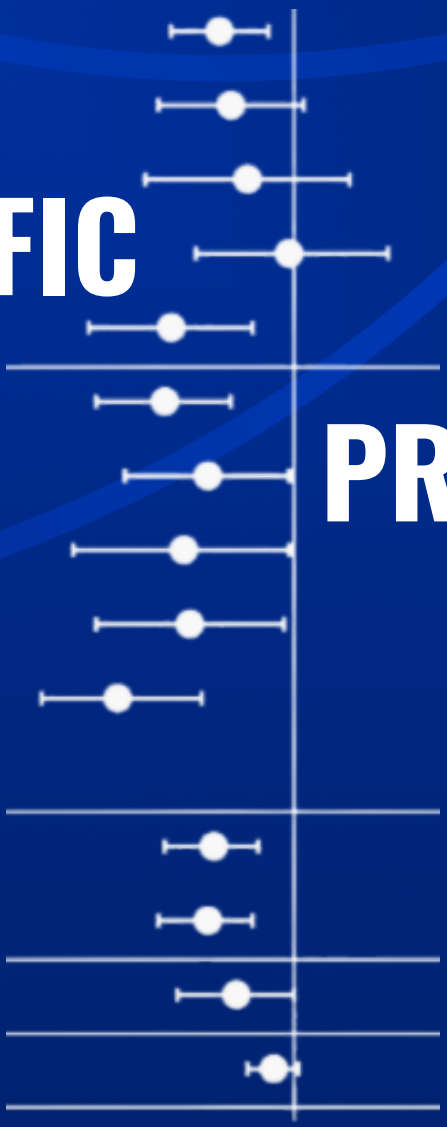
CVCT

December 8 - 10, 2025
The Mayflower Hotel, Washington DC

SCIENTIFIC PROGRAM



22nd Global Cardio Vascular Clinical Trialists Forum

FACULTY

ACADEMY

1. William Abraham (Columbus, OH, USA)
2. David Adlam (Leicester, UK)
3. Anubha Agarwal (St Louis, MI, USA)
4. Alberto Aimo (Pisa, ITA)
5. Rasha al Lamee (London UK)
6. Christine Albert (Los Angeles, CA, USA)
7. Jaime Almandoz (Dallas, TX, USA)
8. Jason Andrade (Vancouver, CAN)
9. Erik Arstad (London, UK)
10. Aravind Asokan (Durham, NC, USA)
11. Dan Atar (Oslo, NOR)
12. Julie Aultman (Akron, OH, USA)
13. Sherif Wagdy Ayad (Alexandria, EGY)
14. Michel Azizi (Paris, FRA)
15. Guiomar Mendieta Badimon (Barcelona, ESP)
16. Johannes Bauersachs (Hannover, GER)
17. Tina Baykaner (Stanford, CA, USA)
18. Rishi Bansal (Boston, MA, USA)
19. Alexander Blood (Boston, MA, USA)
20. Barry Borlaug (Rochester, MN, USA)
21. Biykem Bozkurt (Houston, TX, USA)
22. Jenifer Brown (Boston, MA, USA)
23. Daniel Burkhoff (New York, NY, USA)
24. John Burnett (Rochester, MN, USA)
25. Liam Brunham (Vancouver, CA)
26. Javed Butler (Dallas, TX, USA)
27. Jawad H Butt (Copenhagen, DEN)
28. Rob Califf (Bethesda, MA, USA)
29. Valeria Caso (Perugia, ITA)
30. Safia Chatur (Boston, MA, USA)
31. Rishi Chandiramani (Baltimore, MA, USA)
32. Vijay Chopra (Gurgaon, IND)
33. Mina Chung (Cleveland, OH, USA)
34. Caroline Coats (Glasgow, UK)
35. David Cohen (New York, NY, USA)
36. Kevin Costa (New York, NY, USA)
37. Maria Rosa Costanzo (Naperville, IL, USA)
38. Vincent Cottin (Lyon, France)
39. Jonathan Cunningham (Boston, MA, USA)
40. Don Cutlip (Boston, MA, USA)
41. Lesley Curtis (Durham, NC, USA
42. Zainab Dakhil (Baghdad, IQ)
43. Asita De Silva (Kelaniya, LK)
44. Sharlene Day (Philadelphia, PA, USA)
45. Ron Do (New York, NY, USA)
46. Sharmila Dorbala (Boston, MA, USA)
47. Issa Dahabreh (Boston, MA, USA)
48. Jessilyn Dunn (Durham, NC, USA),
49. Mariam Elmegaard (Herlev, DEN)
50. Michael Ewer (Houston, TX, USA)
51. Joao Ferreira (Porto, POR)
52. Brian Ference (Ann Arbor; MI, USA)
53. Enrico Ferro (Boston, MA, USA),
54. James Floyd (Seattle, WA, USA)
55. Marianna Fontana (London, UK)
56. Alan Fraser (Cardiff, UK)
57. Marat Fudim (Durham, NC, USA)
58. Valentin Fuster (New York, NY, USA)
59. Prakriti Gaba (Boston, MA, USA),
60. Habib Gamra (Sousse, TN)
61. Elvin Geng (St. Louis, MO, USA)
62. Michael Gibson (Boston, MA, USA)
63. Nicolas Girerd (Nancy, FRA)
64. Mardi Gomberg-Maitland (Washington, DC,USA)
65. Esther Gonzalez (Madrid, ESP)
66. Celina Gorre (WomenHeart, Washington, DC, USA)
67. Sascha Goonewardena (Ann Arbor, MI, USA)
68. Christopher Granger (Durham, NC, USA)
69. Jennifer Green (Durham, NC, USA)
70. Barry Greenberg (San Diego, CA, USA)
71. John Gregson (London, UK)
72. Patricia Guimaraes (São Paulo, BRA)
73. Mayra Guerrero (Rochester, MN, USA)
74. Edip Gurol (Boston, USA)
75. Roger Hajjar (Boston, MA, USA)
76. Joshua Hare (Miami, FL, USA)
77. Hiddo Lambers Heerspink (Groningen, NED)
78. Adam Helms (Ann Arbor, MI, USA)
79. Adrian Hernandez (Durham, NC, USA)
80. Stephane Heymans (Maastricht, NED)
81. Carolyn Ho (Boston, MA, USA)
82. Jessie Holtzman (San Franscico, CA, USA)
83. Christoph Hornik (Durham, NC, USA)
84. Mark Huffman (St Louis, MI, USA)
85. Marc Humbert (Paris, FRA)
86. Kathryn Hyzak (Ohio, OH, USA)
87. Riccardo Inciardi (Brescia, ITA)

88. Sneha Jain (Stanford, CA, USA)
89. Jim Januzzi (Boston, MA, USA)
90. Stefan Janssens (Leuven, BE)
91. Meg Jardine (Sydney, AUS)
92. Ania Jastreboff (New Haven, CT, USA)
93. Chokri Jeribi (ESHMOUN, TUN)
94. Nona Jiang (Boston, MA, USA)
95. Niels Jongs (Groningen, NED)
96. Philip Joseph (Hamilton, CAN)
97. Peter Juni (Oxford, UK),
98. William Schuyler Jones (Durham, NC, USA)
99. Pia Kamstrup (Herlev, DEN)
100. David Kandzari (Atlanta, GA, USA)
101. Naresh Kanumilli (Manchester, UK)
102. Aaron Kaplan (Lebanon, NH, USA)
103. Jens Kastrup (Copenhagen, DEN)
104. Sanjay Kaul (Los Angeles, CA, USA)
105. Steve Kawut (Philadelphia, PEN, USA)
106. Sander Kersten (Wageningen, NED)
107. Mohammad Shahzeb Khan (Dallas, TX, USA)
108. Shahnaz Khan (Washington, DC, USA)
109. Yuri Kim (Boston, MA, USA)
110. Paulus Kirchhof (Hambourg, GER)
111. Darae Ko (Boston, USA)
112. Christos P Kotanidis (Oxford, UK)
113. Mitchell Krucoff (Durham, NC, USA)
114. Vijay Kunadian (Newcastle upon Tyne, UK)
115. Luke Laffin (Cleveland, OH, USA)
116. Christina Lalani (Boston, MA, USA)
117. Carolyn Lam (Singapore, SIN)
118. David Lanfear (Detroit, MI, USA)
119. Alexandra Lansky (New Haven, CT, USA)
120. Martin Landray (Oxford, UK)
121. Matthew Lee (Glasgow, UK),
122. Xinli Li (Nanjing, CHN)
123. Michael Lincoff (Cleveland, OH, USA)
124. Ildiko Lingvay (Dallas, TX, USA)
125. Sheldon Litwin (Charleston, SC, USA)
126. Renato Lopes (Durham, NC, USA)
127. Mads Engelmann (Copenhagen, DEN)
128. Jamie McCabe (Rochester, NY, USA)
129. Darren McGuire (Dallas, TX, USA)
130. William McIntyre (Hamilton, CAN)
131. Vallerie McLaughlin (Ann Arbor, MI, USA)
132. Douglas Mann (St Louis, MI, USA)
133. Pradeep Mammen (Kansas City, MO, USA)
134. Eduardo Marban (Los Angeles, CA, USA)
135. Greg Marcus (San Francisco, CA, USA),
136. Brad Maron (Baltimore, MA,USA)
137. Nicholas A. Marston (Boston, MA, USA)
138. Ahmad Masri (Portland, OR, USA)
139. Felipe Martinez (Cordoba, ARG),
140. Sheila Martins (Porto Alegre, BR)
141. Kaitlin Mayne (Glasgow, UK)
142. Alexandre Mebazaa (Paris, FRA)
143. Mandeep Mehra (Boston, MA, USA)
144. Roxana Mehran (New York, NY, USA)
145. Tom Melvin (Dublin, IRE)
146. Robert Mentz (Durham, USA)
147. Javier Morales (East Hills, NY, USA)
148. Paul Muntner (Birmingham, AL, USA)
149. Patricia Musolino (Boston, MA, USA)
150. Peder Myhre (Oslo, NO)
151. Ann Marie Navar (Dallas, TX, USA)
152. Brendon L Neuen (Sydney, AUS)
153. Mpiko Ntsekhe (Cape Town, ZAF)
154. Ntobeko Ntusi (Cape Town, ZAF)
155. Chris O'Connor (Falls Church, VA, USA)
156. Michelle O'Donoghue (Boston, MA, USA)
157. Iacopo Olivotto (Florence, ITA)
158. Oyere Onuma (Boston, MA, USA)
159. Maria A Pabon (Boston, MA, USA)
160. Milton Packer (Dallas, TX, USA)
161. Neha Pagidipati (Durham, NC, USA)
162. Ambarish Pandey (Dallas, TX, USA)
163. Victoria Parikh (Stanford, CA, USA)
164. Abdul Parwani (Berlin, GER)
165. Rod Passman (Chicago, IL, USA)
166. Alexander Peikert (Graz, AUT)
167. Aline Pedroso (New Haven, CT, USA)
168. Emerson Perin (Houston, TX, USA)
169. Mark Petrie (Glasgow, UK)
170. Jonathan Piccini (Durham, NC, USA)
171. Bertram Pitt (Ann Arbor, MI, USA)
172. Stuart Pocock (London, UK)
173. Sumanth Prabhu (St. Louis, MO, USA)
174. Iona Preston (Boston, MA, USA)
175. Silvia Priori (Pavia, ITA)
176. Janani Rangaswami (Washington, DC, USA)
177. Paul Ridker (Boston, MA, USA)
178. Andreas Rillig (Hamburg, GER)
179. Frank Rockhold (Durham, NC, USA)
180. Anthony Rodgers (Sydney, AUS)
181. Toby Rogers (Bethesda, MD, USA)
182. Robert S. Rosenson (New York, NY, USA)
183. Xavier Rossello (Madrid, ESP)
184. Peter Rossing (Copenhague, DEN)
185. Christian Ruff (Boston, MA, USA)
186. Donna Ryan (Baton Rouge, USA)
187. Marc Sabatine (Boston, MA, USA)
188. Sara Saberi (Ann Arbor, MI, USA)
189. Rajan Saggar (San Francisco, CA, USA)

190. Sandeep Sahay (Houston, TX, USA)
191. Yasuhiko Sakata (Osaka, JPN)
192. Clara Saldarriaga (Medellín, COL)
193. Naveed Sattar (Glasgow, UK)
194. Harald Schmidt (Philadelphia, PA, USA)
195. Ruth Frikke Schmidt (Copenhagen, DEN)
196. Gregory Schwartz (Denver, CO, USA)
197. Bruno Scheller (Homburg, GER)
198. Michele Senni (Bergamo, ITA)
199. Abhinav Sharma (Montreal, CAN)
200. Leslee Shaw New York, NY, USA)
201. Tabassome Simon (Paris, FRA)
202. Gérald Simonneau (Paris, FRA)
203. Olivier Sitbon (Paris, FRA)
204. Scott Solomon (Boston, MA, USA)
205. John Spertus (Kansas City, MO, USA)
206. Madeline Sterling (New York, NY, USA)
207. Gregg Stone (New York, NY, USA)
208. Varun Sundaram (Cleveland, OH, USA)
209. Stefano Taddei (Pisa, ITA),
210. Pam Taub (San Diego, CA, USA)
211. Ryan Tedford (Charleston, USA)
212. Jeffrey Testani (New Haven, CT, USA)
213. Thomas Thum (Hannover, GER)
214. Jan Tijssen (Amsterdam, NED)
215. Lale Tokgözoğlu (Ankara, TR)
216. Daniela Tomasoni (Brescia, ITA)
217. Rhian Touyz (Montreal, CAN)
218. Jasper Tromp (Singapore, SIN)
219. Mintu Turakhia (Stanford, CA, USA)
220. Katherine Tuttle (Spokane, WA, USA)
221. James E Udelson (Boston, MA, USA)
222. Jean-Luc Vachiéry (Brussels, BEL)
223. Muthiah Vaduganathan (Boston, MA, USA)
224. Harriette Van Spall (Hamilton, CAN)
225. Orly Vardeny (Minneapolis,MN, USA)
226. Frances Varian (Sheffield, UK)
227. Corey Ventetuolo (Providence, RI, USA)
228. Ron Waksman (Washington, DC, USA)
229. Nelson Wang (Boston, MA, USA)
230. Christoph Wanner (Wurzburg, GER)
231. Karol Watson (Los Angeles, CA, USA)
232. Jason Weatherald (Edmonton, CA)
233. Michael Weber (New York, NY, USA)
234. Dirk Westermann (Freiburg, GER)
235. Bryan Williams (London, UK)
236. Anders Berg Wulff (Copenhagen, DEN)
237. Lijing Yan (Kunshan, CHN)
238. Clyde Yancy (Chicago, IL, USA)
239. Robert Yeh (Boston, MA, USA)
240. Faiez Zannad (Paris, FRA)
241. Michael Zile (Charleston, SC, USA)
242. Peter-Paul Zwetsloot (Rotterdam, NED)

JOURNAL/MEDIA

243. Folkert Asselbergs (EHJ, NED)
244. Michael Basson (Nature Medicine, USA)
245. Kirsten Bibbins-Domingo (JAMA, USA)
246. Nico Bruining (EHJ Digital Health, NED)
247. Gregory Curfman (JAMA, USA)
248. Flavia Geraldes (The Lancet, UK)
249. Rohan Khera (JAMA, USA)
250. Harlan Krumholz (JACC, USA)
251. Jane Leopold (NEJM, USA)
252. Evangelos Oikonomou (EHJ, USA)
253. Jennifer Sargent (Metabologia, USA)
254. Helena Wang (Lancet, CHN),
255. Chloe Wilson (The Lancet, UK)
256. Ron Winslow (Ex Wall Street Journal, USA)

INDUSTRY

257. George Adams (Cordis, USA)
258. Philip Adamson (CVRx, USA)
259. Eric Adler (Lexeo Therapeutics, USA)
260. Nataliya Agafonova (Longeveron, USA)
261. Bassil Akra (Akra Team, GER)
262. David Albert (AliveCor, USA)
263. Faraz Ali (Tenaya, USA)
264. Greg Aubert (LexeoTx, USA)
265. Pernille Auerbach (NovoNordisk, DEN)
266. Sameer Bansilal (Alnylam, USA)
267. Robert Beardsley (Cirrus Therapeutic, USA)
268. Vince Benn (KBP, USA)
269. Scott Berry (Berry Consultants, USA)
270. Angie Bethel (Lilly, USA)
271. Robert Blaustein (Edgewise, USA)
272. Juuso Blomster (Cardiosignal, USA)
273. Karine Bourgeois (4Teen4, GER)
274. Maria Borentain (Bayer, GER)
275. Sandeep Brar (Medtronic, USA)
276. Meike Brinker (Bayer, GER)
277. Gabriel Brooks (Solid Biosenses, USA)
278. Martina Brueckmann (Boehringer, GER)
279. David Bühlmann (Roche, USA)
280. Mathijs Bunck (Eli Lilly, USA)
281. Rafael Cavalcante (Boston Scientific, USA)
282. Roberta Chapman (J&J MedTech, USA)
283. William Chutkow (FNIH, Novartis, USA)
284. Martine Clozel (Idorsia, CH)
285. Allison Connolly (Abbott, USA)

