewpoint
Stuart Pocock (London, GBR)**

**What's next? The consequence of EMPEROR-PRESERVED on the ongoing HFpEF trials.
John McMurray (Glasgow, GBR)**

**Mechanistic insight.
Milton Packer (Dallas, USA) vs. Christopher Wilcox (Washington, USA)**

**Regulatory viewpoints
Angeles Alonso (MHRA, GBR)
Bob Temple (FDA, USA)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**HEART FAILURE WITH PRESERVED EJECTION FRACTION
Part I: Interpreting the results of EMPEROR-PRESERVED
Chairpersons : Carolyn Lam (Singapore, SIN) & Naveed Sattar (Glasgow, GBR)**

Panelists: Angeles Alonso (MHRA, GBR); Tomas Andersson (AstraZeneca, SWE); Stefan Anker (Berlin, GER); Biykem Bozkurt (Houston, USA); Martina Brueckmann (Boehringer Ingelheim, GER); Javed Butler (Jackson, USA); John Cleland (Glasgow, USA); Lisa Emmens (Groningen, NED); Joao Ferreira (Porto, POR); Gerasimos Filippatos (Athens, GRE); Nick Hartshorne-Evans (London, GBR); Carolyn Lam (Singapore, SIN); John McMurray (Glasgow, GBR); Robert Mentz (Durham, USA); Freny Mody (Los Angeles, USA); Milton Packer (Dallas, USA); Ambarish Pandey (Dallas, USA); Bertram Pitt (Ann Arbor, USA); Stuart Pocock (London, GBR); Krishna Prasad (MHRA, GBR); Lothar Roessig (Bayer, GER); Naveed Sattar (Glasgow, GBR); Scott Solomon (Boston, USA); Piotr Szymanski (Warsaw, POL); Bob Temple (FDA, USA); John Teerlink (San Francisco, USA); Adriaan Voors (Groningen, NED); Christopher Wilcox (Washington, USA); Janet Wittes (StatCollaborative, USA); Faiez Zannad (Paris, FRA); Shelley Zieroth (Manitoba, CAN)

**Room: Gustave Courbet
Thursday 02 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**

**HEART FAILURE WITH PRESERVED EJECTION FRACTION. LIGHT AT THE END OF THE TUNNEL?
Part II. Implementing the results of EMPEROR-PRESERVED
Chairpersons : John Cleland (Glasgow, USA) & Biykem Bozkurt (Houston, USA)**

**SGLT2is across the spectrum of HF ejection fraction. EMPEROR-POOLED.
Milton Packer (Dallas, USA)**

**EMPEROR Preserved and Pooled secondary subgroup analyses
Faiez Zannad (Paris, FRA)**

**EMPEROR-PRESERVED in context. The evidence so far in HFpEF.
Scott Solomon (Boston, USA)**

**Industry viewpoint
Tomas Andersson (AstraZeneca, SWE); Martina Brueckmann (Boehringer Ingelheim, GER);
David Platt (Novartis, USA); Lothar Roessig (Bayer, GER)**

**Regulatory viewpoint
Krishna Prasad (MHRA, GBR)
Bob Temple (FDA, USA)**

**Patient viewpoint
Nick Hartshorne-Evans (London, GBR)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**HEART FAILURE WITH PRESERVED EJECTION FRACTION. LIGHT AT THE END OF THE TUNNEL?
Part II. Implementing the results of EMPEROR-PRESERVED
Chairpersons : John Cleland (Glasgow, USA) & Biykem Bozkurt (Houston, USA)**

Panelists: Angeles Alonso (MHRA, GBR); Tomas Andersson (AstraZeneca, SWE); Stefan Anker (Berlin, GER); Biykem Bozkurt (Houston, USA); Martina Brueckmann (Boehringer Ingelheim, GER); John Cleland (Glasgow, USA); Joao Ferreira (Porto, POR); Gerasimos Filippatos (Athens, GRE); Nick Hartshorne-Evans (London, GBR); Carolyn Lam (Singapore, SIN); John McMurray (Glasgow, GBR), Robert Mentz (Durham, USA); Freny Mody (Los Angeles, USA); Milton Packer (Dallas, USA); Ambarish Pandey (Dallas, USA); David Platt (Novartis, USA); Krishna Prasad (MHRA, GBR); Scott Solomon (Boston, USA); John Teerlink (San Francisco, USA); Bob Temple (FDA, USA); Adriaan Voors (Groningen, NED); Janet Wittes (StatCollaborative, USA); Faiez Zannad (Paris, FRA); Shelley Zieroth (Manitoba, CAN)

**Room: Gustave Courbet
Thursday 02 December, 2021
18.00-20.30 CET / 12.00 - 14.30 EST**

**TAILORING MEDICAL THERAPY TO HEART FAILURE CLINICAL PROFILES
Chairpersons : Stefan Anker (Berlin, GER) & Harriette Van Spall (Hamilton, CAN)**

Shall we move away from EF-centric HF trials?
Faiez Zannad (Paris, FRA)

Chronic stable HFrEF trials. Are we closing the march? Digoxin DECISION and Vericiguat VICTOR trials
Adriaan Voors (Groningen, NED)

Inpatients acute decompensated and the lower end of the EF spectrum.
John Teerlink (San Francisco, USA)

Post myocardial infarction heart failure.
Marc Pfeffer (Boston, USA)

Worsening chronic heart failure
Robert Mentz (Durham, USA)

Ischemic heart failure
Adriaan Voors (Groningen, NED)

Diabetic cardiomyopathy
Ambarish Pandey (Dallas, USA)

Amyloidosis heart failure
Shelley Zieroth (Manitoba, CAN)

Anything special with HFpEF patients with highest Ejection Fractions?
Barry Borlaug (Rochester, USA)

How to generate evidence for phenotype-based therapy?
Janet Wittes (StatCollaborative, USA)

What would it take to approve phenotype-based heart failure indications?
Regulatory viewpoint
Robert Temple (FDA, USA); Prasad Krishna (CHMP, GBR)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**OPPORTUNITIES AND CHALLENGES OF HEART FAILURE STRATIFIED MEDICINE TRIALS
Chairpersons: Stefan Anker (Berlin, GER) & Harriette Van Spall (Hamilton, CAN)**

Panelists: Tomas Andersson (AstraZeneca, SWE); Angeles Alonso (MHRA, GBR); Stefan Anker (Berlin, GER); Jan Biegus (Wroclaw, POL); Barry Borlaug (Rochester, USA); Biykem Bozkurt (Houston, USA); Martina Brueckmann (Boehringer Ingelheim, GER); Antonio Cannata (London, GBR); Joao Ferreira (Porto, POR); Gerasimos Filippatos (Athens, GRE); Nick Hartshorne-Evans (London, GBR); Karl-Patrik Kresoja (Leipzig, GER); Carolyn Lam (Singapore, SIN); John McMurray (Glasgow, GBR); Robert Mentz (Durham, USA); Freny Mody (Los Angeles, USA); Ambarish Pandey (Dallas, USA); Milton Packer (Dallas, USA); Marc Pfeffer (Boston, USA); Bertram Pitt (Ann Arbor, USA); Krishna Prasad (CHMP, GBR); Lothar Roessig (Bayer, GER); Scott Solomon (Boston, USA); John Teerlink (San Francisco, USA); Robert Temple (FDA, USA); Marcus Antony Urey (San Diego, USA); Harriette Van Spall (Hamilton, CAN); Adriaan Voors (Groningen, NED); Janet Wittes (StatCollaborative, USA); Faiez Zannad (Paris, FRA); Shelley Zieroth (Manitoba, CAN)

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS. Part 1.
Chairpersons :Hiddo Heerspink (Groningen, NED) & Ivonne Schulman (NIH, USA)

Where we came from? CKD: A huge burden and unmet need. Epidemiology and management so far
George Bakris (Chicago, USA)

Renal outcomes in chronic kidney disease trials, in diabetes and non-diabetes patients.

Kidney endpoints definitions and performance in CV trials
Vlado Perkovic (Sydney, AUS)

The journey from RASi to SGLT2i
Hiddo Heerspink (Groningen, NED)

CKD and atherosclerotic CVD. The inflammation/anti-Interleukin 6 pathway
Paul Ridker (Boston, USA)

What are the specific challenges of designing/conducting kidney outcomes trials

In diabetes with SGLT2i
Christoph Wanner (Wurzburg, GER)

In diabetes with mineralocorticoid receptor antagonists
George Bakris (Chicago, USA)

In heart failure trials
Finnian Mc Causland (Boston, USA)

Can we compare drugs without head-to-head trials?
Population adjusted indirect comparison - Matched indirect comparison (MAIC)
Neil Hawkins (Glasgow, GBR)

MAIC Applied to FIDELIO-DKD and CREDENCE
Peter Rossing (Copenhagen, DEN)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS
Chairpersons: Hiddo Heerspink (Groningen, NED), Ivonne Schulman (NIH, USA)

Panelists: George Bakris (Chicago, USA); Cynthia Chauhan (Wichita, USA); Maria Rosa Costanzo (Naperville, USA); Kristina Dunder (EMA, SWE); Murray Epstein (Miami, USA); Patrick Gee (Chesterfield, USA); Jyothis Thomas George (Novonordisk, DEN); Neil Hawkins (Glasgow, GBR); Sibylle Hauske (Boehringer Ingelheim, GER); Hiddo Heerspink (Groningen, NED); Robert Lawatscheck (Bayer, GER); Adeera Levin (Vancouver, CAN); Finnian Mc Causland (Boston, USA); Peter Mol (EMA, NED); Richard Nkulikiyinka (Bayer, GER); Vlado Perkovic (Sydney, AUS); Frederik Persson (Copenhaguen, DEN); Piotr Ponikowski (Cracow, POL); Prabir Roy-Chaudhury (North Carolina, USA); Paul Ridker (Boston, USA); Peter Rossing (Copenhagen, DEN); Jérôme Rossert (AstraZeneca, USA); Patrick Rossignol (Nancy, FRA); Ivonne Schulman (NIH, USA); Aliza Thompson (FDA, USA); Thomas Thuren (Novartis, USA); Subodh Verma (Toronto, CAN); Christoph Wanner (Wurzburg, GER); Fred Yang (KBP, USA); Faiez Zannad (Paris, FRA)

**Room : Jean-Auguste-Dominique Ingres
Thursday 02 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS. Part 2.
Chairpersons : Maria Rosa Costanzo (Naperville, USA) & Christoph Wanner (Wurzburg, GER)

The case of end stage renal disease.
Patrick Rossignol (Nancy, FRA)

Opportunities with novel MRAs.
Bertram Pitt (Ann Arbor, USA)

Mechanisms of MRA cardiokidney protection
Subodh Verma (Toronto, CAN)

IV iron in CKD and heart failure trials
Piotr Ponikowski (Cracow, POL)

Potassium binders trials enabling cardiokidney protective therapy.
Javed Butler (Jackson, USA)

Practical use of potassium binders
Murray Epstein (Miami, USA)

NIH/NIDDK viewpoint
Ivonne Schulman (NIH, USA)

Regulatory expectations for the future cardio kidney trials.
Peter Mol (EMA, NED)
Aliza Thompson (FDA, USA)

Patients viewpoints
Cynthia Chauhan (Wichita, USA), Patrick Gee (Chesterfield, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

CARDIOKIDNEY PROTECTIVE STRATEGIES. IMPLEMENTING THE ACCUMULATING EVIDENCE
Chairpersons: Maria Rosa Costanzo (Naperville, USA) & Christoph Wanner (Wurzburg, GER)

Panelists : George Bakris (Chicago, USA); Javed Butler (Jackson, USA); Finnian Mc Causland (Boston, USA); Cynthia Chauhan (Wichita, USA); Kristina Dunder (EMA, SWE); Maria Rosa Costanzo (Naperville, USA); Murray Epstein (Miami, USA); Patrick Gee (Chesterfield, USA); Jyothis Thomas George (Novonordisk, DEN); Neil Hawkins (Glasgow, GBR); Sibylle Hauske (Boehringer Ingelheim, GER); Hiddo Heerspink (Groningen, NED); Robert Lawatscheck (Bayer, GER); Adeera Levin (Vancouver, CAN); Peter Mol (EMA, NED); Richard Nkulikiyinka (Bayer, GER); Bertram Pitt (Ann Arbor, USA); Vlado Perkovic (Sydney, AUS); Frederik Persson (Copenhaguen, DEN); Piotr Ponikowski (Cracow, POL); Paul Ridker (Boston, USA); Jérôme Rossert (AstraZeneca, USA); Patrick Rossignol (Nancy, FRA); Prabir Roy-Chaudhury (North Carolina, USA); Ivonne Schulman (NIH, USA), Aliza Thompson (FDA, USA); Thomas Thuren (Novartis, USA); Subodh Verma (Toronto, CAN); Christoph Wanner (Wurzburg, GER); David Wheeler (London, GBR); Fred Yang (KBP, USA)