286. Stefano Corda (Bayer, GER)
287. Bjorn Dahlof (Cereno, SWE)
288. Matt Daniels (NovoNordisk, DEN)
289. Alex M. DePaoli (Rona Therapeutics, USA)
290. Victoria DiBiaso (Sanofi, FRA)
291. Punag Divanji (Cytokinetics, USA)
292. Nancy Dreyer (Dreyer LLC, USA)
293. Rich Dujmovic (Boston Scientific, USA)
294. Janssen Ellen (J&J, USA)
295. Anders Gaarsdal Holst (Acesion, DEN)
296. Anders Gabrielsen (Ribocure, CHN)
297. Tomasz Gasior (Boehringer, GER)
298. Samvel Gasparyan (AstraZeneca, USA)
299. Jyothis George (NodThera, USA)
300. Claudio Gimpelewicz (Novartis, SWI)
301. Nicholas Giovannone (Regeneron, USA)
302. Ruchira Glaser (Novartis, SWI)
303. Christine Gouillard (US2AI, SIN)
304. Craig Granowitz (Lexicon, USA)
305. Dmitry Gryaznov (Viatris, USA)
306. Nicole Haratani (Supira Medical, USA)
307. Steve Heitner (Cytokinetics, USA)
308. Jennifer Hellawell (Arrowhead, USA)
309. Rob Hemmings (Consilium,
310. Salmonson and Hemmings, UK)
311. Graeme Hickey (Medtronic, USA)
312. Robert Hillman (Celecor, USA)
313. Udo Hoffmann (Cleerly, USA)
314. Brad Horst (Boston Scientific, USA)
315. Kees Hovingh (Novo Nordisk, DEN)
316. Christian Hunter (Abbott, USA)
317. Thomas Idorn (Novo Nordisk, DEN)
318. Silviu Itescu (Mesoblast Ltd, USA)
319. Vinny Jindal (Secretome Therapeutics, USA)
320. Rebecca Juliano (Marea, USA)
321. Odd Erik Johansen (Roche, USA)
322. Per Johanson (Astrazeneca, SWE)
323. Takehiko Kaneko, (Heartseed, JPN)
324. Navin Kapur (JnJ, USA)
325. Sekar Kathiresan (Verve Therapeutics, USA)
326. Filip Knop (NovoNordisk, DEN)
327. Lisette Koeneman (Lilly, USA)
328. Mikhail Kosiborod (Astrazeneca, USA)
329. Stuart Kupfer (Cytokinetics, USA)
330. Francesca Lawson (Corteria, USA)
331. Anissa Lamarque (Olink, SWE)
332. Anastasia Lesogor (Novartis, USA)
333. Liping Liu (HighTide, CN)
334. Victor Lopes (Trialmed, Thermofisher, USA)
335. Steven Lubitz (Novartis, USA)
336. Ciaran McMullan (Merck, USA)
337. Maulik Majmudar (Biofourmis, USA)
338. Mark Mallon (George Medicines, UK)
339. Judy Meadows (Regeneron, USA)
340. Christian Medom Madsen (NovoNordisk, DEN)
341. Ofri Mosenzon (Regeneron, USA)
342. Gillian Murtagh (Bridgebio, USA)
343. Maureen O'Connor (35Pharma, USA)
344. Christopher O'Donnell (Novartis, USA)
345. Mahesh Patel (Merck, USA)
346. Nirav Patel (Medtronic, USA)
347. Marc Penn (Foment Bio, USA)
348. Shira Perl (Astrazeneca, USA)
349. Adam Phillips (Apple, USA)
350. Sam Popa (United Therapeutics, USA)
351. Juergen Prochaska (Boehringer Ingelheim, GER)
352. Franck Rahaghi (United Therapeutics, USA)
353. Ishu Rao (Impulse Dynamics, USA)
354. Lothar Roessig (AskBio/bayer, GER)
355. Campbell Rogers (Heartflow, USA)
356. David Rosenbaum (Astrazeneca, USA)
357. Harry Rowland (Endotronix Edwards, USA)
358. Giacomo Ruotolo (Lilly, USA)
359. Carlos Sanmarco (Pulmovant, USA)
360. Patrick Schloemer (Bayer, GER)
361. Christoph Schumacher (Damian Pharma, CH)
362. Maria Sejersten Ripa (NovoNordisk, DEN)
363. Marvin Sinsakul (AstraZeneca, USA)
364. Robin Shaw (TikkunLev Therapeutics, USA)
365. Jordan Shin (Haya Therapeutics, USA)
366. Kenneth Stein (Boston Scientific, USA)
367. Bergur Stefansson (Roche, USA)
368. Dominic Steubl (Boehringer, GER)
369. Norman Stockbridge (S & S Consulting, USA)
370. Elena Startseva (Boehringer, GER)
371. Mikhail Sumin (Boehringer, GER),
372. Megan Sutton (Everygene, USA)
373. Filip Surmont (HighTide, CHN)
374. Maturin Tchoumi (Roche, TUN)
375. Pamela Tenaerts (Medable, Inc, USA)
376. Maxime Touzot (Owkin, FRA)
377. Pierluigi Tricoci (Lilly, USA)
378. Sam Tsimikas (Ionis, USA)
379. Martin Unverdorben (Daiichi Sankyo, JAP)
380. Alessia Urbinati (Merck, USA)
381. Scott Vafai (Verve Therapeutics, USA)
382. Eugene Wang (Help Tx, CN)
383. John Whang (BridgeBio, USA)
384. Kael Wherry (Medtronic, USA)
385. Janet Wittes (Wittes LLC, USA)
386. Jie Zeng (Rona Therapeutics, USA)

REGULATORY

387. Stephen Browning (FDA, USA)
388. Alison Cave (MHRA, UK)
389. Jennifer Clark (FDA, USA)
390. Eileen Craig (FDA, USA)
391. Mark Da Costa (TUV Sud, IRE)
392. Aneesh Deoras (FDA. USA)
393. Milou-Daniel Drici (ANSM, FRA)
394. Mona Fiuzat (FDA, USA)
395. Charu Gandotra (FDA, USA)
396. Lydia Glaw (FDA, USA)
397. Austin Hu (FDA, USA)
398. Rekha Kambhampati (FDA, USA)
399. Rani Khatib (NHS England, UK)
400. Clara Kim (FDA, USA)
401. Audrey Dindji Kodia (AIRP, CI)
402. William Koh (FDA, USA)
403. Maciej Kostrubiec (EMA, POL)
404. Marco Marchetti (AGENAS, ITA)
405. Mauro Moscucci (FDA, USA)
406. Rachel Neubrander (FDA, USA)
407. Radoslaw Parma (EU, Katowice, POL)
408. Gabriella Passacquale (EMA, ITA)
409. Ileana Piña (FDA, USA)
410. Jordan Pomeroy (FDA, USA)
411. Vinay Prasad (FDA, USA)
412. Mitch Psotka (FDA, USA)
413. Sindy Pulgarin (DMPB, CO),
414. Sam Raben (FDA, USA)
415. Mark Rothmann (FDA, USA)
416. Anindita Saha (FDA, USA)
417. Fortunate Senatore (FDA, USA)
418. Bindi Shah (FDA, USA)
419. John Sharretts (FDA, USA)
420. Raymond Soccio (FDA, USA)
421. Michelle Tarver (FDA, USA
422. Aliza Thompson (FDA, USA)
423. Bernard Vasseur (FDA, USA)
424. Evan Walrath (FDA, USA)
425. Changfu Wu (FDA, USA)
426. Erica Young (FDA, USA)
427. Bram Zuckerman (FDA, USA)

NIH / PUBLIC HEALTH INSTITUTIONS

428. Patrice Desvigne-Nickens (NHLBI, USA)
429. David Goff (NIH, USA)
430. Ahmed Hasan (NHLBI, USA)
431. Cara Lewis (NHLBI, USA)
432. George Mensah (NHLBI,USA)
433. Veronique Roger (NIH, USA)
434. Yves Rosenberg (NHLBI, USA)
435. Lei Xiao (NIH/NHLBI-USA)

PATIENTS/PATIENTS REPRESENTATIVES

436. Alessia Argiro (Florence, ITA)
437. Jacqueline Alikhaani (Los Angeles, USA)
438. Sadegh Alikhaani (Los Angeles, USA)
439. Marc Bains (HeartLife Foundation, CAN)
440. Colleen Brunetti (Pulmonary Hypertension Association, USA)
441. Jillianne Code (HeartLife, CAN)
442. Robin Gage (HFSA, USA)
443. Patrick Gee (iAdvocate, USA)
444. Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)
445. Mellanie True Hills (Stop AFib, USA)
446. Corinne Hudson (Pumping Marvellous Foundation, UK)
447. Trudie Lobban (Arrhythmia Alliance, UK)
448. Isabelle Lousada (Amyloidosis Research Consortium, USA)
449. Steve Macari (Poitiers, FRA)
450. Greg Merritt (Patient Is Partner, Brighton, USA)
451. Caius Mersa (Romanian Heart Foundation, RO)
452. Rhonda Monroe (Baltimore, MD, USA)
453. Scott Reavis (National Pancreas Foundation, USA)
454. Juddson Rupp (Charlotte, NC, USA)
455. Lisa Salberg (HCMA, USA)
456. George Sands (Sands Collaborative, USA)
457. Michelle Watts (FH Europe Foundation, USA)

PAYER / ECONOMISTS

458. Burçak Aydın (Bruxelles, BEL)
459. Steve Farmer (ex-CMS, USA)

MONDAY, DECEMBER 8TH

COFFEE BREAKS – LUNCH – FOOD AND BEVERAGE - MODERATED POSTER SPACE AT BALLROOM

PALM COURT

8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:30	14:30 - 16:30	16:30 - 17:00	17:00 - 19:30
POLYPILL PART 1 view details >>		POLYPILL PART 2 view details >>		STAT MASTER CLASS 3 view details >>		REAL WORD EVIDENCE view details >>

EAST

8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:30	14:30 - 16:30	16:30 - 17:00	17:00 - 19:30
AFIB BURDEN view details >>		AFib OUTCOMES IN TRIALS view details >>		CELL THERAPY view details >>		WEARABLES IN TRIALS view details >>

STATE

8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:30	14:30 - 16:30	16:30 - 17:00	17:00 - 19:30
STAT MASTER CLASS 1 view details >>		STAT MASTER CLASS 2 view details >>		ALDO TARGETS TRIALS view details >>		GUIDELINES view details >>

CHINESE

8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:30	14:30 - 16:30	16:30 - 17:00	17:00 - 19:30
PAH 1 view details >>		PAH 2 view details >>				PATIENT INSIGHTS INTO CTs view details >>

BALLROOM

14:30 - 16:30	16:30 - 17:00	17:00 - 19:30
EVIDENCE GENERATION FOR AI APPS, Part1 view details >>		EVIDENCE GENERATION FOR AI APPS, Part 2 view details >>

14.00 – 14.30: KEYNOTE LECTURE BY VALENTIN FUSTER

19:30 - 21:00: WALK TO THE HEART HOUSE, ACC RECEPTION

TUESDAY, DECEMBER 9TH

COFFEE BREAKS – LUNCH – FOOD AND BEVERAGE - MODERATED POSTER SPACE AT BALLROOM

PALM COURT

7:00 - 8:30	8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
CVCT APAC view details >>	LB--CVCT 1 view details >>		AI MASTER CLASS view details >>		iCVCT MECHANICAL CIRCULATORY SUPPORT view details >>		iCVCT DRUG COATED ELUTING BALLOONS view details

EAST

7:00 - 8:30	8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
CVCT LATAM view details >>	LB--CVCT 4 view details >>		POST MI view details >>		REPORTING THE RESULTS OF CLINICAL TRIALS view details >>		PREVENTION TRIALS view details

STATE

8:15 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
LB--CVCT 2 view details >>		HYPERTROPHIC CARDIOMYOPA-THIES view details >>		AMYLOIDOSIS view details >>		THE FUTURE OF CKD TRIALS view details >>

CHINESE

7:00 - 8:30	8:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
CVCT Africa ME view details >>	LB--CVCT 3 view details >>		BREAKTHROUGH DEVICES US vs EU view details >>		MENDELIAN RANDOMISATION FOR CT view details >>		GENE THERAPY BASICS view details

19:30-21:00
RECEPTION AT AMBASSADOR RESIDENCE

WEDNESDAY, DECEMBER 10TH

COFFEE BREAKS – LUNCH – FOOD AND BEVERAGE - MODERATED POSTER SPACE AT BALLROOM

PALM COURT

7:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
OBESITY INCRETINS MUSCLE HEALTH view details >>		OBESITY CKM view details >>		HF DEVICES view details >>		HFREF view details >>

EAST

7:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
CHOLESTEROL view details >>		LIPOPROTEIN(A) view details >>		TRIGLYCERIDE view details >>		iCVCT THROMBOSIS TRIALS view details >>

STATE

7:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
HYPERTENSION view details >>		AI FOR CV TRIALS view details >>		iCVCT STRUCTURAL HEART INTERVENTIONS view details >>		CHRONIC KIDNEY DISEASE view details >>

CHINESE

7:30 - 10:30	10:30 - 11:00	11:00 - 13:00	13:00 - 14:00	14:00 - 16:00	16:00 - 16:30	16:30 - 18:30
GENE THERAPY TRIAL DESIGN view details >>		ADIPOKINE HYPOTHESIS FOR HFPEF view details >>		IMPLEMENTATION SCIENE GLOBAL REGULATORY SUMMIT view details >>		BIOLOGICS view details >>

BALLROOM

7:30 - 10:30
GCRFF PLATFORM TRIALS view details >>

Palm court
Monday, December 8, 2025
08:30 -10:30

FIXED DOSE COMBINATION – POLYPILL TRIALS
Part 1: Clinical Trials Update and Expanding the Polypill Concept Across Therapeutic Areas
Chairpersons: Oyere Onuma (Boston, MA, USA) & Valentin Fuster (New York, NY, USA)

CV Event Reduction with CV Polypills – A Global Perspective
Philip Joseph (Hamilton, CAN)

Aspirin-statin-BP polypills and the Ferrer CNIC experience
Valentin Fuster (New York, NY, USA)

Polypills for prevention of stroke – experience from Brazil
Sheila Martins (Porto Alegre, BR)

The Promise of Heart Failure Polypills: From Concept to Clinical Reality
Anubha Agarwal (St Louis, MI, USA)

Polypill For Heart Failure With Reduced Ejection Fraction: The POLY-HF TRIAL
Ambarish Pandey (Dallas, TX, USA)

Polypills in Cardio-Renal-Metabolic Syndromes
Hiddo Heerspink (Groningen, NED)

Hypertension polypills
Nelson Wang (Boston, MA, USA)

Four component QUADRO pill
Stefano Taddei (Pisa, ITA)

TRIDENT trial results
Asita De Silva (Kelaniya, LK)

The CVCT Multi-Stakeholder Think Tank Debate
FIXED DOSE COMBINATION – POLYPILL TRIALS
Part 1: Common And Distinct Features Across Therapeutic Areas.
New drug classes, and future clinical priorities.
Chairpersons Oyere Onuma (Boston, MA, USA) & Valentin Fuster (New York, NY, USA)

Panelists: Anubha Agarwal (St Louis, MI, USA), Ankeet Bhatt (Kaiser Permanente, USA), Asita De Silva (Kelaniya, LK), Valentin Fuster (New York, NY), Habib Gamra (Sousse, TN), Mark Huffman (St Louis, MI, USA), Philip Joseph (Hamilton, CAN), Mark Mallon (George Medicines, UK), Sheila Martins (Porto Alegre, BR), Oyere Onuma (Boston, MA, USA), Ambarish Pandey (Dallas, TX, USA), Hiddo Heerspink (Groningen, NED), Anthony Rodgers (Sydney, AUS), Norman Stockbridge (S & S Consulting, USA), Stefano Taddei (Pisa, IT), Nelson Wang (Boston, MA, USA)

Palm court
Monday, December 8, 2024
11:00 -13:00

FIXED DOSE COMBINATION – POLYPILL TRIALS
Part 2: Regulatory, reimbursement and access
Chairpersons: Rhonda Monroe (BOOST-Better Outcomes Optimal Scientific Therapies, Charlotte, NC, USA) & Anthony Rodgers (Sydney, AUS)

Fixed-Dose Combinations. Demonstrating Novel Claims
Norman Stockbridge (S & S Consulting, USA)

Statistical Viewpoint. Partial Factorial and Other Novel Trial Designs Options.
Janet Wittes (Wittes LLC, USA)

What Implementation Science Has to Offer to Inform Polypill Scale Up
Mark Huffman (St Louis, MI, USA)

Real World Evidence and HEOR Evaluation of Polypills
Ankeet Bhatt (Kaiser, CV Research, USA).

Industry viewpoints
Making Polypills Profitable: Industry Challenges and Commercial Opportunities
Mark Mallon (George Medicines, UK), Martin Unverdorben (Daiichi Sankyo, JAP)

World Heart Federation roadmap on single pill combination therapies
Habib Gamra (Sousse, TUN)

Primary care viewpoints
Naresh Kanumili (Manchester, UK), Javier Morales (East Hills, NY, USA)

Patient's viewpoint
The Patient Voice: Living with Chronic Disease and the Promise of Polypills
Rhonda Monroe (BOOST-Better Outcomes Optimal Scientific Therapies, NC, USA)

The CVCT Multi-Stakeholder Think Tank Debate

FIXED DOSE COMBINATION – POLYPILL TRIALS
Part 2: Charting the Course for Polypill Adoption
Chairpersons: Rhonda Monroe (BOOST-Better Outcomes Optimal Scientific Therapies, NC, USA) & Anthony Rodgers (Sydney, AUS)

Panelists: Anubha Agarwal (St Louis, MI, USA), Ankeet Bhatt (Kaiser, CV Research, USA), Asita De Silva (Kelaniya, LK), Valentin Fuster (New York, NY, USA), Habib Gamra (Sousse, TN), Hiddo Heerspink (Groningen, NED), Mark Huffman (St Louis, MI, USA), Naresh Kanumili (Manchester, UK), Mark Mallon (George Medicines, UK), Rhonda Monroe (BOOST-Better Outcomes Optimal Scientific Therapies, NC, USA), Javier Morales (East Hills, NY, USA), Oyere Onuma (Boston, MA, USA), Ambarish Pandey (Dallas, TX, USA), Anthony Rodgers (Sydney, AUS), Juddson Rupp (Charlotte, NC, USA), Norman Stockbridge (S & S Consulting, USA), Stefano Taddei (Pisa, ITA), Martin Unverdorben (Daiichi Sankyo, JAP), Janet Wittes (Wittes LLC, USA)

Monday, December 8, 2025
14:00 - 14:30

PLENARY KEYNOTE LECTURE

Evolving New Imaging for Primary and Primordial Prevention - PESA, PRECAD, REACT, PESA-BRAIN & SHE STUDIES

VALENTIN FUSTER
Mount Sinai Fuster Heart Hospital & CNIC

Palm court
Monday, December 8, 2025
14:30 -16:30

CVCT MASTERCLASS - 3
Chairpersons: Jan Tijssen (Amsterdam, NED) & Gregg Stone (New York, NY, USA)

Estimands
Rob Hemmings (Consilium, Salmonson and Hemmings, UK)
Discussant: Mark Rothmann (FDA, USA)

What is an estimand?
Why is the concept useful to trialists and regulators?
How to incorporate estimands into trial protocols and SAPs.
Their value in defining analysis strategies when intercurrent events arise.