Room : Jean-Auguste-Dominique Ingres
Thursday 02 December, 2021
18.00-20.30 CET / 12.00 - 14.30 EST

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS
Part 3. Renal endpoint issues in cardio kidney trials
Chairpersons : Adeera Levin (Vancouver, CAN) & David Wheeler (London, GBR)

Challenges and applicability of the eGFR slope as an endpoint in diabetes, HF and CKD trials

Nephrology viewpoint.
Christoph Wanner (Wurzburg, GER)

Cardiology viewpoint.
Javed Butler (Jackson, USA)

Is albuminuria a valid surrogate endpoint?
Murray Epstein (Miami, USA)

KHI clinical trial outcomes for kidney failure. Any need for an update?
Adeera Levin (Vancouver, CAN)

Reporting and adjudication of kidney safety endpoints.
Prabir Roy-Chaudhury (North Carolina, USA)

Regulatory comments about endpoints in cardio kidney trials
Peter Mol (EMA, NED)
Aliza Thompson (FDA, USA)

Navigating the cardiokidney metabolic space. Industry viewpoints
Jyothis Thomas George (Novonordisk, DEN), Sibylle Hauske (Boehringer Ingelheim, GER), Richard Nkulikiyinka (Bayer, GER); Jérôme Rossert (AstraZeneca, USA), Fred Yang (KBP, USA)

Patients viewpoints
Cynthia Chauhan (Wichita, USA), Patrick Gee (Chesterfield, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

REASSESSING ENDPOINT SIGNIFICANCE IN CARDIOKIDNEY TRIALS.
Chairpersons: Adeera Levin (Vancouver, CAN) & David Wheeler (London, GBR)

Panelists : George Bakris (Chicago, USA); Javed Butler (Jackson, USA); Finnian Mc Causland (Boston, USA); Cynthia Chauhan (Wichita, USA); Kristina Dunder (EMA, SWE); Maria Rosa Costanzo (Naperville, USA); Murray Epstein (Miami, USA); Raul Angel A Garcia (Kansas City, USA); Patrick Gee (Chesterfield, USA); Jyothis Thomas George (Novonordisk, DEN); Neil Hawkins (Glasgow, GBR); Sibylle Hauske (Boehringer Ingelheim, GER); Hidde Heerspink (Groningen, NED); Robert Lawatscheck (Bayer, GER); Adeera Levin (Vancouver, CAN); Peter Mol (EMA, NED); Richard Nkulikiyinka (Bayer, GER); Vlado Perkovic (Sydney, AUS); Frederik Persson (Copenhague, DEN); Piotr Ponikowski (Cracow, POL); Paul Ridker (Boston, USA); Jérôme Rossert (AstraZeneca, USA); Patrick Rossignol (Nancy, FRA); Prabir Roy-Chaudhury (North Carolina, USA); Ivonne Schulman (NIH, USA); Aliza Thompson (FDA, USA); Subodh Verma (Toronto, CAN); Christoph Wanner (Wurzburg, GER); David Wheeler (London, GBR); Fred Yang (KBP, USA); Faiez Zannad (Paris, FRA)

**Room: Eugène Delacroix
Thursday 02 December, 2021
13.00 -15.00 CET / 07:00 -09:00 EST**

PUBLISHING AND AUTHORSHIP OF MAJOR TRIALS RESULTS

Chairpersons: John Keaney (NEJM, Boston, USA) & Stuart Spencer (The Lancet, London, GBR)

**How major journals may contribute to make trials better?
Chana Sacks (NEJM Evidence, USA)**

Publishing the information before the information.

**The role of press releases: complying with Securities and Exchange Commission (SEC) vs. fueling speculation?
Ron Winslow (Ex Wall Street Journal, Portland, USA)**

**Late Breaking Clinical Trials and media coverage at major international meetings
Mariell Jessup (AHA, Hingham, USA)**

**The role of pre-print and pre-print servers publications
Joseph Ross (New Haven, USA)**

Authorship roles, authorship rules.

**What deserves authorship?
Stuart Spencer (The Lancet, London, GBR)**

**How much access to data authors should have in order to take responsibility for the publication?
Marc Pfeffer (Boston, USA)**

**How to fill the authorship diversity gap?
Harriette Van Spall (Hamilton, CAN)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**THE EDITORS' DEBATE Part 1. PUBLISHING AND AUTHORSHIP OF MAJOR TRIALS RESULTS
Chairpersons: John Keaney (NEJM, Boston, USA), Stuart Spencer (The Lancet, London, GBR)**

Panelists: Filippo Crea (EHJ, Rome, ITA); Joseph Hill (Circulation, Dallas USA); Larry Husten (CVCTCardiobrief, New York, USA); John Keaney (NEJM, Boston, USA), Jonathan Kaltman (NIH, USA); Mariell Jessup (AHA, Hingham, USA), Marc Pfeffer (Boston, USA); Emma Raderschadt (Boehringer Ingelheim, GER); Joseph Ross (New Haven, USA); Sébastien Roux (Idorsia, CH); Chana Sacks (NEJM Evidence, USA); Stuart Spencer (The Lancet, London, GBR); Harriette Van Spall (Hamilton, CAN); Stephanie Weber (Idorsia, CH); Ron Winslow (Ex Wall Street Journal, Portland, USA) ; Faiez Zannad (Paris, FRA)

**Room: Eugène Delacroix
Thursday 02 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**



**MAXIMIZING SCIENTIFIC KNOWLEDGE PRODUCTION FROM TRIAL DATA.
Chairpersons: Filippo Crea (EHJ, Rome, ITA) & Robert Golub (JAMA, Chicago, USA)**

**Trial reporting guidelines (CONSORT, extensions, etc..)
Robert Golub (JAMA, Chicago, USA)**

**The role of secondary results publications
Faiez Zannad (Paris, FRA)**

**The value of pooled trials and meta-analysis publications
Stuart Pocock (London, GBR)**

**Publications stemming from accessible shared data. Anyone is taking control?
Filippo Crea (EHJ, Rome, ITA)
Jonathan Kaltman (NIH, USA)**

**Challenges with publishing artificial intelligence analyses of trial databases.
Joseph Hill (Circulation, Dallas USA)**

**The role of social media
Larry Husten (CVCTCardiobrief, New York, USA)**

**Knowledge translation. The value of plain language summary publications
Emma Raderschadt (Boehringer Ingelheim, GER)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate



**MAXIMIZING SCIENTIFIC KNOWLEDGE PRODUCTION FROM TRIAL DATA.
Chairpersons: Filippo Crea (EHJ, Rome, ITA), Robert Golub (JAMA, Chicago, USA)**

**Panelists: Filippo Crea (EHJ, Rome, ITA); Robert Golub (JAMA, Chicago, USA); Joseph Hill (Circulation, Dallas USA);
Larry Husten (CVCTCardiobrief, New York, USA); John Keaney (NEJM, Boston, USA), Jonathan Kaltman (NIH, USA);
Mariell Jessup (AHA, Hingham, USA); Stuart Pocock (London, GBR); Emma Raderschadt (Boehringer Ingelheim, GER);
Sébastien Roux (Idorsia, CH); Chana Sacks (NEJM Evidence, USA); Rupa Sarkar (The Lancet Digital Health, GBR);
Stuart Spencer (The Lancet, London, GBR); Harriette Van Spall (Hamilton, CAN); Ron Winslow (Ex Wall Street Journal,
Portland, USA) ; Faiez Zannad (Paris, FRA)**

Room: Eugène Delacroix
Thursday 02 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST



THE INNOVATION LANDSCAPE, Part 1: BIOTECH RAPID FIRE AND READINESS FOR TRANSLATION
Chairpersons: Gemma Figtree (Sydney, AUS) & Thomas Thum (Hannover, GER)

Targeting CAD susceptibility and resilience factors.
Gemma Figtree (Sydney, AUS)

Flow cytometry platelet FcyRIIIa for personalized medicine?
Pete DiBattiste (Prolocor, USA)

Microbiome and Cardiometabolic disease
Wilson Tang (Cleveland, USA)

Antisense Oligonucleotides - siRNA
Thomas Thum (Hannover, GER)

Moderna mRNA therapeutics for CV disease
Ruchira Glaser (Moderna, USA)

The regulatory landscape for biologics and other innovative therapies
Narumi Okura (PMDA, JAP)

Payer's viewpoint. How to value innovation?
Louis Jacques (ADVI, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



THE INNOVATION LANDSCAPE, Part 1: BIOTECH READINESS FOR TRANSLATION.
Chairpersons: Gemma Figtree (Sydney, AUS), Thomas Thum (Hannover, GER)

Panelists: Rahul Agrawal (Cardior Pharmaceuticals, GER); Roberto Bolli (Louisville, USA); Jim Carr (Stealth, USA); Linda Cripe (Columbus, USA); Pete DiBattiste (Prolocor, USA); Gemma Figtree (Sydney, AUS); Ibon Garitaonandia (Cellprothera, FRA); Al Gianchetti (Xylocor, USA); Ruchira Glaser (Moderna, USA); Barry Greenberg (San Diego, USA); Philippe Henon (Cellprothera, FRA); Silviu Itescu (Mesoblast, USA); Louis Jacques (ADVI, USA); Narumi Okura (PMDA, JAP); Marc Semigran (Renovacor, USA); Monica Shah (IQVIA, USA); Fernando Suarez (IBM, USA); Wilson Tang (Cleveland, USA); Thomas Thum (Cardior Pharmaceuticals, GER); Claudia Ulbrich (Cardior, GER)

**Room: Toulouse Lautrec
Thursday 02 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST**



DEVELOPMENTS IN ATHEROSCLEROSIS FAMILIAL HYPERCHOLESTEROLEMIA TRIALS
Chairpersons: Daniel Rader (Philadelphia, USA) & Robert S. Rosenson (New York, USA)

Atherosclerosis Drug Discovery
Daniel Rader (Philadelphia, USA)

Genetics of familial hypercholesterolemia: What is an extreme heterozygous FH phenotype?
Raul Santos (São Paulo, USA)

Immunotherapies with proprotein convertase subtilisin kexin inhibitors and angiotensin like protein inhibitors
Robert S. Rosenson (New York, USA)

Endpoints in trials of LDL cholesterol lowering in severe heterozygous FH. Is a clinical outcome trial necessary? The role of vascular imaging?
Jagat Narula (New York, USA)

Industry viewpoint
Shazia Ali (Regeneron, USA), Siddique Abbasi (Amgen, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



DEVELOPMENTS IN FAMILIAL HYPERCHOLESTEROLEMIA TRIALS
Chairpersons: Daniel Rader (Philadelphia, USA) & Robert S. Rosenson (New York, USA)

Panelists : Siddique Abbasi (Amgen, USA); Shazia Ali (Regeneron, USA) ; Nadia Bouabdallaoui (Montreal, CAN); Daein Choi (New York, USA); Ron Do (New York, USA); Brian Ference (Oxford, GBR), Sascha Goonewardena (Ann Arbor, USA); Narimon Honarpour (Amgen, USA); Helina Kassahun (Amgen, USA) ; Wolfgang Koenig (München, GER); Gerard Kornelis Hovingh (Novonordisk, DEN); Jagat Narula (New York, USA); Robert Pordy (Regeneron, USA); Aruna Pradhan (Boston, USA); Krishna Prasad (MHRA, GBR); Daniel Rader (Philadelphia, USA); Robert S. Rosenson (New York, USA) ; Giacomo Ruotolo (Eli Lilly, USA); Raul Santos (São Paulo, USA); Craig Sponseller (Kowa, USA); Erik Stroes (Amsterdam, NED); Jean Claude Tardif (Montreal, CAN); Sotirios Tsimikas (Ionis, USA)

**Room: Toulouse Lautrec
Thursday 02 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**

LIPOPROTEIN (a) INHIBITORS LOWERING DRUGS TRIALS
Chairpersons: Wolfgang Koenig (Münich, GER) & Sascha Goonewardena (Ann Arbor, USA)

Lipoprotein(a): the nexus of inflammation and thrombosis in ASCVD
Sascha Goonewardena (Ann Arbor, USA)

Genetic evidence why Lp(a)-lowering might make sense
Florian Kronenberg (Innsbruck, AUS)

PCSK9 inhibitors
Gregory Schwartz (Colorado, USA)

Lp(a) inhibitors
Erik Stroes (Amsterdam, NED)