Discussion

Alternative to ITT analysis
Jan Tijssen (Amsterdam, NED)
Discussant: Stuart Pocock (London, UK)

Analysis by intention to treat is mandatory for most pivotal trials.
When can alternatives (modified ITT, per protocol, as treated) be of value?
Precise pre-definition is key to success.
Modern analysis techniques (e.g., instrumental variables) will be presented.

Discussion

Bayesian methods
Scott Berry (Berry Consultants, USA)
Discussant : Jennifer Clark (FDA, USA)

Bayesian statistical approaches for design, conduct, and reporting of major trials.
How can we enhance its understanding to the broad trialist community
What are the merits (and problems) In a Bayesian approach.
How to demystify their complexities.

Discussion

Palm court
Monday, December 8, 2025
17:00 -19:30

WHAT AND WHEN REAL WORLD DATA MAY COMPLEMENT TRIAL BASED EVIDENCE
Chairpersons: Nancy Dreyer (Dreyer LLC, USA) & Adrian Hernandez (Durham, NC, USA)

From Joint Scientific Consultation to Joint Clinical Assessment: Leveraging RWD to Strengthen Regulatory–HTA Synergies
Marco Marchetti (AGENAS, ITA)

Perspectives on Fit-For-Purpose RWD for Regulatory and Coverage Decision Making
Rani Khatib (NHS, UK)

How Advances in RWE Quality and Reliability Strengthen Decision-Making
Alison Cave (MHRA, UK)

Primary care physician viewpoint
Javier Morales (East Hills, NY, USA)

Propensity Matched Arm, External Controls and Natural History Studies
Jennifer Christian (Target RWE, USA)

What Happens if Safety or Effectiveness Signals in Real World and Clinical Trial are Divergent?
Adrian Hernandez (Durham, NC, USA)

RWD for Device development.
Harry Rowland (Endotronix Edwards, USA), Graeme Hickey (Medtronic, USA)

Real case examples of designing fit for purpose RWE for Device therapy and Transitional Coverage of Emerging Technologies (TCET)

Implantable Pulmonary Artery Pressure Sensors
Allison Connolly (Abbott, USA)

Cardiac Contractility Modulation
Ishu Rao (Impulse Dynamics, USA)

Renal Denervation
Kael Wherry (Medtronic, USA)

Transcatheter tricuspid valve replacement/Tricuspid Transcatheter edge-to-edge repair
Mayra Guerrero (Rochester, MN, USA)

Regulatory viewpoint
Clara Kim (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

WHEN REAL WORLD DATA MAY COMPLIMENT TRIAL BASED EVIDENCE?
Chairpersons: Nancy Dreyer (Dreyer LLC, USA) & Adrian Hernandez (Durham, NC, USA)

Panelists: Alison Cave (MHRA, UK), Jennifer Christian (Target RWE, USA), Allison Connolly (Abbott, USA), Zainab Dakhil (Baghdad, IQ), Nancy Dreyer (Dreyer LLC), Mariam Elmegaard (Herlev, DEN), Enrico Ferro (Boston, MA, USA), Mayra Guerrero (Rochester, MN, USA), Adrian Hernandez (Durham, DC, USA), Graeme Hickey (Medtronic, USA), Rani Khatib (NHS England, UK), Clara Kim (FDA,USA), Darae Ko (Boston, USA), Marco Marchetti (AGENAS, ITA), Javier Morales (East Hills, NY, USA), Ishu Rao (Impulse Dynamics, USA), Harry Rowland (Endotronix Edwards, USA), Kael Wherry (Medtronic, USA)

East
Monday, December 8, 2025
08:30 -10:30

ATRIAL FIBRILLATION BURDEN: AN APPROVABLE INDICATION?
Chairpersons: Mina Chung (Cleveland, OH, USA) & Paulus Kirchhof (Hamburg, GER)

Arrhythmia Management Via Consumer Electronics: Lessons from Apple Heart
Mike Gibson (Boston, MA, USA)

The Ongoing Paradigm Shift: AF Burden-Reducing Interventions for Outcome Reduction
Jonathan Piccini (Durham, NC, USA)

AF Burden After AF Ablation (OPTION, CIRCA-DOSE, OCEAN)
Jason Andrade (Vancouver, CAN)

From EAST STROKE to LAAOS IV: The Spectrum of Enhanced Stroke Prevention in Patients With AF
Valeria Caso (Perugia, ITA)

Low-Burden Atrial Fibrillation: Known Unknowns and Clinical Challenges for Stroke Prevention.
William McIntyre (Hamilton, CAN)

Industry Viewpoints
Steve Lubitz (Novartis, USA), Nirav Patel (Medtronic, USA), Kenneth Stein (Boston Scientific, USA)

Regulatory Viewpoint
Bindi Shah (FDA, USA)

Payer's Viewpoint: What Trial Endpoints Will Influence Future Payment Approaches?
Steve Farmer (ex-CMS, USA)

The View of a Professional Organisation
Mina Chung (Cleveland, OH, USA)

Patients' Viewpoint: What Matters to Patients?
Melanie True Hills (Stop AFib, USA)

The CVCT Multi-Stakeholder Think Tank Debate
AF BURDEN AND OTHER TRIAL ENDPOINT CONSIDERATIONS. HOW TO CONVINCE THE RESPECTIVE STAKEHOLDERS?
Chairpersons: Mina Chung (Cleveland, OH, USA) & Paulus Kirchhof (Hamburg, GER)

Panelists : Jason Andrade (Vancouver, CAN), Valeria Caso (Perugia, ITA), Mina Chung (Cleveland, OH, USA), Steve Farmer (ex-CMS, USA), Paulus Kirchhof (Hamburg, GER), Darae Ko (Boston, USA), Steve Lubitz (Novartis, USA), William McIntyre (Hamilton, CAN), Nirav Patel (Medtronic, USA),Jonathan Piccini (Durham, NC, USA), Bindi Shah (FDA, USA), Kenneth Stein (Boston Scientific, USA), Melanie True Hills (Stop AFib, USA), Trudie Lobban (Arrhythmia Alliance, UK)

East
Monday, December 8, 2025
11:00 -13:00

SHOULD CARDIOVASCULAR TRIALS REMAIN BLIND TO THE OUTCOME ATRIAL FIBRILLATION?
Chairpersons: Christine Albert (Los Angeles, CA, USA) & Tina Baykaner (Stanford, CA, USA)

Intersection of AF and HFpEF Diagnostic Criteria: Impact on Trial Inclusion, Interpretation and Future Directions
Barry Borlaug (Rochester, MN, USA)

Tackling HFpEF via AF Ablation: The Innovative CABAHFPEF Collaboration
Abdul Parwani (Berlin, GER)

AF ablation in HF trial
Marc Petrie (Glasgow, UK)

AF Ablation in Heart Failure: Essential Treatment or Questionable Benefit? We need adequately powered trials.
Milton Packer (Dallas, TX, USA)

The relevance of quantifying AF in Cardiovascular Trials
Andreas Rillig (Hamburg, GER)

Are Annual ECGs Still Sufficient in 2025?
Unmasking the AF Signal in SGLT2i and GLP-1RAs Trials
Varun Sundaram (Cleveland, OH, USA)

Pragmatic Monitoring for AF: How Much is Enough?
Rod Passman (Chicago, IL, USA)

Regulatory Viewpoints: The Importance of AF outcomes for CV Drugs Approval.
Charu Gandotra (FDA, USA)

Industry viewpoint
Anders Gaarsdal Holst (Acesion, DEN)

NIH viewpoint
Patrice Desvigne-Nickens (NHLBI, USA)

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

The CVCT Multi-Stakeholder Think Tank Debate

SHOULD CARDIOVASCULAR TRIALS REMAIN BLIND TO THE OUTCOME ATRIAL FIBRILLATION?
Chairpersons: Christine Albert (Los Angeles, CA, USA) & Tina Baykaner (Stanford, CA, USA)

Panelists : Christine Albert (Los Angeles, CA, USA), Tina Baykaner (Stanford, CA, USA), Barry Borlaug (Rochester, MN, USA), Patrice Desvigne-Nickens (NHLBI, USA), Charu Gandotra (FDA,USA), Christopher Granger (Durham, NC, USA), Anders Gaarsdal Holst (Acesion, DEN), Paulus Kirchhof (Hamburg, GER), Darae Ko (Boston, USA), Trudie Lobban (Arrhythmia Alliance, UK), Milton Packer (Dallas, TX, USA), Abdul Parwani (Berlin, GER), Rod Passman (Chicago, IL, USA), Marc Petrie (Glasgow, UK), Andreas Rillig (Hamburg, GER), Varun Sundaram (Cleveland, OH, USA), Melanie True Hills (Stop AFib, USA)

East
Monday, December 8, 2025
14:30 -16:30

CELL THERAPY HEART FAILURE TRIALS
CELLS, DELIVERY, AND DISEASE-SPECIFIC STRATEGIES
Chairpersons: Philippe Menasché (Paris, FRA) & Emerson Perin (Houston, USA)

Is Cell Delivery Route Important? (5 min each)

Transendocardial Delivery of Stem Cells: Insights from Danish Phase II And SCIENCE Trials
Jens Kastrup (Copenhagen, DEN)

Status Of Catheter-Based Cell/Extracellular Vesicle Delivery.
Stefan Janssens (Leuven, BE)

Intravenous Delivery of Cells/Cell Products: The Magic Bullet?
Joshua Hare (Miami, FL, USA)

Systemic Delivery of Cell Therapy: The Intravenous Approach in the HOPE Trials
Eduardo Marban (Los Angeles, CA, USA)

What Type of Cells?

Mesenchymal Stem Cell Therapy for Dilated Cardiomyopathy: Lessons from POSEIDON and the PATH AHEAD
Joshua Hare (Miami, FL, USA)

Mesenchymal Stromal Cells or IPSC-Derived Cardiomyocytes for in Heart Failure from Ischemic Heart Disease? Clinical Evidence from the DREAM-HF Trial
Emerson Perin (Houston, TX, USA)

Do We Believe in Cell Extracts - 'Secretome' Rather Than Cell?
Vinny Jindal (Secretome Therapeutics, USA)

15.10-15.20
Role of the Immune System for Shaping the Future of Cell/Exosome Therapy
Sumanth Prabhu (St. Louis, MO, USA)

Design, and Safety and Efficacy Endpoints Related Issues.

Industry Viewpoints
Nataliya Agafonova (Longeveron, USA), Silviu Itescu (Mesoblast Ltd, USA), Marc Penn (Foment Bio, USA), Takehiko Kaneko (Heartseed, JPN), Jiaxian Wang (Help Tx, CN)

The essentials for think tank discussion.
Philippe Menasché (Paris, FRA)

The CVCT Multi-Stakeholder Think Tank Debate
HOW TO STREAMLINE CELL THERAPY INNOVATION, NOT COMPROMISING THE LEVEL OF EVIDENCE
Chairpersons: Philippe Menasché (Paris, FRA) & Emerson Perin (Houston, TX, USA)

Panelists : Nataliya Agafonova (Longeveron, USA), Matt Daniels (NovoNordisk, DEN), Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), Silviu Itescu (Mesoblast Ltd, USA), Stefan Janssens (Leuven, BE), Vinny Jindal (Secretome Therapeutics, USA), Takehiko Kaneko (Heartseed, JPN), Jens Kastrup (Copenhage, DEN), Eduardo Marban (Los Angeles, CA, USA), Philippe Menasché (Paris, FRA), Caius Mersa (Romanian Heart Foundation, RO), Marc Penn (Foment Bio, USA), Emerson Perin (Houston, TX, USA), Sumanth Prabhu (St. Louis, MO, USA), Jiaxian Wang (Help Tx, CN)

East
Monday, December 8, 2025
17:00 -19:30

WEARABLES FOR CV TRIALS
Chairperson: Abhinav Sharma (Montreal, CAN) & Mike Gibson (Boston, USA)

Remote digital monitoring to accelerate obtaining outcomes in clinical trials
Greg Marcus (San Francisco, CA, USA)

Can we trust commercial devices to conduct fully remote clinical trials?
John Spertus (Kansas City, MO, USA)

Continuous monitoring in the part of remote clinical trials.
Opportunities and challenges.
Jessilyn Dunn (Durham, NC, USA)

Consumer vs. medical grade vs. approved for use in clinical trials
Christopher Granger (Durham, NC, USA)

Framework for Analytical Validation of Digital Health-Based Actigraphy and Signal Measures in Heart Failure Trials: VALIDATE-HF Program
Abhinav Sharma (Montreal, CAN)

Wearable devices in clinical trials. An enhancer? A distraction? Ready for use?
Industry use cases and viewpoints
Maria Borentain (Bayer, USA)
Punag Divanji (Cytokinetics, USA)

Commercial devices for use in regulated clinical trials.
Industry viewpoints
David Albert (AliveCor, USA)
Maulik Majmudar (Biofourmis, USA)
TBD (Kardigan, USA)
Juuso Blomster (Cardiosignal, USA)
Mintu Turakhia (iRhythm, USA)

Regulatory clearance for collecting endpoints in trials using wearables.
Regulatory viewpoint
Stephen Browning (FDA, USA)

Do people with lived experience even like wearable devices?
Patient viewpoint
Corinne Hudson (Pumping Marvellous Foundation, UK)

The CVCT Multi-Stakeholder Think Tank Debate
WEARABLES FOR CV TRIALS. READY FOR PRIME TIME?
Chairperson: Abhinav Sharma (Montreal, CAN) & Mike Gibson (Boston, MA, USA)

Panelists: David Albert (AliveCor, USA), Marc Bains (HeartLife, CAN), Juuso Blomster (Cardiosignal, USA), Maria Borentain (Bayer, USA), Stephen Browning (FDA, USA), Punag Divanji (Cytokinetics, USA), Jessilyn Dunn (Durham, NC, USA), Greg Marcus (San Francisco, CA, USA), Mike Gibson (Boston, MA, USA), Christopher Granger (Durham, NC, USA), Corinne Hudson (Pumping Marvellous Foundation, UK), Maulik Majmudar (Biofourmis, USA), Abhinav Sharma (Montreal, CAN), John Spertus (Kansas City, MO, USA), Mintu Turakhia (iRhythm, USA)

State
Monday, December 8, 2025
8:30 -10:30

CVCT STATISTICS MASTERCLASS 1
Chairpersons: Stuart Pocock (London, UK) & Janet Wittes (Wittes LLC, USA)

Covariate adjustment
Stuart Pocock (London, UK)
Discussant : William Koh (FDA, USA)

Why do it? How to do it.
Key is to pre-define covariates of prognostic relevance.
Well-planned, covariate adjustment gains modest power.
Modern methods will be compared with established techniques.

Discussion

Subgroup analysis
Janet Wittes (Wittes LLC, USA)
Discussant : Peter Juni (Oxford, UK)

When can they influence trial claims?
When done well they are of value.
Post hoc claims can be menace.
How to do them well and how to shrink exaggerated findings.

Discussion

Multiple outcomes
Gregg Stone (New York, NY, USA)
Discussant: Bram Zuckerman (FDA, USA)

Making sense of the totality of evidence.
Primary (co-primary), secondary and exploratory outcomes all add insights.
How do trialists, journals and regulators handle secondary claims?

Discussion

State
Monday, December 8, 2025
11:00 -13:00

CVCT STATISTICS MASTERCLASS - 2
Chairpersons: Frank Rockhold (Durham, NC, USA) & Xavier Rossello (Madrid, ESP)

Extension studies
Xavier Rossello (Madrid, ESP)
Discussant : Frank Rockhold (Durham, NC, USA)

Statistical challenges arising from extension studies
Many trials need extended follow up beyond the primary report.
Session will give guidance of how to do it well.
Different types of extensions will be presented.

Discussion

Meta-analysis and systematic reviews
Sanjay Kaul (Los Angeles, CA, USA)
Discussant : Flavia Geraldes (The Lancet, UK)

What constitutes a meaningful quality meta-analysis?
How do so many fail?
The tortuous statistical complexities, and how to simplify them into core messages.
Merits of individual patient data and network meta-analyses.

Discussion

Composite end points
John Gregson (London, UK)
Discussant : Javed Butler (Dallas, TX, USA)

The challenge in choosing a meaningful primary composite.
The common problem of inconsistency across components.
The pros and cons of hierarchical composites.
Repeat event analysis and competing risk analysis.