Sample size estimates in approval trial for Lp(a) lowering drugs. Insight from HORIZON
Brian Ference (Oxford, GBR)

Industry viewpoint
Helina Kassahun (Amgen, USA), Santica Marcovina (MedPace, USA), Giacomo Ruotolo (Eli Lilly, USA); Sotirios Tsimikas (Ionis, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

LIPOPROTEIN (a) INHIBITORS LOWERING DRUGS TRIALS
Chairpersons: Wolfgang Koenig (Münich, GER) & Sascha Goonewardena (Ann Arbor, USA)

Panelists: Siddique Abbasi (Amgen, USA); Shazia Ali (Regeneron, USA); Nadia Bouabdallaoui (Montreal, CAN); Ron Do (New York, USA); Brian Ference (Oxford, GBR); Sascha Goonewardena (Ann Arbor, USA); Pia R Kamstrup (Copenhagen, DEN); Helina Kassahun (Amgen, USA); Wolfgang Koenig (Münich, GER); Gerard Kornelis Hovingh (Novonordisk, DEN); Florian Kronenberg (Innsbruck, AUS); Waqas Malick (New York, USA); Santica Marcovina (MedPace, USA); Jagat Narula (New York, USA); Robert Pordy (Regeneron, USA); Aruna Pradhan (Boston, USA); Robert S. Rosenson (New York, USA); Giacomo Ruotolo (Eli Lilly, USA); Raul Santos (São Paulo, USA); Gregory Schwartz (Colorado, USA); Craig Sponseller (Kowa, USA); Erik Stroes (Amsterdam, NED); Jean Claude Tardif (Montreal, CAN); Sotirios Tsimikas (Ionis, USA);

**Room: Toulouse Lautrec
Thursday 02 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST**



TARGETING ATHEROSCLEROSIS AND INFLAMMATION TRIALS
Chairpersons: Peter Libby (Boston, USA) & Jean Claude Tardif (Montreal, CAN)

Leveraging natural selection studies to identify inflammatory targets for cardiovascular intervention.
Ron Do (New York, USA)

Targeting inflammation for atherosclerosis therapy
Wolfgang Koenig (Münich, GER)

Colchicine in the prevention of cardiovascular events
Nadia Bouabdallaoui (Montreal, CAN)

Anti-cytokine Agents
Paul Ridker (Boston, USA)

Industry viewpoint
Gerard Kornelis Hovingh (Novonordisk, DEN)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



**TARGETING ATHEROSCLEROSIS AND INFLAMMATION TRIALS. THE VALUE OF BIOPROFILE-GUIDED
THERAPY TRIALS**

Chairpersons: Peter Libby (Boston, USA) & Jean Claude Tardif (Montreal, CAN)

Panelists: Siddique Abbasi (Amgen, USA); Shazia Ali (Regeneron, USA); Nadia Bouabdallaoui (Montreal, CAN); Ron Do (New York, USA); Brian Ference (Oxford, GBR), Sascha Goonewardena (Ann Arbor, USA); Narimon Honarpour (Amgen, USA); Helina Kassahun (Amgen, USA); Wolfgang Koenig (Münich, GER); Florian Kronenberg (Innsbruck, AUS); Gerard Kornelis Hovingh (Novonordisk, DEN); Peter Libby (Boston, USA); Santica Marcovina (MedPace, USA); Jagat Narula (New York, USA); Robert Porody (Regeneron, USA); Aruna Pradhan (Boston, USA); Paul Ridker (Boston, USA); Robert S. Rosenson (New York, USA); Giacomo Ruotolo (Eli Lilly, USA); Aleesha Shaik (New York, USA); Raul Santos (São Paulo, USA); Craig Sponseller (Kowa, USA); Erik Stroes (Amsterdam, NED); Jean Claude Tardif (Montreal, CAN); Sotirios Tsimikas (Ionis, USA)

Room : Alfred Sisley
Friday 03 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST



NEW HFREF GUIDELINES... SO WHAT? IS HFREF THERAPY BECOMING TOO COMPLICATED, TOO EXPENSIVE?
Chairpersons: Nick Hartshorne-Evans (London, GBR) & Ileana Pina (Detroit, USA)

Why are we not doing a good job with existing therapies?
Gregg C. Fonarow (San Francisco, USA)

Is HF therapy becoming too complicated?
Ileana Pina (Detroit, USA)

Is HF therapy is becoming too expensive?
Daniel Mark (Durham, USA)

Is hospital admission the right place/time for optimizing HF therapy?
Elke Platz (Boston, USA)

Are guidelines useful?
Pro: Theresa McDonagh (London, GBR)
Con: Milton Packer (Dallas, USA)

Industry viewpoints
Tomas Andersson (AstraZeneca, SWE), Salim Shah (Sarfez, USA)

Patients viewpoint
Nick Hartshorne-Evans (London, GBR), Jillianne Code (Vancouver, CAN)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



HOW IMPLEMENTATION OF HFREF THERAPY MAY BE MADE SIMPLER AND AFFORDABLE ?
Chairpersons: Nick Hartshorne-Evans (London, GBR) & Ileana Pina (Detroit, USA)

Panelists: Tomas Andersson (AstraZeneca, SWE); Supria Batra (Washington, USA); Jillianne Code (Vancouver, CAN); Patrice Desvigne-Nickens (NIH, USA); Joao Ferreira (Porto, POR); Gregg C. Fonarow (San Francisco, USA); Charu Gandotra (FDA, USA); Nick Hartshorne-Evans (London, GBR); Ewa Jankowska (Wroclaw, POL); Armin Koch (EMA, GER); Theresa McDonagh (London, GBR); Daniel Mark (Durham, USA); Marco Metra (Brescia, ITA); Freny Mody (Los Angeles, USA); Milton Packer (Dallas, USA); Ileana Pina (Detroit, USA); Elke Platz (Boston, USA); Salim Shah (Sarfez, USA); Faiez Zannad (Paris, FRA)

Room : Alfred Sisley
Friday 03 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST



SHOULD NOT THE FUTURE HFREF TRIALS RATHER BE IMPLEMENTATION TRIALS?
Chairpersons: Gregg C. Fonarow (San Francisco, USA) & Christopher O'Connor (Washington, USA)

Staging individual foundational HFREF drug drugs.
Biykem Bozkurt (Houston, USA)

How to investigate whether low doses of everything may be an option?
Marco Metra (Brescia, ITA)

Would fixed combinations help, and what trial should be done in this space?
Joao Ferreira (Porto, POR)

Regulatory comments about fixed combination trials
Charu Gandotra (FDA, USA)
Armin Koch (EMA, GER)

The role of HF Collaboratory
Christopher O'Connor (Washington, USA)

The role of the NIH
Patrice Desvigne-Nickens (NIH, USA)

Industry viewpoints
Joerg Koglin (Merck, USA), Lothar Roessig (Bayer, GER)

Patients viewpoint
Jillianne Code (Vancouver, CAN), Nick Hartshorne-Evans (London, GBR)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



MOVING TOWARDS HEART FAILURE THERAPY IMPLEMENTATION STRATEGIES TRIALS
Chairpersons: Gregg C. Fonarow (San Francisco, USA) & Christopher O'Connor (Washington, USA)

Panelists: Tomas Andersson (AstraZeneca, SWE); Jillianne Code (Vancouver, CAN); Patrice Desvigne-Nickens (NIH, USA); Joao Ferreira (Porto, POR); Gregg C. Fonarow (San Francisco, USA); Anders Gabrielse (AstraZeneca, SWE); Charu Gandotra (FDA, USA); Nick Hartshorne-Evans (London, GBR); Armin Koch (EMA, GER); Joerg Koglin (Merck, USA); Maria Leonsson-Zachrisson (AstraZeneca, SWE); Theresa McDonagh (London, GBR); Daniel Mark (Durham, USA); Marco Metra (Brescia, ITA); Freny Mody (Los Angeles, USA); Christopher O'Connor (Washington, USA); Lothar Roessig (Bayer, GER); Faiez Zannad (Paris, FRA)

THE INNOVATION LANDSCAPE
PART 2 : GENE, CELL AND RARE DISEASE THERAPIES. PATHWAYS FOR APPROVAL
Chairpersons: Monica Shah (IQVIA, USA) & Wilson Tang (Cleveland, USA)

Gene and cell therapies in heart failure. Is there a way forward?
Barry Greenberg (San Diego, USA)

Cardiovascular Cell and Gene Therapy - Innovative Approaches to Optimize Clinical Development
Monica Shah (IQVIA, USA)

The role of cell therapy with autologous mesenchymal stromal cells and c-kit positive cardiac cells
Roberto Bolli (Louisville, USA)

Mesoblast: DREAM-HF and AMICI cell therapy trials
Silviu Itescu (Mesoblast, USA)

Cellprothera: The potential of expanded CD34+ stem cells
Ibon Garitaonandia (Cellprothera, FRA)

Xylocor: Gene therapy stimulating endogenous self-revascularization for ischemic heart disease.
Al Gianchetti (Xylocor, USA)

Renovacor gene replacement therapy for dilated cardiomyopathies
Marc Semigran (Renovacor, USA)

Drug Development in Rare Disease Cardiomyopathies. Challenges to bring therapies through the pipeline.
Linda Cripe (Columbus, USA)

Stealth biotherapeutics: Elamipretide for mitochondrial cardiomyopathies
Jim Carr (Stealth, USA)

The industry landscape. Big Pharma-Biotech partnerships.
Rahul Agrawal (Cardior Pharmaceuticals, GER)

Innovative Licensing and Access Pathway (ILAP), An integrated approach to regulation and patient access
Dan O'Connor (MHRA, GBR)

Patients viewpoint
Emily Milligan (Barth Syndrome Foundation, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

THE INNOVATION LANDSCAPE
Part 2: RARE DISEASE CARDIOMYOPATHIES PATHWAYS FOR APPROVAL
Chairpersons: Monica Shah (IQVIA, USA) & Wilson Tang (Cleveland, USA)

Panelists : Rahul Agrawal (Cardior Pharmaceuticals, GER); Roberto Bolli (Louisville, USA); Jim Carr (Stealth, USA); Linda Cripe (Columbus, USA); Pete DiBattiste (Prolocor, USA); Gemma Figtree (Sydney, AUS); Ibon Garitaonandia (Cellprothera, FRA); Al Gianchetti (Xylocor, USA); Ruchira Glaser (Moderna, USA); Barry Greenberg (San Diego, USA); Philippe Henon (Cellprothera, FRA); Silviu Itescu (Mesoblast, USA); Louis Jacques (ADVI, USA); Emily Milligan (Barth Syndrome Foundation, USA); Dan O'Connor (MHRA, GBR); Marc Semigran (Renovacor, USA); Monica Shah (IQVIA, USA), Wilson Tang (Cleveland, USA)

Room : Paul Gauguin
Friday 03 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST



HOW CLOSE ARE WE TO A “REASONABLY LIKELY” AND “UNIVERSAL” CARDIOVASCULAR SURROGATE ENDPOINT?

Chairpersons: David Lanfear (Detroit, USA) & Peter Ganz (San Francisco, USA)

Biologic plausibility of machine-learning selected proteins – is it adequate?
David Lanfear (Detroit, USA)

Why surrogate endpoints are important to “Critical Path Initiative”
Declan Doogan (Juvenescence, USA)

What is the FDA’s framework for evidentiary standards for surrogate endpoints as drug development tools
Jeff Siegel (FDA, USA)

Industry viewpoint – what are the benefits and risks of using surrogate endpoints in drug development
Andrea Ballagi (Olink, SWE), Agim Beshiri (Abbott Diagnostics, USA), Serge Masson (Roche, CH)

How biomarkers may fulfil the “Universality” requirement for surrogacy?
Jeff Siegel (FDA, USA)

Practitioner view – how do surrogates help medical practice
Peter Ganz (San Francisco, USA)

Proteomic surrogate program design, results to date
Steve Williams (Somalogic, USA)

How to secure robustness of surrogates to geographic and ethnic variation
Joe Coresh (Baltimore, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



ROADMAP TOWARDS ACTIONABLE “UNIVERSAL” SURROGATE ENDPOINT FOR CARDIOVASCULAR TRIALS
Chairpersons: David Lanfear (Detroit, USA) & Peter Ganz (San Francisco, USA)

Panelists : Andrea Ballagi (Olink, SWE); Agim Beshiri (Abbott Diagnostics, USA) ; Joe Coresh (Baltimore, USA); Declan Doogan (Juvenescence, USA); Peter Ganz (San Francisco, USA); David Lanfear (Detroit, USA); Serge Masson (Roche, CH); John O’Sullivan (Sydney, AU); Jeff Siegel (FDA, USA); Steve Williams (Somalogic, USA); Janet Wittes (StatColaborative, USA)

**Room : Paul Gauguin
Friday 03 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**



PRIMARY PREVENTION. RECENT AND ONGOING TRIALS
Chairpersons: Jun Cai (Fu Wai, CN) & Rita Redberg (San Francisco, USA)

**Cholesterol lowering. Ready for primary prevention?
Dave Soergel (Novartis, USA)**

Blood pressure lowering therapy.

**Reassessing “optimal” blood pressure control:
SPRINT final results.
Suzanne Oparil (Birmingham, USA)**

**Intensive blood pressure control in older patients
Jun Cai (Fu Wai, CN)**

**The NIH perspective
Lawrence Fine (NIH, USA)**

**Shall we move away from recommendations based on threshold and/or floor/targets BP values? Insight from the latest Blood Pressure Lowering Treatment Trialists' Collaboration.
Kazem Rahimi (Oxford, GBR)**

**The Effect of Salt Substitute, Salt diet on Cardiovascular Events and Death. Is the evidence solid enough?
Bruce Neal (Sydney, AUS)**

**Renal denervation in hypertension. Regression to the truth?
Michel Azizi (Paris, FRA)**

**Polypill with or without Aspirin for primary prevention. The TIPS trials.
Philip Joseph (Hamilton, CAN)**

**Patient viewpoint
Marietta Verbakel (Nijmegen, NED)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate



PRIMARY PREVENTION. RECENT AND ONGOING TRIALS
Chairpersons: Jun Cai (Fu Wai, CN) & Rita Redberg (San Francisco, USA)

Panelists: Sadegh Alikhaani (Los Angeles, USA); Michel Azizi (Paris, FRA); Jun Cai (Fu Wai, CN); Lawrence Fine (NHLBI, USA); Philip Joseph (Hamilton, CAN); Freny Mody (Los Angeles, USA); Peter Muntendam (G3Pharmaceuticals, USA); Bruce Neal (Sydney, AUS); Suzanne Oparil (Birmingham, USA); Kazem Rahimi (Oxford, GBR); Rita Redberg (San Francisco, USA); Jeff Siegel (FDA, USA); Dave Soergel (Novartis, USA); Robert Temple (FDA, USA); Marietta Verbakel (Nijmegen, NED); Faiez Zannad (Paris, FRA)

Room : Paul Gauguin
Friday 03 December, 2021
18.00 - 20.00 CET / 12.00 - 14.30 EST



PROMOTING THE PRIMARY PREVENTION TRIALS AGENDA
Chairpersons: Eldrin Lewis (Stanford, USA) & Rita Redberg (San Francisco, USA)

How to promote primary prevention research

Regulatory solutions.

Premarket access based on (universal) surrogates, and extended patent life allowing for longer/larger trials?
Robert Temple (FDA, USA)

Reliance on surrogate endpoints
Jeff Siegel (FDA, USA)

NIH contribution
Lawrence Fine (NHLBI, USA)

The case of food products
Peter Muntendam (G3Pharmaceuticals, USA)

Is primary prevention cost-effective? Who should fund CV primary prevention trials
Rita Redberg (San Francisco, USA)

Air pollution and climate change as major rising threats to cardiovascular health. Call for building the evidence.
Sanjay Rajagopalan (Cleveland, USA)

Patient Perspective
Sadegh Alikhaani (Los Angeles, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



PROMOTING THE PRIMARY PREVENTION TRIALS AGENDA
Chairpersons: Eldrin Lewis (Stanford, USA) & Rita Redberg (San Francisco, USA)

Panelists: Sadegh Alikhaani (Los Angeles, USA); Michel Azizi (Paris, FRA); Jun Cai (Fu Wai, CN); Lawrence Fine (NHLBI, USA); Eldrin Lewis (Stanford, USA); Peter Muntendam (G3Pharmaceuticals, USA); Suzanne Oparil (Birmingham, USA); Kazem Rahimi (Oxford, GBR); Sanjay Rajagopalan (Cleveland, USA); Rita Redberg (San Francisco, USA); Jeff Siegel (FDA, USA); Dave Soergel (Novartis, USA); Robert Temple (FDA, USA); Faiez Zannad (Paris, FRA)



DEVELOPMENTS IN HYPERTRIGLYCERIDEMIA TRIALS
Chairpersons: Erik Stroes (Amsterdam, NED) & Aruna Pradhan (Boston, USA)

The selective PPAR-alpha modulator (SPPARM-a) Pemafibrate in patients with diabetes (PROMINENT).
Aruna Pradhan (Boston, USA)

The prevention of acute pancreatitis vs atherosclerotic cardiovascular disease. What is an approval therapeutic target:
TGs < 500 mg/dL or an outcome trial?
Signe E J Hansen (Copenhagen, DEN)

Early development in therapies that lower triglyceride-rich lipoproteins

Apo C-III inhibitors
Sotirios Tsimikas (Ionis, USA)

Immunotherapies with angiotensin-like 3 inhibitors, in severe hypertriglyceridemia
Robert S. Rosenson (New York, USA)

siRNA inhibitors: Apo-CIII or ANGPTL3?
Erik Stroes (Amsterdam, NED)

Industry viewpoint
James Hamilton (Arrowhead, USA), Robert Pordy (Regeneron, USA); Giacomo Ruotolo (Eli Lilly, USA), Sotirios Tsimikas (Ionis, USA); Calin Pater (Kowa, CH)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



DEVELOPMENTS IN HYPERTRIGLYCERIDEMIA TRIALS
Chairpersons: Erik Stroes (Amsterdam, NED) & Aruna Pradhan (Boston, USA)

Panelists : Siddique Abbasi (Amgen, USA); Shazia Ali (Regeneron, USA) ; Nadia Bouabdallaoui (Montreal, CAN); Ron Do (New York, USA); Brian Ference (Oxford, GBR); Sascha Goonewardena (Ann Arbor, USA); James Hamilton (Arrowhead, USA); Signe Hansen (Copenhagen, DEN); Neil Hounslow (Kowa, GBR); Helina Kassahun (Amgen, USA); Wolfgang Koenig (Münich, GER); Gerard Kornelis Hovingh (Novonordisk, DEN); Jagat Narula (New York, USA); Aruna Pradhan (Boston, USA); Robert S. Rosenson (New York, USA); Robert Pordy (Regeneron, USA); Daniel Rader (Philadelphia, USA); Giacomo Ruotolo (Eli Lilly, USA); Raul Santos (São Paulo, USA); David Soergel (Novartis, USA) ; Craig Sponseller (Kowa, USA); Erik Stroes (Amsterdam, NED); Jean Claude Tardif (Montreal, CAN); Sotirios Tsimikas (Ionis, USA); Ori Waksman (New York, USA)

**Room: Camille Pissarro
Friday 03 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**

OBESITY TRIALS: WEIGHT LOSS AND CARDIOVASCULAR OUTCOME TRIALS WITH GIP AND/OR GLP-1 RECEPTOR AGONISTS

Chairpersons : Jennifer Green (Durham, USA) & Mikhail Kosiborod (Kansas City, USA)

Obesity GLP1RA trials: weight loss and CV prevention
Elke Platz (Boston, USA)

Obesity in HFpEF patients

A distinct phenotype, potentially responsive to GLP-1 and or GIP/GLP-1RA?
Barry Borlaug (Rochester, USA)

The SUMMIT tirzepatide HFpEF in obesity trial
Milton Packer (Dallas, USA)

The STEPP HFpEF trials
Mikhail Kosiborod (Kansas City, USA)

Statistician viewpoint: Opportunities and challenges of hierarchical endpoint testing
John Gregson (London, GBR)

Industry viewpoint
Kristine Buchholtz (NovoNordisk, DEN), Masahiro Murakami (Eli Lilly, USA)

Regulatory viewpoint
John Sharretts (FDA, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

OBESITY TRIALS : WEIGHT LOSS AND CARDIOVASCULAR OUTCOME TRIALS WITH GIP AND/OR GLP-1 RECEPTOR AGONISTS

Chairpersons: Jennifer Green (Durham, USA) & Mikhail Kosiborod (Kansas City, USA)

Panelists: Barry Borlaug (Rochester, USA); Kristine Buchholtz (NovoNordisk, DEN); Jennifer Green (Durham, USA); John Gregson (London, GBR); Mikhail Kosiborod (Kansas City, USA); Saul Malozowski (NIDDK, USA); Masahiro Murakami (Eli Lilly, USA); Milton Packer (Dallas, USA); Elke Platz (Boston, USA); John Sharretts (FDA, USA)

**Room: Camille Pissarro
Friday 03 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST**

SGLT2i and GLP1RA CARDIO METABOLIC TRIALS

Chairpersons : Darren McGuire (Dallas, USA) & Mikhail Kosiborod (Kansas City, USA)

Insight from newest trials

Is Dual SGLT inhibitor different (SOLOIST and SCORED)?
Bertram Pitt (Ann Arbor, USA)

AMPLITUDE-O, and the potential of GLP1RA + SGLT2i therapy.
Naveed Sattar (Glasgow,GBR)

SGLT inhibitors trials: A class effect?
Darren McGuire (Dallas, USA)

GLP1RA in diabetes a diverse family?
Mikhail Kosiborod (Kansas City, USA)

Respective indications of SGLT2i and GLP1RA.
Jennifer Green (Durham, USA)

Compare them or combine them? What trials for the future?
Milton Packer (Dallas, USA)

Industry viewpoint

Kristine Buchholtz (NovoNordisk, DEN), Craig Granowitz (Alexion, USA); Nardev Khurmi (Sanofi, USA); Anna Maria Langkilde (AstraZeneca, SWE), James Strait (Merck, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

SGLT2i and GLP1RA CARDIO METABOLIC TRIALS. WHAT NEXT?

Chairpersons: Darren McGuire (Dallas, USA) & Mikhail Kosiborod (Kansas City, USA)

Panelists: Kristine Buchholtz (NovoNordisk, DEN); Javed Butler (Jackson, USA); Irina Elyubaeva (Servier, FRA); Marino Fernandez (Boehringer Ingelheim, GER); Jyothis Thomas George (Novonordisk, DEN), Craig Granowitz (Alexion, USA); Jennifer Green (Durham, USA); Josephine Harrington (Durham, USA); Hiddo Heerspink (Groningen, NED); Nardev Khurmi (Sanofi, USA); Mikhail Kosiborod (Kansas City, USA); Anna Maria Langkilde (AstraZeneca, SWE); Darren McGuire (Dallas, USA); Peter Mol (EMA, NED); Milton Packer (Dallas, USA); Frederik Persson (Copenhaguen, DEN); Marc Pfeffer (Boston, USA); Bertram Pitt (Ann Arbor, USA); Jérôme Rossert (AstraZeneca, USA); Naveed Sattar (Glasgow,GBR); James Strait (Merck, USA); Christoph Wanner (Wurzburg, GER); David Wheeler (London, GBR), Faiez Zannad (Paris, FRA)

**Room : Auguste Rodin
Friday 03 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST**

HRS-EHRA-CVCT joint session. IMPLANTABLE DEVICES AND MONITORING HEART FAILURE TRIALS
Chairpersons: Biykem Bozkurt (Houston, USA) & Thomas Deering (Atlanta, USA)
& Gerhard Hindricks (Leipzig, GER)

Overview of competitive technologies (BAT, CCM, Shunt, Other)
William Abraham (Columbus, USA)

Reassessing CRT-P vs. CRT-D (RESET CRT)
Nikolaos Dages (Leipzig, GER)

SCD risk prediction model across the EF spectrum and the case for risk guided ICD trials
Wojciech Zareba (Rochester, USA)

Which patients are eligible for implantable HF Cardiac Monitors? The trial evidence so far and real world data.
Mike Zile (Charleston, USA)

How to overcome the hurdles of implementing guideline-directed HF device therapy
Cecilia Linde (Stockholm, SWE)

Regulatory viewpoints
Andrew Farb (FDA, USA)

Regulatory scientist viewpoint
Alan Fraser (Cardiff, GBR)

Patients viewpoints
Trudie Lobban (London, GBR)
Marietta Verbakel (Nijmegen, NED)

Industry viewpoints
Dan Schaber (Medtronic, USA)

HTA's Viewpoint
Piotr Szymanski (Warsaw, POL)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**ELECTROPHYSIOLOGY & HEART FAILURE SIBLINGS:
CAN WE BRIDGE THE GAP OR DOES SIBLING RIVALRY KILL US?**
Chairpersons: Biykem Bozkurt (Houston, USA) & Thomas Deering (Atlanta, USA)
& Gerhard Hindricks (Leipzig, GER)