Discussion

State
Monday, December 8, 2025
14:30 -16:30

ALDOSTERONE TARGETS TRIALS: THREE DECADES AND STILL EVOLVING

Chairpersons: Maria Rosa Costanzo (Naperville, IL, USA) & Faiez Zannad (Paris, FRA)

Overview of MRA trials in Heart Failure – lessons learned
Scott Solomon (Boston, MA, USA)

Aldosterone physiology – MR dependent and MR independent
Bertram Pitt (Ann Arbor, MI, USA)

Higher aldosterone levels with MRA and non-genomic effects of aldosterone – clinically relevant?
Jeffrey Testani (New Haven, CT, USA)

ASI and MR modulators – theoretical advantages
Muthiah Vaduganathan (Boston, MA, USA)

Ongoing clinical trials with ASI and MR modulators
Javed Butler (Dallas, TX, USA)

Role of ASI in preventing heart failure
Neha Pagidipati (Durham, NC, USA)

Role of ASI in chronic kidney disease
Maria Rosa Costanzo (Naperville, IL, USA)

Industry Perspectives
Martina Brueckmann (Boehringer, GER), Mikhail Kosiborod (Astrazeneca, USA), Christoph Schumacher (Damian Pharma, CH)

The CVCT Multi-Stakeholder Think Tank Debate

ALDOSTERONE TARGETS TRIALS – DIFFERENTIATION ISSUES

Chairpersons: Maria Rosa Costanzo (Naperville, IL, USA) & Faiez Zannad (Paris, FRA)

Panelists: Martina Brueckmann (Boehringer, GER), Javed Butler (Dallas, TX, USA), Maria Rosa Costanzo (Naperville, IL, USA), Riccardo Inciardi (Stockholm,SWE), Mikhail Kosiborod (Astrazeneca, USA), Neha Pagidipati (Durham, NC, USA), Bertram Pitt (Ann Arbor, MI, USA), Scott Solomon (Boston, MA, USA), Jeffrey Testani (New Haven, CT, USA), Muthiah Vaduganathan (Boston, MA, USA), Christoph Schumacher (Damian Pharma, CH)

State
Monday, December 8, 2025
17:00 -19:30

EVIDENCE BASED GUIDELINES DEVELOPMENT: MORE CONTROVERSIAL THAN YOU THINK!
STUDY CASE: HEART FAILURE
Chairpersons: Javed Butler (Dallas, TX, USA) & Faiez Zannad (Paris, FRA)

Requirements for a Class I recommendation should be the same for drugs and devices?
Sanjay Kaul (Los Angeles, CA, USA)

Requirements for a Class I recommendation should NOT be the same for drugs and devices?
William Abraham (Columbus, OH, USA)

Guidelines development is a challenging process, but it works!
Xavier Rossello (Madrid, ESP)
Clyde Yancy (Chicago, IL, USA)

Guidelines development is an impossible task, and it is flawed!
Milton Packer (Dallas, TX, USA)

Guidelines development set of rules
Peter Juni (Oxford, UK)

How helpful are the guidelines to the practice of medicine?
Orly Vardeny (Minneapolis,MN, USA)

How helpful are the guidelines to the practice of primary care?
Naresh Kanumilli (Manchester, UK)

When and how payers use medical guidelines
Steve Farmer (ex-CMS, USA)

When do guidelines help or hurt innovation? Industry perspective
Phil Adamson (CVRx, USA)
Maria Sejersten Ripa (NovoNordisk, DEN)

The CVCT Multi-Stakeholder Think Tank Debate
GUIDELINES ARE HERE TO STAY. HOW TO MAKE THEM WORK?
Chairpersons: Javed Butler (Dallas, TX, USA) & Faiez Zannad (Paris, FRA)

Panelists: William Abraham (Columbus, OH, USA), Phil Adamson (CVRx, USA), Javed Butler (Dallas, TX, USA), Safia Chatur (Boston, MA, USA), Steve Farmer (ex-CMS, USA), Peter Juni (Oxford, UK), Naresh Kanumilli (Manchester, UK) , Sanjay Kaul (Los Angeles, CA, USA), Milton Packer (Dallas, TX, USA), Xavier Rossello (Madrid, ESP), Maria Sejersten Ripa (NovoNordisk, DEN), Megan Sutton (Everygene, USA), Orly Vardeny (Minneapolis,MN, USA), Clyde Yancy (Chicago, IL, USA), Faiez Zannad (Paris , FRA)

Chinese
Monday, December 8, 2025
08:30 -10:30

PULMONARY ARTERIAL HYPERTENSION AND HEART FAILURE TRIALS
THE FUTURE OF PULMONARY HYPERTENSION TRIALS
Chairpersons: Marc Humbert (Paris, FRA) & Vallerie McLaughlin (Ann Arbor, MI, USA)

Sotatercept in PAH patients with a high risk of death: a milestone
Marc Humbert (Paris, FRA)

Is mortality a valid endpoint in PAH RCTs: lessons from the sotatercept trials
Vallerie McLaughlin (Ann Arbor, MI, USA)

Trial consideration in Pulmonary Hypertension Associated With Left Heart Disease
Ryan Tedford (Charleston, USA)

Drug development on top of drugs targeting four pathways: how?
Jason Weatherald (Edmonton, CA)

When should an independent DMC stop a trial in PAH?
Steve Kawut (Philadelphia, PA, USA)

Inhaled drugs for PH: challenges and opportunities
Rajan Saggar (San Francisco, CA, USA)

Investigator Viewpoint
Corey Ventetuolo (Providence, MA, USA)

NIH viewpoint
Lei Xiao (NIH/NHLBI-USA)

Regulatory Viewpoint
Mitch Psotka (FDA, USA)

Industry Viewpoint
Mahesh Patel (Merck, USA)

Patient Viewpoint
Colleen Brunetti (Pulmonary Hypertension Association, USA)

The CVCT Multi-Stakeholder Think Tank Debate
PULMONARY ARTERIAL HYPERTENSION INNOVATIVE DESIGNS
Chairpersons: Marc Humbert (Paris, FRA) & Vallerie McLaughlin (Ann Arbor, MI, USA)

Panelists: Sadegh Alikhaani (Los Angeles, USA), Colleen Brunetti (Pulmonary Hypertension Association, USA), Bjorn Dahlof (Cereno, SWE), Mardi Gomberg-Maitland (Washington, DC, USA), Marc Humbert (Paris, FRA), Nona Jiang (Boston, MA, USA), Steve Kawut (Philadelphia, PA, USA), Brad Maron (Baltimore, MA,USA), Vallerie McLaughlin (Ann Arbor, MI, USA) Mahesh Patel (Merck, USA), Sam Popa (United Therapeutics, USA), Iona Preston (Boston, MA, USA), Mitch Psotka (FDA, USA), Rajan Saggar (San Francisco, CA, USA), Sandeep Sahay (Houston, TX, USA), Gérald Simonneau (Paris, FRA), Olivier Sitbon (Paris, FRA), Ryan Tedford (Charleston, USA), Jean-Luc Vachiéry (Brussels, BE), Frances Varian (Sheffield, UK), Corey Ventetuolo (Providence, MA,USA), Jason Weatherald (Edmonton, CA), Lei Xiao (NIH/NHLBI-USA)

Chinese
Monday, December 8, 2025
11:00 -13:00

PULMONARY HYPERTENSION: REMISSION AND CURE
Chairpersons: Mardi Gomberg-Maitland (Washington, DC, USA) & Gérald Simonneau (Paris, FRA)

Embracing Remission or Disease Modification as a goal in PH: Pro
Sandeep Sahay (Houston, TX, USA)

Embracing Remission or Disease Modification as a goal in PH: Con
Iona Preston (Boston, MA, USA)

How to incorporate health of RV in the guidelines: Promises and Obstacles
Jean-Luc Vachiéry (Brussels, BE)

Initial and sequential combination therapy in PAH with cardiovascular comorbidities
Olivier Sitbon (Paris, FRA)

Activin Signaling Inhibitors in left-heart disease associated PH
Mardi Gomberg-Maitland (Washington, DC, USA)

PH-ILD: an update of current RCTs
Vincent Cottin (Lyon, France)

Ex Vivo Lung Perfusion: A Solution to Organ Scarcity
Sam Popa (United Therapeutics, USA)

Regulatory Viewpoint
Mitch Psotka (FDA, USA)

Investigator Viewpoint
Brad Maron (Baltimore, MD)

Patient Viewpoint
Coleen Brunetti (Pulmonary Hypertension Association)

Industry Viewpoints
Mahesh Patel (Merck, USA), Carlos Sanmarco (Pulmovant, USA), Franck Rahaghi (United Therapeutics, USA)

The CVCT Multi-Stakeholder Think Tank Debate
PULMONARY ARTERIAL HYPERTENSION INNOVATIVE DESIGNS
Mardi Gomberg-Maitland (Washington, DC, USA) & Gérald Simonneau (Paris, FRA)

Panelists: Marc Bains (HeartLife, Canada), Colleen Brunetti (Pulmonary Hypertension Association, USA), Vincent Cottin (Lyon, France), Bjorn Dahlof (Cereno, SWE), Mardi Gomberg-Maitland (Washington, DC, USA), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PA, USA), Steven Macari (AVEC, France), Brad Maron (Baltimore, MA, USA), Vallerie McLaughlin (Ann Arbor, MI, USA) , Mahesh Patel (Merck, USA), Iona Preston (Boston, MA, USA), Sam Popa (United Therapeutics, USA), Mitch Psotka (FDA, USA), Franck Rahaghi (United Therapeutics, USA), Rajan Saggar (San Francisco, CA, USA), Sandeep Sahay (Houston, TX, USA), Carlos Sanmarco (Pulmovant, USA), Olivier Sitbon (Paris, FRA), Jean-Luc Vachiéry (Brussels, BE), Frances Varian (Sheffield, UK)

Chinese
Monday, December 8, 2025
17:00 -19:30

CVCT PATIENT ENGAGEMENT MASTERCLASS
PATIENTS AS PARTNERS THROUGHOUT THE RESEARCH LIFECYCLE
HOW TO INTEGRATE PATIENT INSIGHTS INTO CLINICAL STUDIES?
Chairpersons: Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK) & Rhonda Monroe (BOOST, Charlotte, NC, USA)

MASTERCLASS Introduction : Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)

CVCT's Formal Commitment to Patient Engagement : Faiez Zannad (Paris, FRA)

Effective Trial Design: Why engage patient trialists?
Patient Viewpoint : Mellanie True Hills (Stop AFib, USA)

Regulatory Viewpoint : TBD

Industry Viewpoints : Roberta Chapman (J&J MedTech, USA), Victoria DiBiaso (Sanofi, FRA)

The Clinical Trial Lifecycle: When do you engage patient trialists?
Patient Viewpoint : Marc Bains (HeartLife Foundation, CAN)

Ex-Industry Viewpoint : George H. Sands (Sands Collaborative, USA)

Regulatory Viewpoint : Maciej Kostrubiec (EMA, POL), Bernard Vasseur (FDA, USA)

Research Roles and Responsibilities: How do you engage patient trialists?
Patient Viewpoint : Greg Merritt (Patient Is Partner, Brighton, USA)

Clinical Viewpoint : John Spertus (Kansas City, MO, USA)

Key Research Consideration: Representation : Alessia Argiro (Florence, ITA)

Remuneration for Patient Engagement : Celina Gorre (WomenHeart, Washington, DC, USA)

Case Study: ADAPTABLE : Rob Califf (Bethesda, MA, USA)

Research Outcomes Should Result in Effective Health Policy : Jillianne Code (HeartLife, CAN)

Pragmatic Examples of Effective Patient Engagement: What's Possible? : Rhonda Monroe (Charlotte, NC, USA)

Embedding the Patient Voice in Your Research: A Quickstart Guide for Researchers : Faiez Zannad (Paris, FRA)

Patients viewpoints. Patient Centered Organizational Resources: EUPATI, PCORI
Steve Macari (Poitiers, FRA), Jacqueline Alikhaani (Los Angeles, CA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

HOW TO INTEGRATE PATIENT INSIGHTS INTO CLINICAL STUDIES?
Chairpersons : Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK) & Rhonda Monroe (BOOST, Charlotte, NC, USA)

Panelists: Jacqueline Alikhaani (Los Angeles, USA),), Sadegh Alikhaani (Los Angeles, USA), Alessia Argiro (Florence, ITA), Marc Bains (HeartLife Foundation, CAN), Rob Califf (Bethesda, MD), Roberta Chapman (J&J MedTech, USA), Jillianne Code (HeartLife, CAN), Victoria DiBiaso (Sanofi, FRA), Robin Gage (HFSA, USA), Celina Gorre (WomenHeart, USA), Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), Maciej Kostrubiec (EMA, POL), Trudie Loban (Heart Rhythm Alliance, London, UK), Steve Macari (Poitiers, FRA), Greg Merritt (Patient Is Partner, Brighton, USA), Rhonda Monroe (Charlotte, NC, USA), Juddson Rupp (Charlotte, NC, USA), George H. Sands (Sands Collaborative, USA), John Spertus (Kansas City, MO, USA), Mellanie True Hills (Stop AFib, USA), Bernard Vasseur (FDA, USA), Faiez Zannad (Paris, FRA)

Ballroom
Monday, December 8, 2025
14:30 -16:30

EVIDENCE-GENERATION TO SUPPORT SCALING ARTIFICIAL INTELLIGENCE APPLICATIONS FOR CARDIOVASCULAR CARE - Part 1

Chairpersons: Kirsten Bibbins-Domingo (JAMA, USA) & Harlan Krumholz (JACC, USA)

Why RCTs remain the gold standard for validating AI in cardiovascular medicine
Ankeet Bhatt (Kaiser Permanente, USA)

High-quality evidence for AI using real-world data and observational methods
Lesley Curtis (Durham, NC, USA)

What journals look for in high-quality evidence on AI innovations in cardiology
Harlan Krumholz (JACC, USA)
Rohan Khera (JAMA, USA)

The evolving evidence landscape of AI-enabled consumer-grade cardiovascular devices
Aline Pedroso (New Haven, CT, USA)

AI-driven imaging platform for coronary artery disease clinical trials
Udo Hoffmann (Cleerly, USA)

Regulatory viewpoints. Evolving regulatory framework for evidence standards in AI-driven cardiovascular tools
Michelle Tarver (FDA, USA)
Gabriella Passacquale (EMA, ITA)

Regulatory/payers' viewpoints. Aligning AI innovation with expectations in cardiovascular health.
Michelle Tarver (FDA, USA), Aneesh Deoras (FDA. USA)

The CVCT Multi-Stakeholder Think Tank Debate

HOW TO PROGRESS TO EVIDENCE-BASED ARTIFICIAL INTELLIGENCE

Chairpersons: Kirsten Bibbins-Domingo (JAMA, USA) & Harlan Krumholz (JACC, USA)

Panelists: David Albert (AliveCor, USA), Ankeet Bhatt (Kaiser Permanente, USA), Kirsten Bibbins-Domingo (JAMA, USA), Lesley Curtis (Durham, NC, USA, Aneesh Deoras (FDA. USA), Udo Hoffmann (Cleerly, USA), Brad Horst (Boston Scientific, USA), Rohan Khera (JAMA, USA), Christos P Kotanidis (Oxford, UK), Harlan Krumholz (JACC, USA), Maulik Majmudar (Biofourmis, USA), Gabriella Passacquale (EMA, ITA), Aline Pedroso (New Haven, CT, USA), Adam Phillips (Apple, USA), Campbell Rogers (Heartflow, USA), Michelle Tarver (FDA, USA), Mintu Turakhia (iRhythm, USA)

Ballroom
Monday, December 8, 2025
17:00 -19:30

SCALING ARTIFICIAL INTELLIGENCE APPLICATIONS FOR CARDIOVASCULAR CARE – Part 2
LEARNING FROM THE EXPERIENCE OF PHARMACEUTICAL AND DEVICE COMPANIES
Chairpersons: Kirsten Bibbins-Domingo (JAMA, USA) & Harlan Krumholz (JACC, USA)

Industry viewpoints.

AI-based cardiovascular endpoints
Adam Phillips (Apple, USA)
Mintu Turakhia (iRhythm, USA)

AI-enabled remote clinical trials
Maulik Majmudar (Biofourmis, USA)

AI-enabled safety monitoring in clinical trials
David Albert (AliveCor, USA)

Integrating AI in cardiovascular devices
Brad Horst (Boston Scientific, USA)

Integrating AI in atherosclerosis trials
Udo Hoffmann (Cleerly, USA)

Balancing evidence generation with product development in AI companies
Campbell Rogers (Heartflow, USA)

The CVCT Multi-Stakeholder Think Tank Debate
HOW TO PROGRESS TO EVIDENCE-BASED ARTIFICIAL INTELLIGENCE
Chairpersons: Kirsten Bibbins-Domingo (JAMA, USA) & Harlan Krumholz (JACC, USA)

Panelists: David Albert (AliveCor, USA), Ankeet Bhatt (Kaiser Permanente, USA), Kirsten Bibbins-Domingo (JAMA, USA), Lesley Curtis (Durham, NC, USA, Udo Hoffmann (Cleerly, USA), Brad Horst (Boston Scientific, USA), Rohan Khera (JAMA, USA), Christos P Kotanidis (Oxford, UK), Harlan Krumholz (JACC, USA), Maulik Majmudar (Biofourmis, USA), Gabriella Passacquale (EMA, ITA), Aline Pedroso (New Haven, CT, USA), Adam Phillips (Apple, USA), Campbell Rogers (Heartflow, USA), Michelle Tarver (FDA, USA), Mintu Turakhia (iRhythm, USA)

Palm Court
Tuesday, December 9, 2025
07:00 -08:30

CVCT APAC
CARDIOMETABOLIC TRIALS IN ASIA: UNIQUE CONSIDERATIONS
Chairpersons: Carolyn Lam (Singapore, SIN), Lijing Yan (Kunshan, CHN)

Standard of care for cardiometabolic disease: How does Asia differ?
Yasuhiko Sakata (Osaka, Japan)

Racial/ethnic differences in heart failure diagnostics: How does this impact cardiometabolic screening in Asia?
Peder Myhre (Oslo, NO)

Trials of Traditional Medicines for Cardiometabolic Disease: How to account for their effect?
Xinli Li (Nanjing, CHN)

Polypill cardiometabolic trials: Why Asia?
Asita de Silva (Kelaniya, LK)

Heart failure care. How does Asia differ?
Vijay Chopra (Gurgaon, IND)

Industry's viewpoint
Anders Gabrielsen (Ribocure, CHN)

Editors' viewpoint
Helena Wang (Lancet, CHN)

The CVCT Multi-Stakeholder Think Tank Debate
CARDIOMETABOLIC TRIALS IN ASIA: UNIQUE CONSIDERATIONS
Chairpersons: Carolyn Lam (Singapore, SIN), Lijing Yan (Kunshan, CHN)