Panelists : William Abraham (Columbus, USA); Philip Adamson (Abbott, USA); Biykem Bozkurt (Houston, USA); Luis Bras Rosario (European Heart Network, POR); Nikolaos Dages (Leipzig, GER); Thomas Deering (Atlanta, USA); Andrew Farb (FDA, USA); Alan Fraser (Cardiff, GBR); Cecilia Linde (Stockholm, SWE); Trudie Lobban (London, GBR); Roxana Mehran (New York, USA); Dan Schaber (Medtronic, USA); Kenneth Stein (Boston Scientific, USA); Piotr Szymanski (Warsaw, POL); Marietta Verbakel (Nijmegen, NED); Nadim Yared (CVRx, USA); Wojciech Zareba (Rochester, USA); Mike Zile (Charleston, USA); Bram Zuckerman (FDA, USA)

**Room : Auguste Rodin
Friday 03 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**



iCVCT. HEMODYNAMIC SUPPORT DEVICES TRIALS
Chairpersons: Navin Kapur (Boston, USA) & George Dangas (New York, USA)

**Mechanical support devices in shock. A bird's eye view on current data
Temporal and regional trends in mechanical support devices use in shock**

**European Perspective
Alaide Chieffo (Milano, ITA)**

**North American Perspective
Navin Kapur (Boston, USA)**

**Smart machines and machine learning for Hemodynamic Support Devices: Case Example- Impella
Dawn Bardot (AbioMed, USA)**

**Which support device if any should I use in shock? Issues with Current Trial designs
Holger Thiele (Leipzig, GER)**


**Innovative approaches for screening pts with hemodynamic collapse for enrollment in trials
Chuck Simonton (Abiomed, USA)**

**Trials to evaluate use of Hemodynamic support in PCI: PROTECT IV
George Dangas (New York, USA)**

**Door-to-unload trial for anterior STEMI: Challenges in STEMI Trials
Navin Kapur (Boston, USA)**

**MCS in Shock: Current Approved indications and Evidence Gaps
Meir Shinnar (FDA, USA)**

THE iCVCT FORUM Multi-Stakeholder Moderated Debate



TRIALS IN HEMODYNAMIC SUPPORT DEVICES
Chairpersons: Navin Kapur (Boston, USA) & George Dangas (New York, USA)

**Dawn Bardot (AbioMed, USA), Alaide Chieffo (Milano, ITA); George Dangas (New York, USA); Navin Kapur (Boston, USA);
Konstantin Krychtiuk (Durham, USA); Ramesh Mazhari (Washington, USA); Ileana Pina (Detroit, USA), Yves Rosenberg (NIH, USA);
Meir Shinnar (FDA, USA); Chuck Simonton (Abiomed, USA), Holger Thiele (Leipzig, GER), Bram Zuckerman (FDA, USA)**

VALUATION OF DEVICE CLINICAL EVIDENCE FOR COVERAGE PURPOSES
Chairpersons: Roxana Mehran (New York, USA) & Alan Fraser (Cardiff, GBR)

Assessing health technologies: What evidence is needed to convince payers?
Steven Farmer (CMS, USA)

Why and how clinical evidence for payers (“Reasonable and necessary”) differs from regulatory approval (“Safe and effective”).
Progress in the commitment about aligning payers and regulators.
Andrew Farb (FDA, USA)

FDA breakthrough designation and Medicare Coverage of Innovative Technology. Issues and potential solutions
Bram Zuckerman (FDA, USA)

Investigator viewpoint
William Abraham (Columbus, USA)

Industry viewpoints and case studies

Watchman
Kenneth Stein (Boston Scientific, USA)

Cardiomems
Philip Adamson (Abbott, USA)

Barostim
Nadim Yared (CVRx, USA)

Patient’s viewpoint
Cynthia Chauhan (Wichita, USA)

Regulatory scientist viewpoint
Alan Fraser (Cardiff, GBR)

Lawyers viewpoint
Paul M Rudolph (Arnold&Porter, USA)


Empowering patients to grow expertise for evidence valuation.
Phil Collis (European Heart Network, GBR)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW IMPROVING MULTIPLE STAKEHOLDERS UNDERSTANDING, WEIGHTING AND VALUATION OF CLINICAL EVIDENCE MAY HELP MITIGATE CV DEVICE THERAPY IMPLEMENTATION HURDLES?
Chairpersons: Roxana Mehran (New York, USA) & Alan Fraser (Cardiff, GBR)

Panelists: William Abraham (Columbus, USA); Philip Adamson (Abbott, USA); Biykem Bozkurt (Houston, USA); Nikolaos Dages (Leipzig, GER); Thomas Deering (Atlanta, USA); Andrew Farb (FDA, USA); Alan Fraser (Cardiff, GBR); Robert Kowal (Medtronic, USA); Cecilia Linde (Stockholm, SWE); Roxana Mehran (New York, USA); Caius Ovidiu Mersa (European Heart Network, ROM); Phil Collis (European Heart Network, GBR); Paul M Rudolph (Arnold&Porter, USA); Kenneth Stein (Boston Scientific, USA); Nadim Yared (CVRx, USA); Wojciech Zareba (Rochester, USA); Mike Zile (Charleston, USA); Bram Zuckerman (FDA, USA)

**Room : Pierre-Auguste Renoir
Saturday 04 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST**



**iCVCT. ANTITHROMBOTIC THERAPY TRIALS. NEW KIDS ON THE BLOCK.
Chairpersons: Michelle O'Donoghue (Boston, USA) & Gabriel Steg (Paris, FRA)**

What ischemic cost, if any, is tolerable for avoiding bleeding?
Dominick Angiolillo (Miami, USA)

Self-administered subcutaneous anti-thrombotic therapy. Opportunities and trial design issues with Selatogrel
Gabriel Steg (Paris, FRA)

Pre-hospital anti-thrombotic trials
Arnoud van't Hof (Maastricht, NED)

Industry viewpoint
Jack Lawrence (Janssen, USA)
Corine Bernaud (Idorsia, CH), Martin Unverdorben (Daiichi Sankyo, USA), Robert Hillman (Celacor, USA)

Regulatory viewpoint
Ellis Unger (Former FDA experience, USA)

How different should the anti Xla trials be: Population, endpoints, duration of therapy, disease states?
Michael Gibson (Boston, USA)

THE iCVCT FORUM Multi-Stakeholder Moderated Debate



**ANTITHROMBOTIC THERAPY TRIALS. NEW KIDS ON THE BLOCK.
Chairpersons: Michelle O'Donoghue (Boston, USA) & Gabriel Steg (Paris, FRA)**

Panelists : Dominick Angiolillo (Miami, USA); Suzanne Baron (Burlington, USA) ; Deepak Bhatt (Boston, USA), Corine Bernaud (Idorsia, CH), George Dangas (New York, USA); Efthymios Deliargyris (Cytosorbents, USA); Michael Gibson (Boston, USA); Robert Hillman (Celacor, USA); Jack Lawrence (Janssen, USA); Victoria Lee (Cytosorbents, USA); Michelle O'Donoghue (Boston, USA), Manesh Patel (Durham, USA), Duane Pinto (Boston, USA); Sébastien Roux (Idorsia, CH); Frank Sellke (Providence, USA); Gabriel Steg (Paris, FRA), Robert Storey (Sheffield, GBR); Ellis Unger (Former FDA experience, USA); Martin Unverdorben (Daiichi Sankyo, USA); Arnoud van't Hof (Maastricht, NED)

**Room : Pierre-Auguste Renoir
Saturday 04 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**



iCVCT. PERIOPERATIVE MANAGEMENT OF ANTITHROMBOTIC THERAPY
Chairpersons: Suzanne Baron (Burlington, USA) & Deepak Bhatt (Boston, USA)

Perioperative Antiplatelet Therapy Dilemma
Dominick Angiolillo (Miami, USA)

Bridging Antiplatelet Therapy With Cangrelor
George Dangas (New York, USA)

Extracorporeal blood purification from antithrombotic agents: a novel paradigm?
Robert Storey (Sheffield, GBR)

THE iCVCT FORUM Multi-Stakeholder Moderated Debate



PERIOPERATIVE MANAGEMENT OF ANTITHROMBOTIC THERAPY: IMPLICATIONS FOR TRIAL DESIGNS.
Chairpersons: Suzanne Baron (Burlington, USA) & Deepak Bhatt (Boston, USA)

Panelists : Dominick Angiolillo (Miami, USA); Suzanne Baron (Burlington, USA) ; Deepak Bhatt (Boston, USA), Corine Bernaud (Idorsia, CH), George Dangas (New York, USA); Efthymios Deliargyris (Cytosorbents, USA); Robert Harrington (Stanford, USA), Jack Lawrence (Janssen, USA), Victoria Lee (Cytosorbents, USA)Michelle O'Donoghue (Boston, USA), Manesh Patel (Durham, USA), Duane Pinto (Boston, USA), Sébastien Roux (Idorsia, CH) ; Frank Sellke (Providence, USA); Gabriel Steg (Paris, FRA), Norman Stockbridge (FDA, USA), Robert Storey (Sheffield, GBR)

**Room : Pierre-Auguste Renoir
Saturday 04 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST**



iCVCT. TRIALS IN HIGH BLEEDING RISK PATIENTS

Chairperson: Robert Harrington (Stanford, USA) & Frank Sellke (Providence, USA)

PCI device/drug synergy Trials in high-bleeding risk patients
Evolving landscapes in coronary stents for high bleeding risk patients
Stephan Windecker (Bern, CH)

Antiplatelet therapy in high bleeding risk patients: walking a tightrope
Roxana Mehran (New York, USA)

Utility of risk stratification tools in Trials: balancing the ischemic and bleeding risks
Davide Capodanno (Catania, ITA)

Alternative Pathways to reduce Risks: Implications for PCSK9 and Ao A 1 (Human)
John Alexander (Durham, USA)

Alternative Pathways and Future Trial Designs to reduce Risks
Michael Gibson (Boston, USA)

Future trials in high bleeding risk patients: 'speaking the same language':
Regulatory viewpoint
Adrian Magee (FDA, USA)

Industry viewpoint
Sandeep Brar (Medtronic, USA), Victoria Lee (Cytosorbents, USA)

Patient's viewpoint
Robin Martinez (Denver, USA)

THE iCVCT FORUM Multi-Stakeholder Moderated Debate



TRIALS AND HIGH BLEEDING RISK PATIENTS

Chairpersons: Robert Harrington (Stanford, USA) & Frank Sellke (Providence, USA)

Panelists : Alexandre Abizaid (Sao Paulo, BRA); John Alexander (Durham, USA); Dominick Angiolillo (Miami, USA); Sandeep Brar (Medtronic, USA), Davide Capodanno (Catania, ITA), Efthymios Deliargyris (Cytosorbents, USA), Michael Gibson (Boston, USA), Robert Harrington (Stanford, USA); Victoria Lee (Cytosorbents, USA); Renato Lopes (Durham, USA); Adrian Magee (FDA, USA); Robin Martinez (Denver, USA); Roxana Mehran (New York, USA); Duane Pinto (Boston, USA), Frank Sellke (Providence, USA); Stephan Windecker (Bern, CH), Robert Yeh (Boston, USA)

**Room: Paul Cezanne
Saturday 04 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST**

**HRS-EHRA-CVCT joint session. ATRIAL FIBRILLATION
PREVENTION OF PROGRESSION AND MORTALITY & MORBIDITY RISK REDUCTION TRIALS
Chairpersons: Thomas Deering (Atlanta, USA) & Gerhard Hindricks (Leipzig, GER)
& Elaine Hylek (Boston, USA)**

How to approach persistent AF, for the prevention of progression and for morbidity-mortality risk reduction (EAST, RACE etc.)
Paulus Kirchhof (Hamburg, GER)

AF Ablation trials in target patient populations. (Early, persistent, asymptomatic, Heart Failure).
David Callans (Philadelphia, USA)

Surgical left atrial appendage occlusion. The LAAOS III trial in context.
Richard Page (Burlington, USA)

The role of oral anticoagulants after surgical and interventional left atrial appendage occlusion
Gregory Lip (Liverpool, GBR)

Any left opportunity for AFib drug trials? Concept and design of CHANGE Afib
Jonathan Piccini (Durham, USA)

What endpoints are clinically relevant, regulatory approvable and economically valuable in AF trials?
Kimberly Selzman (Salt Lake City, USA)

Investigator viewpoints
Douglas Packer (Rochester, USA)

Regulatory viewpoints
George Van Hare (FDA, USA)
Krishna Prasad (MHRA, GBR)

Payers viewpoints
Piotr Szymanski (Warsaw, POL)

Patients viewpoints
Bill Adams (Erhard, USA)