Panelists: Vince Benn (KBP, USA), Vijay Chopra (Gurgaon, IND), Asita de Silva (Kelaniya, LK), Anders Gabrielsen (Ribocure, CHN), Christine Gouillard (US2AI, SIN), Xinli Li (Nanjing, CHN), Peder Myhre (Oslo, NO), Yasuhiko Sakata (Osaka, JPN), Helena Wang (Lancet, CHN), Lijing Yan (Kunshan, CHN)

Palm court
Tuesday, December 9, 2025
08:30 -10:30

LBCT 1
ELECTROPHYSIOLOGY
Chairpersons: Chairpersons: Tina Baykaner (Stanford, CA), Paulus Kirchhof (Hambourg, GER) Panelists: Christine Albert (Los Angeles, CA, USA), Jonathan Piccini (Durham, NC, USA), Silvia Priori (Pavia, ITA)

Anticoagulant Benefit in Subclinical Atrial Fibrillation Accounting for Competing Risks: A Reanalysis of the ARTESIA Trial

Shao-Wei Lo (1), Darae Ko, Dae Hyun Kim, Long Ngo, Daniel Singer, Sachin Shah, (1)Cleveland Clinic Foundation, Cleveland, USA

Pragmatic Randomized Clinical Trial of Early Dronedarone versus Usual Care to Change and Improve Outcomes in Persons with First-Detected Atrial Fibrillation (CHANGE AFIB)

Belal Suleiman, Sean Pokorney, Jesse Delarosa, Karen Chiswell, Christine Albert, Nadine Allyn, Rosalia Blanco, Javed Butler, Hugh Calkins, Mitchell Elkind, Fonarow Gregg, John Fontaine, David Frankel, Fermann Gregory, Rex Gale, Samantha Johnson, Matthew Kalscheur, Devin Marie Keating, Paulus Kirchhof, Andrew Koren, Joseph Miller, Cyril Ofori, Russo Andrea, Christine Rutan, Benjamin Steinberg, Jonathan Piccini (1)Duke University Medical Center, Durham, USA

Guiding iterative decision-making in anticoagulant dosing including patient preferences of stroke vs bleeding avoidance: A Bayesian Machine Learning model trained on the ENGAGE AF-TIMI 48 trial

C. Michael Gibson (1) , Cathy Chen, Jacqueline Buros-Novik, Eric Novik, Juho Timonen, Eugene Braunwald, Elliott Antman, Eva-Maria Fronk, Matthew Clasen, Robert Giugliano, Martin Unverdorben (1)Baim Institute For Clinical Research, Harvard Medical School, Massachusetts, Boston, USA

Atrial fibrillation catheter ablation follow-up using patient-led, watch- based ECG monitoring

Nikhil Ahluwalia (1) , Hakam Abbass, Ahmed Hussain, Gunkavee Saengkrajang , Rangeena Assadi, Charles Butcher, Maclean Edward, Shohreh Honarbakhsh, Ross J Hunter, Michele Orini, Richard J Schilling (1)St Bartholomew's Hospital, London, Uk, London, UK

Cardiac Resynchronization with or without Defibrillator in Non-Ischemic Cardiomyopathy; A Nationwide Cohort Study (DECIDE-CRT)

Padmini Selvaganesan (1, 2), Mohamad Karnib, Yogesh Reddy, Irfan Helmy, Rosita Zakeri, Imran Rashid, Mohammed N. Osman, Ram Amuthan, Amanda R. Vest, Anselma Intini, James Fang, Jayakumar Sahadevan, Varun Sundaram (1)Case Western Reserve University School Of Medicine, Cleveland, USA (2)Louis Stokes Cleveland Va Medical Center, USA

Patient-centered evaluation of DOACs versus warfarin in atrial fibrillation: a weighted composite and win statistics analyses of the COMBINE-AF dataset

Satoshi Shoji (1), Pishoy Gouda, Caroline Falvey, Huiman Barnhart, Derek Cyr, Robert Mentz, Jonathan Piccini, Manesh Patel, Schuyler Jones, Veraprapas Kittipibul, Min Soo Cho, Manasi Tannu, Shuntaro Sato, Andre Nicolau, Michael Palazzolo, Lars Wallentin, John Eikelboom, Hwanhee Hong, Robert Giugliano, Shelby Reed, Christopher Granger – (1)Duke Clinical Research Institute, Durham, USA

Incidence and clinical impact of insertable cardiac monitor-detected arrhythmias in symptomatic hear failure: Expanded insights from the ALLEVIATE-HF trial

Rami Kahwash (1) , Javed Butler, Muhammad Khan, David Zhang, Jonathan Dukes, Madhu Reddy, Rachel Kaplan Anish Amin, Rahul Kanwar, Shantanu Sarkar, Verla Laager, Jennifer Wehking, Brian Van Dorn, Bart Gerritse, Nirav Patel, Aimee Laechell, Michael Zile (1)The Ohio State University, Columbus, USA

HS235, a next-generation BMP-9/10 sparing activin signaling inhibitor for the treatment of pulmonary hypertension (PH): Initial Phase 1 Healthy Volunteer Biomarker results

Maureen O'connor, Julia Schoelermann, Emilie Brûlé, Claire Viallard, Gauthier Schang, Florian Dilasser, Adam Pelletier, Sarya Aziz, Guillaume Lemieux, Julie Bédard, Monique Champagne, Georges George - (1)35pharma, Montreal, CAN

Palm court
Tuesday, December 9, 2025
11:00 -13:00

AI MASTER CLASS
REIMAGINING CLINICAL TRIALS IN THE AGE OF CONSUMER TECH & LARGE LANGUAGE MODELS
Chairpersons: Mintu Turakhia (Stanford, CA, USA) & Rohan Khera (JAMA, USA)

This masterclass will focus on two key areas where AI will enable clinical trial innovation. We'll focus on consumer technologies, and their growing role in arming clinical research with real-world data, improving patient engagement, and reshaping trial operations. Experts from Apple and academic partners will discuss lessons learned, opportunities for synergy, and practical considerations for integrating consumer tech into trials.

The second half will take a practical dive into large language models (LLMs), what they are, how they work, and how they're already changing clinical research. From case discovery to trial matching to outcome ascertainment, speakers from Microsoft and experts from academia will discuss real-world applications, emerging tools, and future directions.

Designed to be interactive and forward-looking, this session aims to equip participants with a conceptual framework and actionable insights on how AI is rewriting the clinical trial playbook.

Case study 1a: Smartwatch-based remote patient monitoring in heart failure
Mohammad Shahzeb Khan (Dallas, TX, USA)

Case study 1b: Case discovery for clinical trials using consumer wearable devices
Aline Pedroso (New Haven, CT, USA)

Case study 2 : The 34,000 Participant Virtual Heartline Trial: The Future of Direct to Participant Trials Without Bricks and Mortar Done at 2% of the Usual Cost
Michael Gibson (Boston, USA)

Using a smartwatch for enhancing the clinical trial enterprise: opportunities and best practices
Adam Phillips (Apple, USA)

Case study 3: Large language models for adjudicating endpoints in trials
Sneha Jain (Stanford, CA, USA)

Arming the EHR for case discovery and defining clinical events using large language models: how to enable the future of pragmatic clinical trials
Jonathan Cunningham (Boston, USA)

An academic perspective on using AI innovations for optimizing clinical trials: challenges and key considerations
Nico Bruining (EHJ Digital Health, NED)
Harriette van Spall (Hamilton, CAN)

The NIH perspective on using AI innovations for optimizing clinical trials
David Goff (NIH, USA)

The CVCT Multi-Stakeholder Think Tank Debate

AI MASTER CLASS
Chairpersons: Mintu Turakhia (Stanford, CA, USA) & Rohan Khera (JAMA, USA)

Panelists : Marc Bains (HeartLife Foundation, CAN), Nico Bruining (EHJ Digital Health, NED), Jonathan Cunningham (Boston, USA), Michael Gibson (Boston, USA), Nicolas Girerd (Nancy, FRA), David Goff (NIH, USA), Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK), Sneha Jain (Stanford, CA, USA), Adam Phillips (Apple, USA), Mohammad Shahzeb Khan (Dallas, TX, USA), Rohan Khera (JAMA, USA), Steve Macari (Poitiers, FRA), Aline Pedroso (New Haven, CT, USA), Mintu Turakhia (Stanford, CA, USA), Harriette van Spall (Hamilton, CAN)

Palm court
Tuesday, December 9, 2025
14:00 -16:00

iCVCT - PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT
Chairpersons: Christina Lalani (Boston, MA, USA) & Bobby Yeh (Boston, USA)

Percutaneous Ventricular Assist Device for High-Risk Percutaneous Coronary Intervention.

Why Randomized Clinical Trials Are So Rare In This Space, And How Can We Overcome This Gap?
Dirk Westermann (Freiburg, GER)

High Risk Percutaneous Coronary Intervention: Current State of Mechanical Cardiac Support Use and What Is Around the Corner?
David Kandzari (Atlanta, GA, USA)

Considerations For High-Risk Percutaneous Coronary Intervention Trials
Nicole Haratani (Supira Medical, USA)

Percutaneous Ventricular Assist Device for Acute Myocardial Infarction Shock

Acute Myocardial Infarction Shock: Current State for Mechanical Circulatory Support and What is Around the Corner?
Mandeep Mehra (Boston, MA, USA)

Regulatory Viewpoint on Trial Designs for Percutaneous Mechanical Circulatory Support in Acute Myocardial Infarction Shock
Mauro Moscucci (FDA, USA)

Industry Viewpoint
Rafael Cavalcante (Boston Scientific, USA)

The evolving landscape of Percutaneous Ventricular Assist Device. What is in the pipeline?
Navin Kapur (JnJ, USA)

Innovations In Trials, Registries and Methods for Percutaneous Ventricular Assist Device Evaluation

Standardizing Definitions: The PVAD ARC Initiative
Christina Lalani (Boston, MA, USA)

The Role of Registries to Support Percutaneous Ventricular Assist Device Evaluation
Mitchell Krucoff (Durham, NC, USA)

Statistical viewpoint
Design Innovations to Power Trials for Percutaneous Ventricular Assist Devices
Issa Dahabreh (Boston, MA, USA)

The iCVCT Multi-Stakeholder Think Tank Debate
DEVICES, TRIALS AND REGISTRIES FOR PERCUTANEOUS VENTRICULAR ASSIST DEVICE MOVING TO THE NEXT PHASE
Chairpersons: Christina Lalani (Boston, MA, USA) & Bobby Yeh (Boston, USA)

Panelists: Rafael Cavalcante (Boston Scientific, USA), Rishi Chandiramani (Baltimore, MA, USA), Issa Dahabreh (Boston, MA, USA), Nicole Haratani (Supira Medical, USA), David Kandzari (Atlanta, GA, USA), Navin Kapur (JnJ, USA), Mitchell Krucoff (Durham, NC, USA), Christina Lalani (Boston, MA, USA), Mandeep Mehra (Boston, MA, USA), Mauro Moscucci (FDA, USA), Dirk Westermann (Freiburg, GER), Bobby Yeh (Boston, USA)

Palm court
Tuesday, December 9, 2025
16:30 -18:30

iCVCT- DRUG-COATED ELUTING BALLOONS
Chairpersons: Don Cutlip (Boston, MA, USA) & Roxana Mehran (New York, NY, USA)

Drug-Coated Balloon for Treatment of In-Stent Restenosis – Contemporary IDE Clinical Trials.

AGENT IDE Randomized Clinical Trial
Bobby Yeh (Boston, MA, USA)

Selution 4 ISR Randomized Clinical Trial.
Don Cutlip (Boston, MA, USA)

PREVAIL Randomized Clinical Trial (ISR Cohort)
David Kandzari (Atlanta, GA, USA)

MAGICAL ISR
Don Cutlip (Boston, MA, USA)

Statistician Viewpoint
Stuart Pocock (London, UK)

Panel Discussion
George Adams (Cordis, USA), Rafael Cavalcante (Boston Scientific, USA), Don Cutlip (Boston, MA, USA), David Kandzari (Atlanta, GA, USA), Roxana Mehran (New York, NY, USA), Stuart Pocock (London, UK), , Bruno Scheller (Homburg, GER), Ron Waksman (Washington, DC, USA), Bobby Yeh (Boston, MA, USA)

Drug-Coated Balloons for Treatment of De Novo Coronary Artery Disease

Drug-Coated Balloons for De Novo Coronary Artery Disease – Historical Perspective and Promise
Bruno Scheller (Homburg, GER)

AGENT DCB STANCE and PREVAIL Randomized Clinical Trial – De Novo Cohort
David Kandzari (Atlanta, GA, USA)

Selution 4 De Novo Small Vessel Randomized Clinical Trial
Ron Waksman (Washington, DC, USA)

Regulatory Viewpoint
Radoslaw Parma (EU, Katowice, POL), Lydia Glaw (FDA, USA)

Statistician Viewpoint
Jan Tijssen (Brussels, BEL)

Panel Discussion
George Adams (Cordis, USA), Rafael Cavalcante (Boston Scientific, USA), Don Cutlip (Boston, MA, USA), Lydia Glaw (FDA, USA), David Kandzari (Atlanta, GA, USA), Martin Leon (New York, NY, USA), Roxana Mehran (New York, NY, USA), Radoslaw Parma (EU, Katowice, POL), Stuart Pocock (London, UK), Bruno Scheller (Homburg, GER), Jan Tijssen (Brussels, BEL), Ron Waksman (Washington, DC, USA), Bobby Yeh (Boston, MA, USA)

East
Tuesday, December 9, 2025
07:00 -08:30

CVCT LATAM
CLINICAL RESEARCH IN LATIN AMERICA
Chairpersons: Felipe Martinez (Cordoba, ARG) & Clara Saldarriaga (Medellín, COL)

Introduction to clinical trials in Latin America
Felipe Martinez (Cordoba, ARG)

What we learn from Latin America in heart failure trials.
Clara Saldarriaga (Medellín , COL)

International collaboration for clinical research .
Renato Lopes (Durham, NC, USA)

New approaches to conduct clinical trials: Are they happening in LATAM?
Patricia Guimaraes (São Paulo, BRA)

Industry viewpoint
Claudio Gimpelewicz (Novartis, SWI)

Regulatory viewpoint
Sindy Pulgarin (DMPB, CO)

The CVCT Multi-Stakeholder Think Tank Debate
LATIN AMERICA IN GLOBAL CLINICAL TRIALS
Chairpersons: Felipe Martinez (Cordoba, ARG) & Clara Saldarriaga (Medellín, COL)

Panelists: Claudio Gimpelewicz (Novartis, SWI), Patricia Guimaraes (São Paulo, BRA), Renato Lopes (Durham, NC, USA), Felipe Martinez (Cordoba, ARG), Maria A Pabon (Boston, MA, USA), Sindy Pulgarin (DMPB, CO), Clara Saldarriaga (Medellín, COL)

East
Tuesday, December 9, 2025
08:30 -10:30

LBCT 4, First Half
Cardio-kidney-metabolic
Chairpersons: Jennifer Green (Durham, NC, USA), Christoph Hornik (Durham, NC, USA)
Panelists: Mintu Turakhia (Stanford, CA, USA), Christoph Wanner (Wurzburg, GER), Rohan Khera (New Haven, CT, USA)

Estimated Benefits of Accelerated Initiation of Combination Therapy for Type 2 Diabetes and Chronic Kidney Disease
Safia Chatur (1), Brian Claggett, Brendon Neuen, Vlado Perkovic, Pratley Richard, Rajiv Agarwal, Hiddo Heerspink, Katherine Tuttle, Scott Solomon, Muthiah Vaduganathan. Massachusetts General Hospital/Harvard Medical School, Boston, USA

Finerenone Across Stages of Cardiovascular-Kidney-Metabolic Syndrome in the FIDELITY Program
Kevin Bryan Lo (1), John Ostrominski, Yasuhiro Yasuhiro, Brian L. Claggett, Rajiv Agarwal, Stefan D. Anker, Gerasimos Filippatos, Peter Rossing, Luis M. Ruilope, Bertram Pitt, Meike Brinker, Patrick Schloemer, Andrea Glasauer, Scott D. Solomon, Muthiah Vaduganathan
Brigham And Women's Hospital, Boston, USA

Evidence of Kidney Protection with HTD1801 (an Anti-Inflammatory Metabolic Modulator (AIMM)) - A Potential Comprehensive Approach to Early Cardiovascular-Kidney-Metabolic (CKM) Syndrome
Filip Surmont (1), Leili Gao, Kui Liu, Leigh Macconell, Meng Yu, Liping Liu, Linong Ji (1)Hightide Therapeutics, Inc., Shenzhen, CHN

Prevalence and prognostic importance of chronic kidney disease in patients with coronary heart disease Results from the INTERASPIRE survey from 14 countries across six WHO regions
Safi Al-Azzawy (1), Dirk De Baquer, John William McEvoy, Agnieszka Adamska, Guy De Backer, Iris Erlund, Sandra Ganly, Catriona Jennings, Kornleia Kotseva, Gregory Lip, Linda Mellbin, Kausik Ray, Terhi Viervaara, David Wood, Per-Henrik Groop, Lars Rydén
Karolinska Institutet, Stockholm, SWE

LBCT 4, Second Half
Artificial Intelligence
Chairpersons: Jennifer Green (Durham, NC, USA), Christoph Hornik (Durham, NC, USA)
Panelists: Mintu Turakhia (Stanford, CA, USA), Christoph Wanner (Wurzburg, GER), Rohan Khera (New Haven, CT, USA)

Simultaneous or sequential initiation of ARNI and SGLT2I in patients with HFrEF: the INITIATE-HFrEF trial
João Pedro Ferreira Faculty Of Medicine of Porto University, POR

Using a large language model for clinical trial source data verification
Simran Makker (1), Samarra Badrouchi, Dongchu Xu, Pablo Marti-Castellote, Brian Claggett, Orly Vardeny, Scott Solomon, Jonathan Cunningham
Brigham And Women's Hospital, Boston, USA

Natural language processing-based adjudication of outcomes in DAPA-HF
Kieran Docherty (1), Pardeep Jhund, Lars Køber, Mark Petrie, Martin Cowie, Sanjay Rathee, Andreas Järemo, Chang Qi, Martin Fredriksson, John Mcmurray. University Of Glasgow, Glasgow, UK