Industry viewpoints
Kenneth Stein (Boston Scientific, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**ATRIAL FIBRILLATION. PREVENTION OF PROGRESSION AND MORTALITY & MORBIDITY RISK REDUCTION.
WHAT NEEDS SHOULD BE MET IN FUTURE TRIALS?
Chairpersons: Thomas Deering (Atlanta, USA) & Gerhard Hindricks (Leipzig, GER)
& Elaine Hylek (Boston, USA)**

Panelists: Bill Adams (Erhard, USA); Ian Barrow (Washington, USA); David Callans (Philadelphia, USA); Ashley Chin (Capetown, SA);
Thomas Deering (Atlanta, USA); Gerhard Hindricks (Leipzig, GER); Elaine Hylek (Boston, USA); Paulus Kirchhof (Hamburg, GER);
Gregory Lip (Liverpool, GBR); Douglas Packer (Rochester, USA); Richard Page (Burlington, USA); Jonathan Piccini (Durham, USA);
Krishna Prasad (MHRA, GBR); Kimberly Selzman (Salt Lake City, USA); Piotr Szymanski (Warsaw, POL); George Van Hare (FDA, USA);
Kenneth Stein (Boston Scientific, USA)

Room: Paul Cezanne
Saturday 04 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST

THE EVOLVING LANDSCAPE OF PULMONARY ARTERIAL HYPERTENSION TRIALS
Part 1- PROGRESS IN TRIAL DESIGN
Chairpersons: Mardi Gomberg-Maitland (Washington, USA) & Marc Humbert (Paris, FRA)

PAH therapy: current status, improved outcomes and objectives of the workshop
Marc Humbert (Paris, FRA)

Traditional design of phase 3 PAH therapy trials
Nazzareno Galiè (Bologna, ITA)

Target patient populations: Phenotyping and risk enrichment aimed at maximizing response rate
Mardi Gomberg-Maitland (Washington, USA)

Seamless phase 2/3 trials. May adaptive design solve the problem?
Paul Hassoun (Baltimore, USA)

May Bayesian approaches help?
Eric Vicaut (Paris, FRA)

Comparator and background therapy issues. Placebo vs. active control, Add-on vs. replacement, Single drug vs. strategies comparisons.
Steve Kawut (Philadelphia, USA)

Pragmatic post approval trials and real world data
Gregory Elliott (Salt Lake City, USA)

Is PAH therapy getting too expensive? Health economics and cost-effectiveness valuation of PAH trials
Isabelle Durand-Zalesky (Paris, FRA)

What drugs are ready for phase 3 clinical trials?
Vallerie McLaughlin (Ann Arbor, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

REDESIGNING PULMONARY ARTERIAL HYPERTENSION TRIALS
Chairpersons: Mardi Gomberg-Maitland (Washington, USA) & Marc Humbert (Paris, FRA)

Panelists: Philip Adamson (Abbott, USA); Raymond Benza (Columbus, USA) ; Athenais Boucly (Paris, FRA) ; Björn Dahlof (Cereno, SWE), Ben Dake (Aerovate Therapeutics, USA) ; Janethe de Oliveira Pena: (Acceleron Pharma, Inc., USA) ; Isabelle Durand-Zalesky (Paris, FRA); Gregory Elliott (Salt Lake City, USA), Charles Fauvel (Columbus, USA) ; Veronica Franco (Columbus, USA) ; Nazzareno Galiè (Bologna, ITA); Simon Gibbs (London, GBR); Hunter Gillies (Aerovate Therapeutics, USA); Wendy Gin-Sing (London, GBR); Mardi Gomberg-Maitland (Washington, USA); Paul Hassoun (Baltimore, USA) ; Marius Hoeper (Hannover, GER); Marc Humbert (Paris, FRA); Steve Kawut (Philadelphia, USA); Howard M. Lazarus (Altavant Sciences, Inc., USA) ; Jane Leopold (Boston, USA); Brad Maron (Boston, USA); Vallerie McLaughlin (Ann Arbor, USA); David Montani (Paris, FRA) ; Nick Morrell (Cambridge, USA); Mahesh Patel (Merck, USA), Ioana Preston (Boston, USA); Mitch Psotka (FDA, USA); Gérald Simonneau (Paris, FRA); Olivier Sitbon (Paris, FRA); Derek Solum (United Therapeutics, USA) ; Bill Symonds (Altavant Sciences, Inc., USA) ; Thennapan Thennapan (Minneapolis, USA) ; Eric Vicaut (Paris, FRA); Scott Visovatti (Columbus, USA) ; Jason Weatherald (Calgary, CAN) ; Antoine Yver (Centessa Pharmaceuticals, USA) ; Roham Zamanian (Stanford, USA); Lawrence S. Zisman (Gossamer Bio Inc, USA)

Room: Paul Cezanne
Saturday 04 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST

THE EVOLVING LANDSCAPE OF PULMONARY ARTERIAL HYPERTENSION PHASE 3 TRIALS
Part 2- REDEFINING CLINICALLY MEANINGFUL ENDPOINTS
Chairpersons: Vallerie McLaughlin (Ann Arbor, USA) & Gérald Simonneau (Paris, FRA)

A critical appraisal of classical endpoints in past and recent PAH phase 3 trials (6MWD, TTCW)
Gerald Simonneau (Paris, FRA)

Proposal of novel endpoints based on actigraphy.
Ioana Preston (Boston, USA)

Validated risk score as primary endpoint predicting mortality.
Raymond Benza (Columbus, USA)

Proposal of novel endpoints based on actigraphy.
Ionna Preston (Boston, USA)

Patient-reported outcomes in PAH
Simon Gibbs (London, GBR)

Hemodynamic remote monitoring endpoints
Raymond Benza (Columbus, USA)

Investigator viewpoint:
Thennapan Thennapan (Minneapolis, USA), Roham Zamanian (Stanford, USA)

Industry Viewpoint
Björn Dahlof (Cereno, SWE), Mahesh Patel (Merck, USA), Philip Adamson (Abbott, USA)

Regulatory viewpoint
Krishna Prasad (MHRA, GBR), Mitch Psocka (FDA, USA)

Patients' viewpoint:
Caius Ovidiu Mersa (European Heart Network, ROM), Jacqueline Alikhaani (Los Angeles, USA)

Payer's viewpoint
Meindert Boysen (NICE, London, GBR)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

WHAT ENDPOINTS ARE CLINICALLY RELEVANT, REGULATORY APPROVABLE AND ECONOMICALLY VALUABLE?
Chairpersons: Vallerie McLaughlin (Ann Arbor, USA), Gérald Simonneau (Paris, FRA)

Panelists : Philip Adamson (Abbott, USA) ; Jacqueline Alikhaani (Los Angeles, USA); Raymond Benza (Columbus, USA); Athenais Boucly (Paris, FRA) ; Björn Dahlof (Cereno, SWE), Ben Dake (Aerovate Therapeutics, USA) ; Janethe de Oliveira Pena: (Accelaron Pharma, Inc., USA) ; Isabelle Durand-Zalesky (Paris, FRA) ; Gregory Elliott (Salt Lake City, USA), Charles Fauvel (Columbus, USA) ; Veronica Franco (Columbus, USA) ; Nazzareno Galiè (Bologna, ITA); Simon Gibbs (London, GBR); Hunter Gillies (Aerovate Therapeutics, USA); Wendy Gin-Sing (London, GBR); Mardi Gomberg-Maitland (Washington, USA); Paul Hassoun (Baltimore, USA) ; Marius Hoepfer (Hannover, GER); Marc Humbert (Paris, FRA); Steve Kawut (Philadelphia, USA); Howard M. Lazarus (Altavant Sciences, Inc., USA) ; Jane Leopold (Boston, USA); Brad Maron (Boston, USA) ; Vallerie McLaughlin (Ann Arbor, USA); Caius Ovidiu Mersa (European Heart Network, ROM) ; David Montani (Paris, FRA) ; Nick Morrell (Cambridge; USA); Mahesh Patel (Merck, USA), Ioana Preston (Boston, USA); Mitch Psocka (FDA, USA); Gérald Simonneau (Paris, FRA); Olivier Sitbon (Paris, FRA); Derek Solum (United Therapeutics, USA) ; Bill Symonds (Altavant Sciences, Inc., USA), Thennapan Thennapan (Minneapolis, USA) ; Eric Vicaut (Paris, FRA); Scott Visovatti (Columbus, USA) ; Jason Weatherald (Calgary, CAN) ; Antoine Yver (Centessa Pharmaceuticals, USA) ; Roham Zamanian (Stanford, USA); Lawrence S. Zisman (Gossamer Bio Inc, USA)

Room: Edgar Degas
Saturday 04 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST

HOW PATIENT REPORTED OUTCOMES MAY IMPACT TRIAL DESIGN, APPROVAL, VALUATION, GUIDELINES AND CARE?

Chairpersons : Clyde Yancy (Chicago, USA) & Faiez Zannad (Paris, FRA)

Review of HRQoL endpoints in randomized trials and definition of minimal clinically important difference (MCID).
Clyde Yancy (Chicago, USA)

How can patient reported outcomes better inform the approval process?

Investigator viewpoint
John Spertus (Kansas City, USA)

Industry viewpoint
Klaus Jensen (Vifor, CH), Masahiro Murakami (Eli Lilly, USA), Lothar Roessig (Bayer, GER), Anna Maria Langkilde (AstraZeneca, SWE)

Regulatory viewpoint
Norman Stockbridge (FDA, USA)

How can healthcare systems better value patient-reported outcome measures?

Findings from HF QoL patient survey and patients' whitepaper recommendations
Nick Hartshone-Evans (London, GBR)

How PROs can be used to improve healthcare quality?
Harriette Van Spall (Hamilton, CAN)

Health economist viewpoint
Phil McEwan (HEOR, GBR)

Payer's viewpoint
Mantovani Lorenzo (Milano, ITA)

How can clinical guidelines incorporate recommendations relevant to patient reported outcome?

THE CVCT FORUM Multi-Stakeholder Moderated Debate

HOW PATIENT REPORTED OUTCOMES MAY IMPACT TRIAL DESIGN, APPROVAL, * VALUATION, GUIDELINES AND CARE?

Chairpersons : Clyde Yancy (Chicago, USA) & Faiez Zannad (Paris, FRA)

Panelists: Javed Butler (Jackson, USA); Nick Hartshone-Evans (London, GBR); Denis Janssen (Amsterdam, NED); Klaus Jensen (Vifor, CH); Winfried Klausnitzer (Nürnberg, GER); Steven Macari (Poitiers, FRA); Phil McEwan (HEOR, GBR); Anna Maria Langkilde (AstraZeneca, SWE); Mantovani Lorenzo (Milano, ITA); Masahiro Murakami (Eli Lilly, USA); Dan Nguyen (Kansas City, USA); Lothar Roessig (Bayer, GER); John Spertus (Kansas City, USA); Norman Stockbridge (FDA, USA); Clyde Yancy (Chicago, USA); Harriette Van Spall (Hamilton, CAN); Faiez Zannad (Paris, FRA)

**Room: Edgar Degas
Saturday 04 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**



PATIENT VOICE IN CLINICAL TRIAL - GETTING BEYOND LIP SERVICE
Chairpersons: Jillianne Code (Vancouver, CAN) & Robin Martinez (Denver, USA)

Why and how bring the patient voice to the research table. What works and what doesn't work.
Steven Macari (Poitiers, FRA)

Inclusiveness among trial patients participants

Inclusion/exclusion of patients with comorbidities in trials
Patrick Gee (Chesterfield, USA)

Diversity among trial patients participants
Wanda F Moore (Arizona, USA)

How do we reach out to diverse patients? Cultural competency, Unserved minorities, Transgender
Sadegh Alikhaani (Los Angeles, USA)


Making trial language intelligible to all patients

Lay Language publications in Trial Literature when and why do they matter?
Rani Khatib (Leeds, GBR)

Patient's viewpoint
Robin Martinez (Denver, USA)

European Heart Network
Marilena Vrana (European Heart Network, BEL)


THE CVCT FORUM Multi-Stakeholder Moderated Debate



PATIENT VOICE IN CLINICAL TRIAL - GETTING BEYOND LIP SERVICE
Chairpersons: Jillianne Code (Vancouver, CAN) & Robin Martinez (Denver, USA)

Panelists: Bill Adams (Erhard, USA) ; Jacqueline Alikhaani (Los Angeles, USA) ; Sadegh Alikhaani (Los Angeles, USA);
Jillianne Code (Vancouver , CAN); Patrick Gee (Chesterfield, USA); Nick Hartshorne-Evans (London, GBR); Rani Khatib
(Leeds, GBR); Steven Macari (Poitiers, FRA); Robin Martinez (Denver, USA) ; Rob Mentz (JCF, Durham, USA) ; Greg Merritt
(Brighton, USA); Wanda F Moore (Arizona, USA) ; Marilena Vrana (Brussels, BEL) Wanda F Moore (Arizona, USA); Marilena
Vrana (European Heart Network, BEL)

**Room: Edgar Degas
Saturday 04 December, 2021
18.00-20.00 CET/ 12.00 - 14.30 EST**



**CVCT - Women as One joint session
INCREASING EQUITY AND DIVERSE REPRESENTATION AMONG PARTICIPANTS IN
CARDIOVASCULAR CLINICAL TRIALS
Chairpersons: Harriette Van Spall (Hamilton, CAN) & Blanche Cupido (Capetown, SA)**

**Sex and ethnicity: the paradox between disease burden and CV trial representation
Harriette Van Spall (Hamilton, CAN)**

**Geographic equity in CV clinical trials: increasing research capacity and trial enrolment in middle and low income countries.
Faiez Zannad (Paris, FRA)**

**Multi-site investigator initiated trials and the role of diversity in clinical trials leadership
Erin Michos (Baltimore, USA)**

**Leading clinical trials in low income countries: challenges and opportunities
Jaime M. Miranda (Lima, Peru)**

**Harnessing the strength of community: participatory research to enhance racial and ethnic diversity in cardiovascular clinical trials.
Eldrin Lewis (Stanford, USA)**

**What catalyst organizations can do to close diversity gaps in clinical trial leadership.
Rebecca Ortega (North Carolina, USA)**

**Role of industry in increasing equity among clinical trial participants and trial investigators.
Faiez Zannad (Paris, FRA)**

**Navigating the regulatory landscape: progressing from guidance to incentives.
Robert Temple (FDA, USA)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate



**CVCT - Women as One joint session
AGENDA FOR BUILDING EQUITY AND DIVERSE REPRESENTATION IN CARDIOVASCULAR CLINICAL TRIALS
Chairpersons: Harriette Van Spall (Hamilton CAN) & Blanche Cupido (Capetown, SA)**

Panelists: Kelly Jean Craig (IBM, USA); Blanche Cupido (Capetown, SA); Eldrin Lewis (Stanford, USA); Erin Michos (Baltimore, USA); Jaime J Miranda (Lima, PEN); Rebecca Ortega (North Carolina, USA); Elke Platz (Boston, USA); Harriette Van Spall (Hamilton, CAN); Robert Temple (FDA, USA); Faiez Zannad (Paris, FRA); Rayan El-Zein (Kansas City, USA)

WEARABLE, IMPLANTABLE AND DIGITAL HEALTH TRIALS
Chairpersons : Martin Cowie (London, GBR) & Carolyn Lam (Singapore, SIN)

Remote monitoring and digital health tools in CVD management. The evidence so far.
Martin Cowie (London, GBR)

Implantable Loop Recorder to Detect Atrial Fibrillation and Prevent Stroke
Derek Exner (Calgary, CAN)

Smartwatch to Identify Atrial Fibrillation
Christopher Granger (Durham, USA)

How to prevent failure in digital health trials.
Mintu Turakhia (Stanford, USA)

Self test blood K+ for Remote Patient Monitoring of serum K+ in cardiorenal disease
Patrick Rossignol (Nancy, FRA)

Industry viewpoint
Philip Adamson (Abbott, USA), Maurice Berenger (Cardio Renal, FRA), Rob Kowal (Medtronic, USA)

NIH viewpoint
Erin Iturriaga (NIH, NHLBI, USA)

Regulatory scientist viewpoint
Alan Fraser (Cardiff, GBR), Bakul Patel (FDA, USA)

Patient viewpoint.
Patrick Gee (Chesterfield, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

DIGITAL HEALTH SOLUTIONS. WHAT EVIDENCE NEEDED BEFORE ADOPTION?
Chairpersons: Martin Cowie (London, GBR) & Carolyn Lam (Singapore, SIN)

Panelists : Kirkwood Adams (Chapel Hill, USA); Philip Adamson (Abbott, USA); Maurice Berenger (Cardio Renal, FRA); Agim Beshiri (Abbott Dx, USA); Joe Coresh (Baltimore, USA); Martin Cowie (London, GBR); Derek Exner (Calgary, CAN); Alan Fraser (Cardiff, GBR); Patrick Gee (Chesterfield, USA); Christopher Granger (Durham, USA); Adrian Hernandez (Durham, USA); Ziad Hijazi (Uppsala, SWE); Erin Iturriaga (NIH, NHLBI, USA); Jim Januzzi (Boston, USA); Darae Ko (Boston, USA); Rob Kowal (Medtronic, USA); Carolyn Lam (Singapore, SIN); Joann Lindenfeld (Nashville, USA); Alexandre Mebazaa (Paris, FRA); Bakul Patel (FDA, USA); Arshed Quyyumi (Atlanta, USA); Paul Ridker (Boston, USA); Patrick Rossignol (Nancy, FRA); Fred Senatore (FDA, USA); Mintu Turakhia (Stanford, USA); Steve Williams (Somalogic, USA); André Ziegler (Roche, CH)

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY. Part 1 : ONGOING TRIALS
Chairpersons: Joann Lindenfeld (Nashville, USA) & Alexandre Mebazaa (Paris, FRA)

Device guided therapy trials in heart failure.

Cardiomems GUIDE-IT
Joann Lindenfeld (Nashville, USA)

MANAGE HF
Adrian Hernandez (Durham, USA)

ALLEVIATE-HF
Javed Butler (Jackson, USA)

Biomarker triggered optimization of therapy

Patients at risk of heart failure PONTIAC II and ADOPT trials
Carolyn Lam (Singapore, SIN)

In worsening heart failure patients STRONG HF
Alexandre Mebazaa (Paris, FRA)

In secondary prevention. The PRECISION CAD trial
Arshed Quyyumi (Atlanta, USA)

In atrial fibrillation: ABC AFib trial
Ziad Hijazi (Uppsala, SWE)

hsCRP in primary and secondary cardiovascular prevention
Paul Ridker (Boston, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY. Part 1 : ONGOING TRIALS
Chairpersons: Joann Lindenfeld (Nashville, USA) & Alexandre Mebazaa (Paris, FRA)

Panelists: Kirkwood Adams (Chapel Hill, USA), Agim Beshiri (Abbott Dx, USA), Javed Butler (Jackson, USA); Joe Coresh (Baltimore, USA); Martin Cowie (London, GBR); Derek Exner (Calgary, CAN); Alan Fraser (Cardiff, GBR); Christopher Granger (Durham, USA); Camilla Hage (Stockholm, SWE); Adrian Hernandez (Durham, USA); Ziad Hijazi (Uppsala, SWE); Mellanie True Hills (StopAfib.org, Greenwood, USA); Erin Iturriaga (NIH, NHLBI, USA); Jim Januzzi (Boston, USA); Carolyn Lam (Singapore, SIN); Joann Lindenfeld (Nashville, USA); Alexandre Mebazaa (Paris, FRA); Bakul Patel (FDA, USA); Arshed Quyyumi (Atlanta, USA); Paul Ridker (Boston, USA); AnnaLotta Schiller (TATAA, SWE); Fred Senatore (FDA, USA); Kenneth Stein (Boston Scientific, USA); Mintu Turakhia (Stanford, USA); Harriette Van Spall (Hamilton, Canada); Steve Williams (Somalogic, USA); André Ziegler (Roche, GER)

**Room: Vincent Van Gogh
Saturday 04 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST**

**MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY. Part 2 : METHODOLOGICAL ISSUES
Chairpersons: Kirkwood Adams (Chapel Hill, USA) & Ziad Hijazi (Uppsala, SWE)**

Developing prognostic tests from retrospective analysis of large cohort studies
Joe Coresh (Baltimore, USA)

Registry based risk assessment and longitudinal follow up
Christos Varounis (Abbott Dx, USA)

Pitfalls, challenges and potholes when designing and conducting a biomarker guided CV therapy trial?
Jim Januzzi (Boston, USA)

The value of non-siloed, integrated multi-omics analyses
Mikael Kubista (TATAA Biocenter, SWE)

Industry viewpoint:
Agim Beshiri (Abbott Dx, USA), Steve Williams (Somalogic, USA), André Ziegler (Roche, CH)


Regulatory Viewpoint:
Fred Signore (FDA, USA)
Armin Koch (EMA, GER)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY LESSONS LEARNT
AND FUTURE DIRECTIONS
Chairpersons: Kirkwood Adams (Chapel Hill, USA) & Ziad Hijazi (Uppsala, SWE)**

Panelists: Kirkwood Adams (Chapel Hill, USA); Agim Beshiri (Abbott Dx, USA), Javed Butler (Jackson, USA); Joe Coresh (Baltimore, USA); Martin Cowie (London, GBR); Derek Exner (Calgary, CAN); Christopher Granger (Durham, USA); Camilla Hage (Stockholm, SWE); Dominique Gouty (San Diego, USA); Adrian Hernandez (Durham, USA); Ziad Hijazi (Uppsala, SWE); Mellanie True Hills (StopAfib.org, Greenwood, USA); Erin Iturriaga (NIH, NHLBI, USA); Jim Januzzi (Boston, USA); Armin Koch (EMA, GER); Mikael Kubista (TATAA Biocenter, SWE); Carolyn Lam (Singapore, SIN); Joann Lindenfeld (Nashville, USA); Alexandre Mebazaa (Paris, FRA); Bakul Patel (FDA, USA); Arshed Quyyumi (Atlanta, USA); Paul Ridker (Boston, USA); Fred Signore (FDA, USA); Kenneth Stein (Boston Scientific, USA); Mintu Turakhia (Stanford, USA); Christos Varounis (Abbott Dx, USA); Steve Williams (Somalogic, USA); André Ziegler (Roche, CH)

**Room: Edouard Manet
Sunday 05 December, 2021
13.00-15.00 CET / 07:00 -09:00 EST**



iCVCT. REVASCULARIZATION TRIALS
Chairpersons: Donald Cutlip (Boston, USA) & Marie-Claude Morice (Paris, FRA)

Management of left main disease/ MV disease

Coronary imaging for optimal outcomes in left main/MV disease
Akiko Maehara (New York, USA)

Left main revascularization trials: Debate taken from another angle
Frank Sellke (Richmond, USA)


Revascularization trials in patients with diabetes mellitus

Individualizing revascularization approach for patients with DM
David J Cohen (New York, USA)

Industry Viewpoint
Chuck Simonton (Abiomed, USA)

FDA Viewpoint
Adrian Magee (FDA, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate



REVASCULARIZATION TRIALS
Chairpersons: Donald Cutlip (Boston, USA) & Marie-Claude Morice (Paris, FRA)

Alexandre Abizaid (Sao Paulo, BRA), Yousif Ahmad (Los Angeles, USA), Dominick Angiolillo (Miami, USA), Julia Baron (Derby, GBR), Robert Byrne (Dublin, IRE); Davide Cao (New York, USA); David J Cohen (New York, USA), Donald Cutlip (Boston, USA), George Dangas (New York, USA), John Gregson (London, USA); Adrian Magee (FDA, USA); Akiko Maehara (New York, USA); Gary Mintz (Washington, USA), Marie-Claude Morice (Paris, FRA); Johnny Nicolas (New York, USA); Frank Sellke (Richmond, USA), Chuck Simonton (Abiomed, USA); Giulio Stefanini (Milano, ITA)

**Room: Edouard Manet
Sunday 05 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**



**iCVCT – CSTN joint session. SURGICAL TRIALS IN CARDIOVASCULAR DISEASE
Chairpersons: Patrick O’Gara (New York, USA) & Michael Mack (Dallas, USA)**

**Challenges in Creating a Surgical Trials Network: Setting the Stage
Annetine Gelijns (New York, USA)**

**Designing Trials Comparing Percutaneous vs Open Surgical Procedures: the PRIMARY Trial
Joanna Chikwe (Los Angeles, USA)**