AI-Guided Quantification of Atherosclerosis on Coronary CT for Identification of High-Risk Individuals in Non-Obstructive CAD: International, Multi-Center Study
Andrew Choi (1) , Ibrahim Danad, Mouaz Al-Mallah, Mirvat Alasnag, Amro Alsaid, Daniele Andreini, Jeroen Bax, Sabha Bhatti, Ron Blankstein, Kelley Branch, Jan Michael Brendel, Matt Budoff, Ronny Büechel, Filippo Cademartiri, Rhanderson Cardoso, Victor Cheng, Geoffrey Cho, Pedro De Araújo Gonçalves, Carlo Nicolo De Cecco, Roderick Deaño, Augustin Delago, Vucic Esad, Maros Ferencik, Gudrun Feuchtner, Borek Foldyna, David German, Christoph Gräni, Himanshu Gupta, Martin Hadamitzky, Ashraf Hamadan, Dinesh Kalra, Vasileios Kamperidis, Ronald Karlsberg, Omar Khalique, Paul Knaapen, Pietro Lacaita, Erica Maffei, Hugo Marques, Enrico Martin, James Mills, Saima Mushtaq, Prashant Nagpal, Rine Nakanishi, Nick Nurmohamed, Andrew Oehler, Amit Patel, Venkateshwar Polsani, Gianluca Pontone, Alexander Van Rosendael
(1)Department of Cardiology And Radiology George Washington University-Washington, Washington, DC., USA

East
Tuesday, December 9, 2025
11:00 -13:00

INNOVATION (OR LACK THEREOF) IN POST MI TRIALS
Chairpersons: Rasha Al Lamee (London, UK) & Guiomar Mendieta Badimon (Barcelona, ESP)

Outcomes of contemporary patients post myocardial infarction. What are the remaining unmet needs?
Tabassome Simon (Paris, FRA)

Post MI beta-blocker therapy. And now what?
Dan Atar (Oslo, NOR)

Post MI stunned myocardium in 2025
James Udelson (Boston, MA, USA)

Many recent negative trials – PARADISE, EMPACT, DAPA-MI, REDUCE-AMI, CLEAR-MI – Why?
Milton Packer (Dallas, TX, USA)

Why are traditional enrichment criteria failing us? Why low event rates?
William Schuyler Jones (Durham, NC, USA)

Target patient populations for non-acute post MI intervention
Mark Petrie (Glasgow, UK)

Future landscape of post MI interventions – procedures and drugs
Rasha Al Lamee (London, UK)

The CVCT Multi-Stakeholder Think Tank Debate
HOW TO PROMOTE INNOVATIVE TRIALS FOR POST MI
Chairpersons: Rasha Al Lamee (London, UK) & Guiomar Mendieta Badimon (Barcelona, ESP)

Panelists : Rasha Al Lamee (London, UK), Dan Atar (Oslo, NOR), Guiomar Mendieta Badimon (Barcelona, ESP), Greg Merritt (Patient Is Partner, Brighton, USA), Milton Packer (Dallas, TX, USA), Mark Petrie (Glasgow, UK), William Schuyler Jones (Durham, NC, USA), Juddson Rupp (Charlotte, NC), Tabassome Simon (Paris, FRA), Mikhail Sumin (Boehringer, GER), Thomas Thum (Hannover, GER), James Udelson (Boston, MA, USA)

East
Tuesday, December 9, 2025
14:00 -16:00

REPORTING THE RESULTS OF CLINICAL TRIALS.
Chairpersons: Jane Leopold (NEJM, USA) & Chloe Wilson (The Lancet, UK)

Transparent and accurate reporting, journal guidelines
Rita Redberg (San Francisco, CA, USA)

Academic trial leadership: Confidentiality and liability issues.
Legal viewpoint: Michael Ewer (Houston, TX, USA)
Ethical viewpoint: Julie Aultman (Akron, OH, USA)

Academic trial leadership: Ethical considerations, vouching for data integrity, dealing with conflicts of interests
Harriette Van Spall (Hamilton, CAN)

Journal editors's viewpoint
Artificial Intelligence for trial results' reporting and reviewing
Michael Basson (Nature Medicine, USA)

How important are late breakers and simultaneous publications practices.

Editors' viewpoints
Gregory Curfman (JAMA, USA)
Flavia Geraldes (The Lancet, UK)

Regulatory viewpoints
Norman Stockbridge (Stockbridge, LLC, USA), Mona Fiuzat (FDA, USA)

Industry viewpoint
Stefano Corda (Bayer, GER)

Are the standards for publishing results of drug trials and device trials equal?
Jane Leopold (NEJM, USA)

Best practice for communicating clinical trial information to the gerenal public, with impact and dissemination – press releases, social media, academic networks
Ron Winslow (Ex Wall Street Journal, USA)

How patients access trial results.
Plain language summary publications and other issues
Jacqueline Alikhaani (Los Angeles, CA, USA)
Rhonda Monroe (Charlotte, NC, USA)

The CVCT Multi-Stakeholder Think Tank Debate

REPORTING THE RESULTS OF CLINICAL TRIALS.
Chairpersons: Jane Leopold (NEJM, USA) & Chloe Wilson (The Lancet, UK)

Panelists: Jacqueline Alikhaani (Los Angeles, CA, USA), Sadegh Alikhaani (Los Angeles, CA, USA),Julie Aultman (Akron, OH, USA), Stefano Corda (Bayer, GER), Gregory Curfman (JAMA, USA), Michael Ewer (Houston, TX, USA), Mona Fiuzat (FDA, USA), Flavia Geraldes (The Lancet, UK), Christos P Kotanidis (Oxford, UK), Jane Leopold (NEJM, USA) , Michael Basson (Nature Medicine, USA), Rhonda Monroe (Charlotte, NC, USA), Chris O'Connor (Falls Church, VA, USA), Rita Redberg (San Francisco, CA, USA), Norman Stockbridge (Stockbridge, LLC, USA), Harriette Van Spall (Hamilton, CAN), Chloe Wilson (The Lancet, UK), Ron Winslow (Ex Wall Street Journal, USA)

East
Tuesday, December 9, 2025
16:30 -18:30

DCRI joint session
CARDIOVASCULAR PREVENTION TRIALS
HEART FAILURE AS A USE CASE
Chairpersons: Javed Butler (Dallas, TX, USA) & Faiez Zannad (Paris, FRA)

Population attributable risk factors for HF? Move away from HTN, obesity is here
Javed Butler (Dallas, TX, USA)

Molecular biology and bio-informatical analyses for new target identification in cardiomyopathies.
Stephane Heymans (Maastricht, NED)

What is “new onset” disease? Hard events vs. early diagnosis.
Robert Mentz (Durham, USA)

How to assess impact of novel therapies in non-HF trials on HF development? Minimum basics and best-case scenarios
Carolyn Lam (Singapore, SIN)

Multi-organ prevention trials. Seeking multiple indications with a single trial.
Should HF be a part of composite primary or key secondary outcome in all CV, diabetes, and kidney trials?
Faiez Zannad (Paris, FRA)

Ongoing HF Prevention trials
Pam Taub (San Diego, CA, USA)

How streamlined design may help CV prevention trials?
Martin Landray (Oxford, UK)

Industry viewpoints
Mikhail Kosiborod (Astrazeneca, USA)
Juergen Prochaska (Boehringer Ingelheim, GER)
Filip Surmont (HighTide, CN)

What regulatory changes are needed?
Norman Stockbridge (S & S Consulting, USA)

The CVCT Multi-Stakeholder Think Tank Debate
HOW TO STREAMLINE CARDIOVASCULAR PREVENTION TRIALS
Chairpersons: Javed Butler (Dallas, TX) & Faiez Zannad (Paris, FRA)

Panelists: Javed Butler (Dallas, TX, USA), Stephane Heymans (Maastricht, NED), Riccardo Inciardi (Brescia, ITA), Mikhail Kosiborod (Astrazeneca, USA), Carolyn Lam (Singapore, SIN), Martin Landray (Oxford, UK), Matthew Lee (Glasgow, UK),Robert Mentz (Durham, USA), Greg Merritt (Patient Is Partner, Brighton, USA), Caius Mersa (Romanian Heart Foundation, RO), Juergen Prochaska (Boehringer Ingelheim, GER), Filip Surmont (HighTide, CN), Norman Stockbridge (S & S Consulting, USA), Pam Taub (San Diego, CA, USA), Faiez Zannad (Paris, FRA)

State
Tuesday, December 9, 2025
08:15 -10:30

LBCT 2
HEART FAILURE
Chairpersons: Clyde Yancy (Chicago, IL, USA), Maria Rosa Constanzo (Naperville, IL, USA)
Panelists: Barry Greenberg (San Diego, CA, USA), Joao Ferreira (Porto, POR), Mark Petrie (Glasgow, UK)

Updated Phase 1 Clinical Trial Outcomes of CRISPR Gene Editing With Nexiguran Ziclumeran In Patients With Transthyretin Amyloidosis With Cardiomyopathy

Marianna Fontana (1), Scott Solomon, Jörg Täubel, Ed Gane, Björn Pilebro, Andoni Echaniz-Laguna, Brian Claggett, Aviva Petrie, Jessica Kachadourian, Ricardo Rocha, Derek Smith, Alexandra Haagensen, Joy Olbertz, Peijuan Zhu, Carri Boiselle, Adia Leung, David E. Gutstein, Alison Sonderfan (8), Liron Walsh, Julian D. Gillmore. National Amyloidosis Centre, University College London, London, UK

Use of an insertable cardiac monitor-based heart failure risk status algorithm to manage heart failure patients: Primary results of the ALLEVIATE-HF randomized trial

Javed Butler (1, 2), Rami Kahwash, Muhammad Khan, David Zhang, Jonathan Dukes, Madhu Reddy, Anupam Basuray, Elie Gharib, Bart Gerritse, Aimee Laechelt, Jennifer Wehking, Shantanu Sarkar, Brian Van Dorn, Nirav Patel, Verla Laager, Michael Zile
(1)Baylor Scott And White Research Institute, Dallas, USA (2)University Of Mississippi Medical Center, Jackson, USA

Understanding the influence of protocolized intervention pathway implementation in an ICM-based heart failure risk management trial: Results from ALLEVIATE-HF

Michael Zile (1, 2) , Rami Kahwash, Muhammad Khan, David Zhang, Jonathan Dukes, Madhu Reddy, Anupam Basuray, Elie Gharib, Bart Gerritse, Aimee Laechelt, Jennifer Wehking, Shantanu Sarkar, Brian Van Dorn, Nirav Patel, Verla Laager, Javed Butler
(1)Medical University Of South Carolina, Charleston, USA (2)Ralph H. Johnson Department Of Veterans Affairs Health Care System, USA

A self-adapting machine-learning–based model for accurate diuresis prediction in Acute Heart Failure

Gracjan Iwanek (1, 2), Mateusz Guzik, Oleszczak Amadeusz, Karbowiak Iga, Marciniak Dominik, Pagnesi Matteo, Nuñez Julio, Zymlinski Robert, Ponikowski Piotr, Jan Biegus
(1)Clinical Department Of Intensive Cardiac Care, Department Of Cardiology, Institute Of Heart Diseases, Wroclaw Medical University, Wroclaw, POL (2)Institute Of Heart Diseases, Jan Mikulicz Radecki University Hospital In Wroclaw, POL

Heart Failure with Reduced Ejection Fraction Polypill Implementation Strategy in Sri Lanka: A Multi-Center Type I Hybrid Pilot Randomized Clinical Trial

Anubha Agarwal (1) , Asita De Silva, Mansi Agarwal, Saumiyah Ajanthan, Anuradha Dahanayaka, Rupasvi Dhurjati, Chanaka Fernando, Gamini Galappatthy, Charles Goss, Adam Hively, Pathiyil Jayagopal, Padinhare Mohanan, Anushka Patel, Dorairaj Prabhakaran, Mohamed Rahuman, Anthony Rodgers, Karl Roberts, Hyndavi Salwa, Mark Huffman, Abdul Salam
(1)Division Of Cardiology And Global Health Center, Department Of Medicine, Washington University In St. Louis, St. Louis, USA

Systematic treatment and risk stratification of heart failure with N-terminal pro-b-type natriuretic peptide guided care in diabetes mellitus (STRONG-DM) pilot study

Vinayak Subramanian, Kershaw Patel, Jude Moutchia Suh, Muhammad Shariq Usman, Duwayne Willett, Vaishnavi Kannan, Thomas Wang, Ambarish Pandey (1)Ut Southwestern, Dallas, USA

Recognizing Outpatient Worsening Heart Failure as an Endpoint in Clinical Trials: A Cross-Trial Analysis of Patients with Heart Failure with Mildly Reduced and Preserved Ejection Fraction

Safia Chatur (1), Muthiah Vaduganathan, Brian Claggett, Jonathan Cunningham, Akshay Desai, Jhund Pardeep, Carolyn Lam, Sanjiv Shah, Zannad Faiez, Kieran Docherty, John McMurray, Scott Solomon. Massachusetts General Hospital/Harvard Medical School, Boston, USA

Mode of Death and Preceding Clinical Trajectory in Heart Failure with Reduced Ejection Fraction: From the VICTOR Trial

Stephen Greene (1), Faiez Zannad, Nicole Solomon, Marisa Vico, Scott Mckenzie, Fabiana Marcondes-Braga, Juan Esteban Gómez-Mesa, Justin Ezekowitz, Clara Saldarriaga, Michele Senni, James Udelson, Stefano Corda, Ciaran McMullan, Javed Butler
Duke Clinical Research Institute, Durham, USA

Refining Post-Discharge Heart Failure Management in Complex Real-World Populations: Results of an International Delphi Consensus Project

Alexandre Mebazaa (1), Marianna Adamo, Lisa Anderson, Antoni Bayes Genis, Jan Biegus, Jelena Čelutkienė, Stephen J Greene, Ambarish Pandey, Naoki Sato, Matthew Sunter, Harriette Van Spall, Lea Ricci
Université Paris Cité, Inserm UMR-S 942 (mascot), Paris, FRA; Department Of Anesthesiology And Critical Care And Burn Unit, Saint-Louis And Lariboisière Hospitals Aphp, Paris, FRA

State
Tuesday, December 9, 2025
11:00 -13:00

HYPERTROPHIC CARDIOMYOPATHY TRIALS
Chairpersons: Caroline Coats (Glasgow, UK) & Carolyn Ho (Boston, MA, USA)

Myosin Modulation for Cardiomyopathies

Myosin Modulation: Longer Term Results for Efficacy and Safety
Sara Saberi (Ann Arbor, MI, USA)

Is There a Role for Cardiac Myosin Modulators in Non-Obstructive HCM
Ahmad Masri (Portland, OR, USA)

Beyond Cardiac Myosin Inhibitors: SGLT2 Inhibition, Myosin Modulators, and More
Sharlene Day (Philadelphia, PA, USA)

Do We Need to Demonstrate More Than Improving Feel and Function?
Caroline Coats (Glasgow, UK)

How Much is Enough? What Is Needed to Demonstrate Safety for Novel Medications?
Adam Helms (Ann Arbor, MI, USA)

Industry viewpoints
Robert Blaustein (Edgewise, USA)
Craig Granowitz (Lexicon, USA)
Steve Heitner (Cytokinetics, USA)

Patient viewpoint
Lisa Salberg (HCMA, USA)

Regulatory viewpoints
Charu Gandotra (FDA, USA)
Gabriella Passacquale (AIFA-EMA, ITA)

The CVCT Multi-Stakeholder Think Tank Debate

HYPERTROPHIC CARDIOMYOPATHY TRIALS
WHERE ARE WE GOING AND HOW DO WE GET THERE?
Chairpersons: Caroline Coats (Glasgow, UK) & Carolyn Ho (Boston, MA, USA)

Panelists: Alberto Aimo (Pisa, ITA), Robert Blaustein (Edgewise, USA), Caroline Coats (Glasgow, UK), Sharlene Day (Philadelphia, PA, USA), Charu Gandotra (FDA, USA), Craig Granowitz (Lexicon, USA), Steve Heitner (Cytokinetics, USA), Adam Helms (Ann Arbor, MI, USA), Carolyn Ho (Boston, MA, USA), Nona Jiang (Boston, MA, USA), Ahmad Masri (Portland, OR, USA), Gabriella Passacquale (AIFA-EMA, ITA), Sara Saberi (Ann Arbor, MI, USA), Lisa Salberg (HCMA, USA), Peter-Paul Zwetsloot (Rotterdam, NED)

State
Tuesday, December 9, 2025
14:00 -16:00

NEXT-GENERATION TRIALS IN CARDIAC AMYLOIDOSIS: PREVENTION, PRECISION, AND COMBINATION STRATEGIES

Chairpersons: Marianna Fontana (London, UK) & Ahmad Masri (Portland, OR, USA)

Novel Imaging and Circulating Biomarkers in Cardiac Amyloidosis: Are We Getting Closer?
Sharmila Dorbala (Boston, MA, USA)

Screening-At-Large: Are AI-ECG And AI-Echo Ready to Be Deployed?
Rohan Khera (JAMA, USA)
Carolyn Lam (Singapore, SIN)

Do We Need New Endpoints? How Should Future Amyloid Trials Look Like?
Scott Solomon (Boston, MA, USA)

Active Treatment Vs Observation for Early Disease and Variant Carriers
Esther Gonzalez (Madrid, ESP)

Will We Have Pillars in Amyloid Cardiomyopathy? The Case for Mono Vs Combination Therapy, Residual Unmet Need and the Path Forward
Marianna Fontana (London, UK)

How Do We Conduct Trials of Heart Failure Therapies in Patients Treated for Cardiac Amyloidosis?
Daniela Tomasoni (Brescia, ITA)

Industry viewpoints
Sameer Bansilal (Alnylam, USA), Victor Lopes (Trialmed, Thermofisher, USA), Gillian Murtagh (Bridgebio, USA)

Patients' viewpoint
Isabelle Lousada (Amyloidosis Research Consortium, USA)

The CVCT Multi-Stakeholder Think Tank Debate

CARDIAC AMYLOIDOSIS TRIALS. PROGRESSING TO PREVENTION AND COMBINATION THERAPY TRIALS?

Chairpersons: Marianna Fontana (London, UK) & Ahmad Masri (Portland, OR, USA)

Panelists : Alberto Aimo (Pisa, ITA), Sameer Bansilal (Alnylam, USA), Sharmila Dorbala (Boston, MA, USA), Marianna Fontana (London, UK), Robin Gage (HFSA, USA), Esther Gonzalez (Madrid, ESP), Riccardo Inciardi (Brescia, ITA), Rohan Khera (JAMA, USA), Carolyn Lam (Singapore, SIN), Victor Lopes (Trialmed, Thermofisher, USA), Isabelle Lousada (Amyloidosis Research Consortium, USA), Ahmad Masri (Portland, OR, USA), Gillian Murtagh (Bridgebio, USA), Alexander Peikert (Graz, AUT), Scott Solomon (Boston, MA, USA), Daniela Tomasoni (Brescia, ITA), Peter-Paul Zwetsloot (Rotterdam, NED)

State
Tuesday, December 9, 2025
16:30 -18:30

THE FUTURE OF CHRONIC KIDNEY DISEASE TRIALS
Chairpersons: Jim Januzzi (Boston, MA, USA) & Meg Jardine (Sydney, AUS)

Surrogate Outcomes in CKD Trials Are Necessary and Reliable

Pro
Christoph Wanner (Wurzburg, GER)

Con
Mohammad Shahzeb Khan (Dallas, TX, USA)

Are Hierarchical, Dual and/or Nontraditional Composite Outcomes the Answer?
Niels Jongs (Groningen, NED)

Incorporation of Precision Medicine In Trial Design
Hiddo L Heerspink (Groningen, NED)

Enhancing Feasibility: Novel Approaches to Recruitment and Data Collection
Jim Januzzi (Boston, MA, USA)

How is current RCT evidence informing clinical practice? Challenges and future directions
Janani Rangaswami (Washington, DC, USA)

Industry Viewpoints
Samvel Gasparyan (AstraZeneca, USA)
Thomas Idorn (Novo Nordisk, DEN)
Patrick Schloemer (Bayer, GER)
Bergur Stefansson (Roche, USA)
Dominic Steubl (Boehringer, GER)

Regulatory Viewpoint
Aliza Thompson (FDA, USA)

Patient viewpoint
Patrick Gee (iAdvocate, USA)

The CVCT Multi-Stakeholder Think Tank Debate

THE FUTURE OF CHRONIC KIDNEY DISEASE TRIALS
Chairpersons: Jim Januzzi (Boston, MA, USA) & Meg Jardine (Sydney, AUS)

Panelists: Vince Benn (KBP, USA), Samvel Gasparyan (AstraZeneca, USA), Patrick Gee (iAdvocate, USA), Hiddo L Heerspink (Groningen, NED), Thomas Idorn (Novo Nordisk, DEN), Jim Januzzi (Boston, MA, USA), Meg Jardine (Sydney, AUS), Niels Jongs (Groningen, NED), Mohammad Shahzeb Khan (Dallas, TX, USA), Kaitlin Mayne (Glasgow, UK), Janani Rangaswami (Washington, DC, USA), Juddson Rupp (Charlotte, NC), Patrick Schloemer (Bayer, GER), Bergur Stefansson (Roche, USA), Dominic Steubl (Boehringer, GER), Aliza Thompson (FDA, USA), Christoph Wanner (Wurzburg, GER)

Chinese
Tuesday, December 9, 2025
07:00 -08:30

CVCT-PASCAR joint session
CLINICAL RESEARCH IN AFRICA – MIDDLE EAST
ROADMAP FOR SCALE UP.
Chairpersons: Habib Gamra (Sousse, TUN) & Mpiko Ntsekhe (Cape Town, ZAF)

Introduction
Habib Gamra (PASCAR, Sousse, TUN)

Health priorities and intersections of communicable disease with cardio-kidney-metabolism diseases
Mpiko Ntsekhe (Cape Town, ZAF)

Improving cardiovascular trial-based evidence across race and ethnicity. The case of hypertrophic cardiomyopathy
Ntobeko Ntusi (Cape Town, ZAF)

Moving from global registry collaborations toward expanding clinical research capacity in the Middle East
Sherif Wagdy Ayad (Alexandria, EGY)

Upgrading and harmonizing the regulatory environment in the region.

Toward an African Medical Agency?
Audrey Dindji Kodia (AIRP, CI)

A roadmap to stimulate cardiovascular research in Africa and the Middle East
Habib Gamra (PASCAR, Sousse, TUN)

The WHO viewpoint
TBD

The CROs viewpoints
Chokri Jeribi (ESHMOUN, TUN)

The industry viewpoints
Maturin Tchoumi (Roche, TUN)

The CVCT Multi-Stakeholder Think Tank Debate
AFRICA – MIDDLE EAST IN GLOBAL CLINICAL TRIALS
Chairpersons: Habib Gamra (Sousse, TUN) & Mpiko Ntsekhe (Cape Town, ZAF)

Panelists : Sherif Wagdy Ayad (Alexandria, EGY), Zainab Dakhil (Baghdad, IQ), Habib Gamra (PASCAR, Sousse, TUN), Chokri Jeribi (ESHMOUN, TUN), Audrey Dindji Kodia (AIRP, CI), Mpiko Ntsekhe (Cape Town, ZAF), Ntobeko Ntusi (Cape Town, ZAF), Maturin Tchoumi (Roche, TUN)

Chinese
Tuesday, December 9, 2025
08:30 -10:30

LBCT 3, First Half
Acute Coronary Syndrome
Chairpersons: Tabassome Simon (Paris, FRA), Rasha al Lamee (London, UK)
Panelists: Dan Atar (Oslo, NOR), Peter Rossing (Copenhague, DEN)

Zalunfiban At First Medical Contact In Patients With ST Segment Elevation Myocardial Infarction
Arnoud Van 'T Hof (1), Jim Januzzi, Barry Coller, Gilles Montalescot, Jur Ten Berg, Mike Gibson , Janet Wittes
Maastricht University Medical Center, Maastricht, NED

Early and Late Effects of Potent P2Y12 Inhibitor Monotherapy versus DAPT after PCI in Acute Coronary Syndrome: a Pre-specified 30-day landmark analysis from the NEO-MINDSET trial
Caio A M Tavares (1), Patricia O Guimaraes, Marcelo Franken, Otavio Berwanger, Renato Lopes, Dominick J Angiolillo, Marco Valgimigli, Patrick W J C Serruys (6), Yoshinobu Onuma, Jose Carlos Nicolau, Andrei Sposito, Pedro Lemos
Hospital Israelita Albert Einstein, Sao Paulo, Brazil

The value of extended follow-up in early phase device trials: Long-term outcomes of cardiac shockwave therapy beyond the CAST-HF trial
Felix Naegele (1), Michael Graber, Clemens Engler, Jakob Hirsch, Leo Pölzl, Sophia Schmidt, Agner Mayr, Benjamin Henninger, Felix Troger, Mathias Pamminger, Axel Bauer, Ivan Tancevski, Michael Grimm, John Cooke, Can Gollmann-Tepeköylü, Johannes Holfeld
Medical University of Innsbruck, Innsbruck, AUS

Estimating the real-world treatment effect of TAVR in low-risk patients: A transportability study of the Evolut Low-Risk Trial in the TVT Registry
Neel Butala (1), Christina Lalani, Lichen Liang, Yang Song, David Cohen, Issa Dahabreh, Robert Yeh
Rocky Mountain Regional Va Medical Center, Denver, USA

LBCT 3, Second Half
Lipid / Obesity
Chairpersons: Tabassome Simon (Paris, FRA), Rasha al Lamee (London UK)
Panelists: Dan Atar (Oslo, NOR), Peter Rossing (Copenhague, DEN)

Multi-organ magnetic resonance-based imaging improves risk stratification and optimizes treatment allocation in individuals with clinical obesity
Helena Thomaides Brears (1), Tushy Kailayanathan, Edward Jackson, Iulia Popescu, Thuy Nguyen, Michael Harhay, Amreen Dinani, Mark Muthiah, Melanie Davies, Rajarshi Banerjee, Jaime Almandoz, Lee Kaplan, Amitava Banerjee
Perspectum, Oxford, UK

LDL-C Goal Attainment with Enlicitide, an Oral PCSK9 Inhibitor: Additional Analyses from the Phase 3 CORALreef Lipids and HeFH Trials
AAnn Marie Navar (1) , Alberico L. Catapano, Laura Gellis, Elina Mikhailova, Puja Banka, Emil Andreas Asprusten, Dirk Blom, Alberto Cadena, Norman E. Lepor, Julio Nunez, Russell Scott, Erik S. G. Stroes, Jean-Claude Tardif, Kazuhisa Tsukamoto, Min Zhuo, Geraldine Mendizabal, Susan Kourpanidis (4), Samar Froman, Fan Wang, Wenjuan Zhang, Pengfei Zhu, Christie M. Ballantyne
Department of Medicine, Division of Cardiology, University of Texas Southwestern Medical Center, Dallas, Texas, USA

ION775, an siRNA Targeting APOC3 mRNA: Results of a Phase 1 Study In Participants With Moderate Hypertriglyceridemia
Sotirios Tsimikas (1) , Erin Morgan, Jyoti Sharma, Yiwen Deng, Thomas A Prohaska
Ucsd, La Jolla, USA

The trajectory of heart failure with preserved ejection fraction reflects increasing cardiac fat and loss of atrioventricular coupling and atrial contractility: a UK biobank population study
Tushy Kailayanathan (1), Tom Waddell, Helena Thomaides Brears, Iulia Popescu, Thuy Nguyen, Charlie Diamond, Masliza Mahmod, Rajarshi Banerjee, Dennis Andrea, Jose Vargas, Alexander Miras, Malgorzata Wamil, Shahzeb Khan, Amitava Banerjee, James Januzzi
Perspectum, Oxford, UK

Chinese
Tuesday, December 9, 2025
11:00 -13:00

BREAKTHROUGH DEVICES IN THE US AND EU CONTEXT
Chairpersons: Alan Fraser (Cardiff, UK) & Tom Melvin (Dublin, IRE)

When Is a Device Truly a 'Breakthrough'? First-In-Class, vs. A Refinement of an Existing Technology / Intervention.
Rachel Neubrander (FDA, USA)

How Can Industry Get Regulatory Actionable Relevant Advice to Progress a Device to First Clinical Trial?
In the US
Bram Zuckerman (FDA, USA)

In EU
Bassil Akra (Akra Team, GER)

What Clinical Evidence Is Needed to Approve a Breakthrough Device
Tom Melvin (Dublin, IRE)

What Further Evidence to Be Generated Post Approval.
William Abraham (Columbus, OH, USA)

Regulatory viewpoints

Updates on the FDA/CMS programs Medical Coverage for Innovative Technology (MCIT) and Coverage with Evidence Development (CED)
TBD

What is Needed for Breakthrough Devices Coverage? An EU viewpoint
Alan Fraser (Cardiff, UK)

How Europe is investing in people and methodologies to match regulatory acceleration with sustainable evaluation capacity.
Burçak Aydın (Bruxelles, BEL)

Industry viewpoints
Philip Adamson (CVRx, USA), Rich Dujmovic (Boston Scientific, USA), Christian Hunter (Abbott, USA), Navin Kapur (JnJ, USA)

The CVCT Multi-Stakeholder Think Tank Debate
WHY ARE MANUFACTURERS SEEKING APPROVAL IN THE US FIRST, AND HOW CAN THIS BE CHANGED?
Chairpersons: Alan Fraser (Cardiff, UK) & Tom Melvin (Dublin)

Panelists: William Abraham (Columbus, OH, USA), Philip Adamson (CVRx, USA), Bassil Akra (Akra Team, GER), Burçak Aydın (Bruxelles, BEL), Rich Dujmovic (Boston Scientific, USA), Alan Fraser (Cardiff, UK), Christian Hunter (Abbott, USA), Navin Kapur (JnJ, USA), Tom Melvin (Dublin, IRE), Rachel Neubrander (FDA, USA)

Chinese
Tuesday, December 9, 2025
14:00 -16:00

HOW POTENTIAL OF MENDELIAN RANDOMIZATION MAY BE USEFUL TO CLINICAL TRIALISTS
Chairpersons: Ron Do (New York, NY, USA) & Ruth Frikke-Schmidt (Copenhagen, DEN)

Causal insights of modifiable cardiovascular risk factors for dementia risk – potential for efficient prevention and repurposing of drugs.
Ruth Frikke-Schmidt (Copenhagen, DEN)

Mendelian randomization - drug target and safety examples from CHD and stroke.
James Floyd (Seattle, WA, USA)

Does rare variant discovery aid in the identification of causal pathways for cardiovascular diseases and related disorders?
Ron Do (New York, NY, USA)

Causality of lipoprotein(a) – novel implications for dementia
Pia Kamstrup (Copenhagen, DEN)

Pragmatic use of MR to guide cardiometabolic trial design and target selection
Brian Ference (Ann Arbor, MI, USA)

NIH viewpoint
Veronique Roger (NIH, USA)

Industry viewpoints
Kees Hovingh (Novo Nordisk, DEN), Sekar Kathiresan (Verve Therapeutics, USA)

Patient viewpoint:
Jillianne Code (HeartLife, CAN)

The CVCT Multi-Stakeholder Think Tank Debate

HOW POTENTIAL OF MENDELIAN RANDOMIZATION MAY BE USEFUL TO CLINICAL TRIALISTS
Chairpersons: Ron Do (New York, NY, USA) & Ruth Frikke-Schmidt (Copenhagen, DEN)

Panelists : Jillianne Code (HeartLife, CAN), Ron Do (New York, NY, USA), Brian Ference (Ann Arbor; MI, USA), James Floyd (Seattle, WA, USA), Ruth Frikke-Schmidt (Copenhagen, DEN), Kees Hovingh (Novo Nordisk, DEN), Pia Kamstrup (Copenhagen, DEN), Sekar Kathiresan (Verve, USA), Greg Merritt (Patient Is Partner, Brighton, USA), Caius Mersa (Romanian Heart Foundation, RO), Veronique Roger (NIH, USA)

Chinese
Tuesday, December 9, 2025
16:30 -18:30

GENE-BASED CARDIAC THERAPY. PART 1.
THE BASICS. WHAT IT NEEDS TO GET INTO CLINICAL STAGE?
Chairpersons: Barry Greenberg (San Diego, CA, USA) & Yuri Kim (Boston, MA, USA)

Understanding Disease Pathophysiology to Unlock Novel Gene-Based Drug Target Opportunities
Victoria Parikh (Stanford, CA, USA)

What Advancements in Molecular Genetic Tools May Transform Cardiovascular Gene-Based Therapies?
Yuri Kim (Boston, MA, USA)

Genetic testing for the identification of target patient population for gene-based therapies
Megan Sutton (Everygene, USA)

Will Pharmacological Testing Based on Human Engineered Tissue for IND And Fast Track Designation Become the Rule, Post Modernization Act 3.0?
Kevin Costa (New York, NY, USA)
Jordan Pomeroy (FDA, USA)

Vector Related Innovations. What is in the Pipeline
Faraz Ali (Tenaya, USA)
Aravind Asokan (Durham, NC, USA)
Gabriel Brooks (Solid Biosenses, USA)

Seroprevalence, Addressing Neutralizing Antibodies, Redosing in Cardiac Gene Therapy.
Nicholas Giovannone (Regeneron, USA)

No Testing for Neutralizing Antibodies? The GENEPHIT Trial
Lothar Roessig (AsKBio, USA)

Industry viewpoints
Greg Aubert (LexeoTx, USA)

Regulatory viewpoint
Erica Young (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

Gene-Based Cardiac Therapy. Part 1.
WHAT IT NEEDS TO GET GENE THERAPY INNOVATIONS INTO CLINICAL STAGE?
Chairpersons: Barry Greenberg (San Diego, CA, USA) & Yuri Kim (Boston, MA, USA)

Panelists: Faraz Ali (Tenaya, USA), Aravind Asokan (Durham, NC, USA), Greg Aubert (LexeoTx, USA), Gabriel Brooks (Solid Bio, USA), Kevin Costa (New York, NY, USA), Nicholas Giovannone (Regeneron, USA), Barry Greenberg (San Diego, CA, USA), Yuri Kim (Boston, MA, USA), Victoria Parikh (Stanford, CA, USA), Jordan Pomeroy (FDA, USA), Lothar Roessig (AsKBio, USA), Megan Sutton (Everygene, USA), Erica Young (FDA, USA)

Palm court
Wednesday, December 10, 2025
07:30 -10:30

TRIALS OF INCRETIN-BASED WEIGHT MANAGEMENT MEDICINES. LEARNINGS AND OPPORTUNITIES

Part 1: LESSONS FROM RECENT AND ONGOING TRIALS

Chairpersons: Ildiko Lingvay (Dallas, TX, USA) & Donna Ryan (Baton Rouge, USA)

CKM benefits of weight loss medicines: the result of weight loss or direct effects
Naveed Sattar (Glasgow, UK)

SURPASS CVOT: major findings
Michael Lincoff (Cleveland, OH, USA)

Ongoing trials in CKM area: what more can we learn?
Darren McGuire (Dallas, TX, USA)

Will incretin-based medicines have any legacy benefits?
Donna Ryan (Baton Rouge, LA, USA)

Industry viewpoints
Filip Knop (NovoNordisk, DEN), Odd Erik Johansen (Roche, USA), Ofri Mosenzon (Regeneron, USA)

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

The CVCT Multi-Stakeholder Think Tank Debate

WHAT DO WE KNOW AND WHERE ARE THE GAPS ON UNDERSTANDING OBESITY-CV LINKS

Chairpersons: Ildiko Lingvay (Dallas, TX, USA) & Donna Ryan (Baton Rouge, LA, USA)

Panelists : Nick Hartshorne-Evans (Pumping Marvellous, UK), Ania Jastreboff (New Haven, CT, USA), Odd Erik Johansen (Roche, USA), Filip Knop (NovoNordisk, DEN), Michael Lincoff (Cleveland, USA) , Ildiko Lingvay (Dallas, TX, USA), Darren McGuire (Dallas, TX, USA), Ofri Mosenzon (Regeneron, USA), Alexander Peikert (Graz, AUT), Donna Ryan (Baton Rouge, USA), Jennifer Sargent (Metabologia, USA), Naveed Sattar (Glasgow, UK)

Palm court
Wednesday, December 10, 2025
07:30 -10:30

TRIALS OF INCRETIN-BASED WEIGHT MANAGEMENT MEDICINES. LEARNINGS AND OPPORTUNITIES

Part 2 : WEIGHT LOSS AND MUSCLE HEALTH: HYPE OR HOPE?