**Designing Clinical Trials using Digital Health Tools
Alexander Iribarne (Lebanon, USA)**

**Choosing between Highly Controlled and Pragmatic Designs
Emilia Bagiella (New York, USA)**

**The Need for Cardiac Surgery Clinical Trials in Women
Mario Gaudino (New York, USA)**

**Reengineering a Surgical Trials Network for a Pandemic
Peter Kent Smith (Durham, USA)**

**Regulatory viewpoint
Bernard Vasseur (FDA, USA)**

THE iCVCT FORUM Multi-Stakeholder Moderated Debate



**SURGICAL TRIALS IN CARDIOVASCULAR DISEASE
Chairpersons: Patrick O’Gara (New York, USA) & Michael Mack (Dallas, USA)**

Panelists: Emilia Bagiella (New York, USA), Christina Eleanor Barkauskas (Durham, USA), Sanjeev Bhavnani (La Jolla, USA), Michael Bowdish (Los Angeles, USA), Joanna Chikwe (Los Angeles, USA), Mario Gaudino (New York, USA), Annetine Gelijns (New York, USA), Alexander Iribarne (Lebanon, USA), Mariell Jessup (AHA, Hingham, USA), Darae Ko (Boston, USA), Martin Leon (New York, USA), Michael Mack (Dallas, USA), Roxana Mehran (New York, USA), Patrick O’Gara (New York, USA), Jessica Overbey (New York, USA), Peter Kent Smith (Durham, USA); Bernard Vasseur (FDA, USA)

**Room: Edouard Manet
Sunday 05 December, 2021
18.00-20.30 CET / 12.00 - 14.30 EST**



iCVCT. MITRAL AND TRICUSPID VALVE TRIALS
Chairpersons: Jeffrey Borer (New York, USA) & Mayra Guerrero (Rochester, USA)

A tale of two trials COAPT and Mitral FR: Lessons learned, future direction
Milton Packer (Dallas, USA)

Trial Design- Will Medical Management of HF impinge on TMVR?
Clyde Yancy (Chicago, USA)

Mitral Valve Academic Research Consortium: Status Update
Saibal Kar (Los Angeles, USA)

Tricuspid Valve Academic Research Consortium: Why now?
Rebecca Hahn (New York, USA)

Trial design issues in Tricuspid valve disease: Patient population, Endpoints
Susheel Kodali (New York, USA)

Clinician Viewpoint
Jamie Mc Cabe (Washington, USA)

FDA viewpoint
ChangFu Wu (FDA, USA)
Nicole Ibrahim (FDA, USA)

Industry View
Dominic Allocco (Boston Scientific, USA)

THE iCVCT FORUM Multi-Stakeholder Moderated Debate



IMPLICATIONS FOR FUTURE DEVICES IN THIS ARENA
Chairpersons: Jeffrey Borer (New York, USA) & Mayra Guerrero (Rochester, USA)

**Panelists: Dominic Allocco (Boston Scientific, USA); Jeffrey Borer (New York, USA); Biykem Bozkurt (Houston, USA);
Alaide Chieffo (Milano, ITA); Victoria Delgado (Leiden, NED); ChangFu Wu (FDA, USA), Rebecca Hahn (New York, USA);
Saibal Kar (Los Angeles, USA); Susheel Kodali (New York, USA), Karl-Patrik Kresoja (Leipzig, GER); Nicole Ibrahim
(FDA, USA); Jamie Mc Cabe (Washington, USA), Mayra Guerrero (Rochester, USA); Milton Packer (Dallas, USA), Anna
Sonia Petronio (Pisa, ITA); Iliana Pina (Detroit, USA), Gilbert Tang (New York, USA); Jaime Wheeler (Edwards, USA);
Clyde Yancy (Chicago, USA), Ori Ben Yehuda (San Diego, USA), Bram Zuckerman (FDA, USA)**

**Room: Claude Monet
Sunday 05 December, 2021
15.30-17.30 CET / 09.30 - 11.30 EST**

**CHEAPER, FASTER AND MORE EFFICIENT TRIALS. IS PRAGMATIC THE SOLUTION?
Chairpersons: Stephan James (Uppsala, USA) & Wendy Weber (NIH, NCCIH, USA)**

What exactly is a pragmatic Trial?
Stephan James (Uppsala, SWE)

Pragmatic clinical trials embedded in healthcare systems: Lessons from the NIH Collaboratory.
Wendy Weber (NIH, NCCIH, USA)

Lessons from ADAPTABLE. Going virtual, blinding and data sources what's the right balance of tradeoffs.
Robert Harrington (Stanford, USA)

Statistical issues in pragmatic trials
David DeMets (Madison, USA)

Optimisation of Safety Data Collection
Ellis Unger (Former FDA experience, USA)

Are regulators serious about overlooking 'weaknesses' of pragmatic trials?
Mary Thanh-Hai (FDA, USA)
Krishna Prasad (MHRA, GBR)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**PRE-APPROVAL VS. POST-APPROVAL TRIALS. WHERE BEST STREAMLINED TRIALS MAY APPLY?
Chairpersons: Stephan James (Uppsala, USA) & Wendy Weber (NIH, NCCIH, USA)**

Panelists: David DeMets (Madison, USA); Robert Harrington (Stanford, USA); Stephan James (Uppsala, USA); Martin Landray (Oxford, GBR); Renato Lopes (Duke, USA); Greg Merritt (Brighton, USA); Krishna Prasad (MHRA, GBR); Yves Rosenberg (NIH/NHLBI, USA); Mikhail Sumin (Boehringer Ingelheim, GER); Mary Thanh-Hai (FDA, USA); Ellis Unger (Former FDA experience, USA); Wendy Weber (NIH, NCCIH, USA)

**Room: Claude Monet
Sunday 05 December, 2021
18.00-20.00 CET / 12.00 - 14.30 EST**

**MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE APPLIED TO TRIALS.
Chairpersons: Irene Dankwa-Mullan (IBM, USA) & Bernard Gersh (Rochester, USA)**

Designing pragmatic clinical trials to meet the needs of learning healthcare systems
Harriette Van Spall (Hamilton, CAN)

Application of a machine learning risk prediction model to clinical trial design
Barry Greenberg (San Diego, USA)

Artificial intelligence and machine learning in clinical predictive models to promote health equity.
Irene Dankwa-Mullan (IBM, USA)

Power boost for RCTs using treatment-blinded risk stratification with machine learning tools
Devan Mehrotra (Merck, USA)

Case studies of machine learning and artificial intelligence potential for clinical trials.

Undiagnosed Atrial fibrillation. ALIVECORE
Bernard Gersh (Rochester, USA)

Risk of developing heart failure. CardAlc.
Victor Roth Cardoso (Birmingham, GBR)

AI applied to trial data. Owkin
Paul Trichelair (Owkin, FRA)

AI applied to echocardiography.
Jasper Tromp (Singapore, SG)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**WHERE BEST TO USE MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE APPLIED TO TRIALS.
Chairpersons: Irene Dankwa-Mullan (IBM, USA) & Bernard Gersh (Rochester, USA)**

Panelists: Irene Dankwa-Mullan (IBM, USA), Bernard Gersh (Rochester, USA); Barry Greenberg (San Diego, USA); Karola Jering (San Diego, USA); Devan Mehrotra (Merck, USA); Paul Trichelair (Owkin, FRA); Jasper Tromp (Singapore, SG); Harriette Van Spall (Hamilton, CAN)

**A CVCT GLOBAL – CHINA MULTI STAKEHOLDER CROSS TALK
CARDIORENAL OUTCOME TRIALS. DESIGN AND APPROVABILITY ISSUES.
Chairpersons: Faiez Zannad (Paris, FRA) & Fred Yang (KPB, USA)**

What are the target patient populations in cardiorenal outcome trials?

Cardiorenal diseases and unmet needs in China

Cardiovascular Trials in China
Yong Huo (Peking, CN)

Resistant hypertension
Jiguang Wang (Shanghai, CN)

Cardiovascular trials in diabetes patients
Linong Ji (Peking, CN)

Challenge of kidney disease in China: implications for the treatment
Hong Zhang (Peking, CN)

Challenges and solutions in cardiorenal clinical trials/outcome studies – Decentralized trials
Jill Loftiss (RedbudMed, CN)

Reimbursement, Pharmacoeconomics and public health consideration

Increasing CV disease burden and pharmaceutical innovation in China
Larry Liu (Merck, USA)

Resistant HTN in CKD patients: Patient care and treatment options in China:
Fred Yang (KBP, USA)

China Reimbursement Environment Evolution and HTA application:
Jianwei Xuan (Sun Yat-Sen University, CN)

China market access CN
Shuo Yang (Sanofi China, CN)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**CARDIORENAL OUTCOME TRIALS. DESIGN AND APPROVABILITY ISSUES.
A GLOBAL – CHINA CROSS TALK
Chairpersons: Faiez Zannad (Paris, FRA) & Fred Yang (KPB, USA)**

Panelists: Maria Rosa Costanzo (Naperville, USA); Yong Huo (Peking University, CN), Linong Ji (Peking, CN); Larry Liu (Merck, USA); Jill Loftiss (RedbudMed, CN); Finnian Mc Causland (Boston, USA); Richard Nkulikiyinka (Bayer, GER); Vlado Perkovic (Sydney, AUS); Bertram Pitt (Ann Arbor, USA), Jérôme Rossert (AstraZeneca, USA); Patrick Rossignol (Nancy, FRA); Ivonne Schulman (NIH, USA), Aliza Thompson (FDA, USA); Subodh Verma (Toronto, CAN); Jiguang Wang (Shanghai, CN); Jianwei Xuan (Sun Yat-Sen University, CN); Fred Yang (KBP, USA), Shuo Yang (Sanofi China, CN); Faiez Zannad (Paris, FRA), Hong Zhang (Peking, CN), Kezhou Zhang (NovoNordisk, CN)

**Room: Jean Baptiste Corot
Sunday 05 December, 2021
15.30-17.30 CET / 09:30 -11:30 EST**

**TREATMENTS OF HEART FAILURE WITH PRESERVED EJECTION FRACTION
BEYOND LV COMPLIANCE. MITIGATING STRESSED BLOOD VOLUME.
Chairpersons: Dan Burkhoff (New York, USA) & Sanjiv Shah (Chicago, USA)**

**Non-myocardial causes of HFpEF symptoms
Barry Borlaug (Rochester, USA)**

**Reducing LA pressure with intra-atrial shunting
William Abraham (V-Wave, Columbus, USA)
Sanjiv Shah (Chicago, USA)**

**The role of increased stressed blood volume in heart failure
Paul Sobotka (Philadelphia, USA)**

**Reducing stressed blood volume with splanchnic ganglion blockade
Marat Fudim (Durham, USA)**

**Reducing stressed blood volume with levosimendan
Stuart Rich (Chicago, USA)**

**How do SGLT-2 inhibitors affect or complement the effects on stressed blood volume?
Javed Butler (Jackson, USA)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate

**TREATMENTS OF HEART FAILURE WITH PRESERVED EJECTION FRACTION
BEYOND LV COMPLIANCE. MITIGATING STRESSED BLOOD VOLUME.
Chairpersons: Dan Burkhoff (New York, USA) & Sanjiv Shah (Chicago, USA)**

Panelists: William Abraham (V-Wave, Columbus, USA); Barry Borlaug (Rochester, USA); Dan Burkhoff (New York, USA) , Javed Butler (Jackson, USA), John Cleland (Glasgow, USA); Joao Ferreira (Porto, POR); Marat Fudim (Durham, USA), Chris Giordano (TenaxThera, USA); Robert Mentz (Durham, USA); Milton Packer (Dallas, USA); Stuart Rich (Chicago, USA); Karl-Philipp Rommel (Leipzig, GER); Hannah Rosenblum (New York, USA); Sanjiv Shah (Chicago, USA), Scott Solomon (Boston, USA); Paul Sobotka (Philadelphia, USA); Faiez Zannad (Paris, FRA)

**Room: Jean Baptiste Corot
Sunday 05 December, 2021
18.00-20.00 CET / 12:00 -14:00 EST**

**LESSONS FROM COVID PRAGMATIC TRIALS & THE ROLE OF INTERNATIONAL TRIALISTS
CONSORTIA**

Chairpersons: Renato Lopes (Duke, USA) & Yves Rosenberg (NIH/NHLBI, USA)

Large, streamlined trials: 20th Century Magic in a 21st Century World
Martin Landray (Oxford, GBR)

The Georges Institute for Global Health
Jha Vivekanand (New Delhi, IND)

The NIH experience
Yves Rosenberg (NIH/NHLBI, USA)

The Brazil Clinical Research Institute experience
Renato Lopes (Duke, USA)

Patient viewpoint
Greg Merritt (Brighton, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate

LESSONS FROM COVID PRAGMATIC TRIALS & THE ROLE OF INTERNATIONAL TRIALISTS CONSORTIA
Chairpersons: Renato Lopes (Duke, USA) & Yves Rosenberg (NIH/NHLBI, USA)

Panelists: David DeMets (Madison, USA); Robert Harrington (Stanford, USA); Stephan James (Uppsala, USA); Martin Landray (Oxford, GBR); Renato Lopes (Duke, USA); Greg Merritt (Brighton, USA); Yves Rosenberg (NIH/NHLBI, USA); Ellis Unger (Former FDA experience, USA); Jha Vivekanand (New Delhi, IND)