Chairpersons: Ildiko Lingvay (Dallas, TX, USA) & Donna Ryan (Baton Rouge, LA, USA)

Weight loss-induced muscle mass loss - Any reason for concern?
Ania Jastreboff (New Haven, CT, USA)

Muscle function is unaltered with weight loss
Naveed Sattar (Glasgow, UK)

Ongoing trials with muscle sparing or muscle stimulating agents
Donna Ryan (Baton Rouge, LA, USA)

Industry perspectives
Robert Beardsley (Cirrus Therapeutic, USA), Mathijs Bunck (Lilly, USA), Pernille Auerbach (NovoNordisk, DEN)

Regulatory perspectives
Raymond Soccio (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

MUSCLE SPARING/BUILDING AGENTS DURING WEIGHT LOSS: A “NEED” OR A “WANT”? SHOULD CERTAIN POPULATION BE TARGETED? WHAT’S THE POTENTIAL FOR ABUSE OR HARM?

Chairpersons: Ildiko Lingvay (Dallas, TX, USA) & Donna Ryan (Baton Rouge, LA, USA)

Panelists : Pernille Auerbach (NovoNordisk, DEN), Robert Beardsley (Cirrus Therapeutic, USA), Mathijs Bunck (Lilly, USA), Ania Jastreboff (New Haven, CT, USA), Filip Knop (NovoNordisk, DEN), Mikhail Kosiborod (AstraZeneca, USA), Michael Lincoff (Cleveland, USA), Ildiko Lingvay (Dallas, TX, USA), Alexander Peikert (Graz, AUT), Donna Ryan (Baton Rouge, LA, USA), Jennifer Sargent (Metabologia, USA), Naveed Sattar (Glasgow, UK), Raymond Soccio (FDA, USA)

Palm court
Wednesday, December 10, 2025
11:00 -13:00

OBESITY CARDIO-KIDNEY-METABOLISM TRIALS
Chairpersons: Ania Jastreboff (New Haven, CT, USA) & Naveed Sattar (Glasgow, UK)

Do we need CVOT for all future weight loss agents?
TBD

The ethics and scientific value of placebo-controlled trials. Should comparative effectiveness trials replace placebo-controlled trials, or should they at least be required?
Peter Juni (Oxford, UK)

The ethics of abrupt drug withdrawal at the trial termination
Jaime Almandoz (Dallas, TX, USA)

The ethics of fair allocation of incretin-based therapies
Harald Schmidt (Philadelphia, PA, USA)

Is weight regaining (after achieving weight loss plateau) an approvable indication in itself?
Ildiko Lingvay (Dallas, TX, USA)

Patient's viewpoint
Steven Macari (AVEC, France)

Primary care viewpoint
Naresh Kanumilli (Manchester, UK)

Industry viewpoints
Kees Hovingh (Novo Nordisk, DEN), Mathijs Bunck (Lilly, USA), Odd Erik Johansen (Roche, USA), Elena Startseva (Boehringer, GER)

Regulatory viewpoints
Raymond Soccio (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate
ALIGNING REGULATORY REQUIREMENTS TO CLINICAL NEEDS.
Chairpersons: Ania Jastreboff (New Haven, CT, USA) & Naveed Sattar (Glasgow, UK)

Panelists: Jaime Almandoz (Dalllas, TX, USA), Mathijs Bunck (Lilly, USA), Patrick Gee (iAdvocate, USA), Kees Hovingh (Novo Nordisk, DEN), Ania Jastreboff (New Haven, CT, USA), Odd Erik Johansen (Roche, USA), Peter Juni (Oxford, UK), Naresh Kanumilli (Manchester, UK), Ildiko Lingvay (Dallas, TX, USA), Steven Macari (AVEC, France), Kaitlin Mayne (Glasgow, UK), Naveed Sattar (Glasgow, UK), Harald Schmidt (Philadelphia, PA, USA), Raymond Soccio (FDA, USA), Elena Startseva (Boehringer, GER)

Palm court
Wednesday, December 10, 2025
14:00 -16:00

REGULATORY STUDIES OF DEVICES DESIGNED TO TREAT HEART FAILURE
Chairpersons: Biykem Bozkurt (Houston, TX, USA) & David Lanfear (Detroit, MI, USA)

Introduction: A Diverse Array of Devices for a Diverse Spectrum of Patients with Heart Failure
Daniel Burkhoff (New York, NY, USA)

The Breakthrough Designation
How The Breakthrough Designation Has Helped Device Development in the US
William Abraham (Columbus, OH, USA)

Challenges Faced by Devices Approved Through the Breakthrough Designation Pathway
Philip Adamson (CVRx, USA)

The Total Product Life Cycle Advisory Program (TAP) Program: Improving the Likelihood of Success to Commercialization.
Evan Walrath (FDA, USA)

Experience In Recent Studies of Devices for Heart Failure: V-Wave, Corvia, TRILUMINATE, TRISCED
Sheldon Litwin (Charleston, SC, USA)
Gregg Stone (New York, NY, USA)

Re-exploring the role of surrogate endpoints in clinical trials for regulatory approvals: TR reduction, BNP, EF, EDV, pVO2, Exercise PCWP
Michael Zile (Charleston, SC, USA)

Regulatory viewpoint
Evan Walrath (FDA, USA)

How guideline committees consider devices that show improvements in PROs without evidence of improvements of heart failure events or mortality
John Spertus (Kansas City, MO, USA)

The CVCT Multi-Stakeholder Think Tank Debate

THE PATH FOR APPROVAL AND ADOPTION OF HEART FAILURE DEVICES
Chairpersons: Biykem Bozkurt (Houston, TX, USA) & David Lanfear (Detroit, MI, USA)

Panelists: William Abraham (Columbus, OH, USA), Philip Adamson (CVRx, USA), Biykem Bozkurt (Houston, TX, USA), Daniel Burkhoff (New York, NY, USA), Margaret Infeld (Boston, MA, USA), David Lanfear (Detroit, MI, USA), Sheldon Litwin (Charleston, SC, USA), Ileana Piña (FDA, USA), Jennifer Sargent (Metabologia, USA), John Spertus (Kansas City, MO, USA), Gregg Stone (New York, NY, USA), Frances Varian (Sheffield, UK), Evan Walrath (FDA, USA), Michael Zile (Charleston, SC, USA), Bram Zuckerman (FDA, USA)

Palm court
Wednesday, December 10, 2025
16:30 -18:30

HEART FAILURE WITH REDUCED EJECTION FRACTION – ARE WE DONE?
Chairpersons: Johannes Bauersachs (Hannover, GER) & Ileana Piña (FDA, USA)

Vericiguat - How to interpret the totality of evidence from VICTOR and VICTORIA?

Mortality results
Javed Butler (Dallas, TX, USA)

Heart Failure Hospitalization results
Faiez Zannad (Paris, FRA)

Journal Editor viewpoint
Flavia Geraldes (The Lancet)

Role of vericiguat in management of HFrEF
Biykem Bozkurt (Houston, TX, USA)

Network meta-analysis of all HFrEF trials
Jasper Tromp (Singapore, SIN)

Regulatory viewpoint
Charu Gandotra (FDA, USA)

Digitalis. Here to stay?
Johannes Bauersachs (Hannover, GER)

Next positive trial in HFrEF – does it have to be 5th or 6th after months (years!) of attempts with the first 4-5?
Michele Senni (Bergamo, ITA)

Industry viewpoints
Stefano Corda (Bayer, GER), Jyothis George (NodThera, USA), Stuart Kupfer (Cytokinetics, USA), Ciaran McMullan (Merck, USA)

The CVCT Multi-Stakeholder Think Tank Debate

HEART FAILURE WITH REDUCED EJECTION FRACTION – THE TOTALITY OF EVIDENCE
Chairpersons: Johannes Bauersachs (Hannover, GER) & Ileana Piña (FDA, USA)

Panelists: Johannes Bauersachs (Hannover, GER), Biykem Bozkurt (Houston, TX, USA), Javed Butler (Dallas, TX, USA), Jawad H Butt (Copenhagen, DEN), Stefano Corda (Bayer, GER), Robin Gage (HFSA, USA), Charu Gandotra (FDA, USA), Flavia Geraldes (The Lancet), Jyothis George (NodThera, USA), Stuart Kupfer (Cytokinetics, USA), Francesca Lawson (Corteria, USA), Ciaran McMullan (Merck, USA), , Caius Mersa (Romanian Heart Foundation, RO), Ileana Piña (FDA, USA), Michele Senni (Bergamo, ITA), Jasper Tromp (Singapore, SIN), Faiez Zannad (Paris, FRA)

East
Wednesday, December 10, 2025
07:30 -10:30

CHOLESTEROL LOWERING THERAPIES TRIALS
Chairpersons: Marc Sabatine (Boston, MA, USA) & Lale Tokgözoğlu (Ankara, TR)

PCSK9 inhibition with RNA inhibitors: Solving barriers to access
Lale Tokgözoğlu (Ankara, TR)

Oral PCSK9 inhibitors – What evidence is necessary for regulatory approval based on multiple successful outcomes with injectables?
Marc Sabatine (Boston, MA, USA), Per Johanson (Astrazeneca, SWE)

Challenges in retention of study participants enrolled into placebo-controlled trials of novel PCSK9 inhibitor therapy
Gregory Schwartz (Denver, CO, USA)

Gene Editing for PCSK9 and ANGPTL3 –Next steps for regulatory approval

Towards a one dose future for treatment of hyperlipidemia: targeting of PCSK9, ANGPTL3, and LPA with in vivo gene editing
Sek Kathiresan (Verve Therapeutics, USA)

CETP Inhibitors – What lessons can we learn from past failures within the class?
Liam Brunham (Vancouver, CA)

Multi-platform Oral therapies
David Rosenbaum (Astrazeneca, USA)

Multi-targeted RNA platforms – designing trials with multiple targets
Alex dePaoli (Rona Therapeutics, USA)

From mechanism to global registration: Navigating cardiovascular/metabolic trials in the era of RNA-based therapies
Anastasia Lesogor (Novartis, USA)

Impact of treatment adherence and persistence to LDL-C lowering therapies on cardiovascular events – The KOMODO Study
Robert Rosenson (New York, NY, USA)

What is the impact of novel cholesterol lowering therapies on health disparities?
Karol Watson (Los Angeles, CA, USA)

Patient viewpoint
Michelle Watts (FH Europe Foundation, USA)

Regulatory viewpoint
John Sharretts (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

CHOLESTEROL LOWERING THERAPIES TRIALS
Chairpersons: Marc Sabatine (Boston, MA, USA) & Lale Tokgözoğlu (Ankara, TR)

Panelists: Liam Brunham (Vancouver, CA), Alex dePaoli (Rona Therapeutics, USA), Per Johanson (Astrazeneca, SWE), Anastasia Lesogor (Novartis, USA), Juddson Rupp (Charlotte, NC), David Rosenbaum (Astrazeneca, USA),Marc Sabatine (Boston, MA, USA), Gregory Schwartz (Denver, CO, USA), John Sharretts (FDA, USA), Lale Tokgözoğlu (Ankara, TR), Scott Vafai (Verve Therapeutics, USA), Karol Watson (Los Angeles, CA, USA), Michelle Watts (FH Europe Foundation, USA), Jie Zeng (Rona Therapeutics, USA)

East
Wednesday, December 10, 2025
11:00 -13:00

TARGETING LIPOPROTEIN(A) MECHANISMS FOR RISK ASSESSMENT
Chairpersons: Michelle O'Donoghue (Boston, MA, USA) & Robert Rosenson (New York, NY, USA)

Introduction - Overview
Design considerations for primary prevention of cardiovascular events with selective Lp (a) inhibitors
Robert Rosenson (New York, NY, USA)

How to incorporate conventional risk factors into the design of primary prevention trials?
Anne Marie Navar (Dallas, TX, USA)
Michelle O'Donoghue (Boston, MA, USA)

Harnessing real world data on Lp(a) for trial design and more efficient trial recruitment.
Paul Muntner (Birmingham, AL, USA)

How to incorporate genetic profiling into the design of primary prevention trials?
Pia Kamstrup (Copenhagen, DEN)

How to incorporate atherosclerosis imaging into the design of primary prevention trials?
Leslee Shaw New York, NY, USA)

Lipoprotein (a) triggered immunothrombosis: Time for an ACS trial?
Sascha Goonewardena (Ann Arbor, MI, USA)

Industry Viewpoints
Angie Bethel (Lilly,USA), David Bühlmann (Roche, USA) Jason Duran (CRISPER Therapeutics, USA)
Sam Tsimikas (Ionis, USA)

Regulatory Viewpoints
Milou-Daniel Drici (ANSM, FRA)
Fortunate Senatore (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

TARGETING LIPOPROTEIN(A) MECHANISMS FOR RISK ASSESSMENT
Chairpersons: Michelle O'Donoghue (Boston, MA, USA) & Robert Rosenson (New York, NY, USA)

Panelists: David Bühlmann (Roche, USA), Angie Bethel (Lilly,USA), Milou-Daniel Drici (ANSM, FRA), Sascha Goonewardena (Ann Arbor, MI, USA), Pia Kamstrup (Copenhagen, DEN), Paul Muntner (Birmingham, AL, USA), Anne Marie Navar (Dallas, TX, USA), Michelle O'Donoghue (Boston, MA, USA), Robert Rosenson (New York, NY, USA) Fortunate Senatore (FDA, USA), Leslee Shaw New York, NY, USA), Sam Tsimikas (Ionis, USA)

East
Wednesday, December 10, 2025
14:00 -16:00

TRIGLYCERIDE RICH LIPOPROTEIN TRIALS
Chairpersons: Sander Kersten (Wageningen, NED) & Anders Berg Wulff (Copenhagen, DEN)

Overview of session

Genetic prioritization of drug targets for cardiometabolic diseases
Ron Do (New York, NY, USA)

Genetic epidemiology – How does genetic epidemiology impact design of clinical trials?
Sekar Kathiresan (Verve Therapeutics, USA)

Apolipoprotein C3 Inhibitors: Targeting multiple diseases in severe hypertriglyceridemia
Nicholas A. Marston (Boston, MA, USA)

ANGPTL4 inhibitors and the rationale for the prevention of cardiovascular events
Sander Kersten (Wageningen, NED)

ANGPTL3 inhibitors: The path for approval – moving beyond orphan indications
Robert Rosenson (New York, NY, USA)
Giacomo Ruotolo (Lilly, USA)
Jennifer Hellawell (Arrowhead, USA)

Industry viewpoints
Alex M. DePaoli (Rona Therapeutics, USA), Jennifer Hellawell (Arrowhead, USA), Rebecca Juliano (Marea, USA), Sam Tsimikas (Ionis, USA)

Regulatory viewpoint
Eileen Craig (FDA, USA)

Patient viewpoint
Scott Reavis (National Pancreas Foundation, USA)

The CVCT Multi-Stakeholder Think Tank Debate

TRIGLYCERIDE RICH LIPOPROTEIN TRIALS
Chairpersons: Sander Kersten (Wageningen, NED) & Anders Berg Wulff (Copenhagen, DEN)

Panelists: Eileen Craig (FDA, USA), Alex M. DePaoli (Rona Therapeutics, USA), Ron Do (New York, NY, USA), Robin Gage (HFSA, USA), Jennifer Hellawell (Pasadena, CA, USA), Rebecca Juliano (Marea, USA), Sekar Kathiresan (Verve Therapeutics, USA), Sander Kersten (Wageningen, NED) , Nicholas A. Marston (Boston, MA, USA), Scott Reavis (National Pancreas Foundation, USA), Robert Rosenson (New York, NY, USA), Giacomo Ruotolo (Lilly, USA), Sam Tsimikas (Ionis, USA), Anders Berg Wulff (Copenhagen, DEN)

East
Wednesday, December 10, 2025
16:30 -18:30

iCVCT - THROMBOSIS TRIALS

Chairpersons: Michael Gibson (Boston, MA, USA) & Vijay Kunadian (Newcastle upon Tyne, UK)

Is it time to revise the primary outcome in atrial fibrillation? Should Intra Cerebral Hemorrhage and ischemic stroke be considered separately?
Michael Gibson (Boston, MA, USA)

Atrial fibrillation, brain health and cognition: existing data and much needed RCTs
Edip Gurol (Boston, USA)

Should infarct size be considered part of a primary endpoint in STEMI Trials?
Gregg Stone (New York, NY, USA)

Standardizing weighting of ischemic and bleeding endpoints.
Has bleeding been given undue emphasis over efficacy endpoints?
Christian Ruff (Boston, MA, USA)

Should patient preferences with respect to bleeding and ischemic endpoints be incorporated in trials?
Mellanie True Hills (Stop AFib, USA)

Should different standards or hierarchies of endpoints be applied to Drug vs Device Trials in the Thrombosis Space or should endpoints be the same?
Jordan Pomeroy (FDA, USA)

Industry viewpoint
Janssen Ellen (J&J, USA)

Pre-Hospital MI trials: CELEBRATE Zalunfiban trial
Michael Gibson (Boston, MA, USA)

Statistician viewpoint
Jan Tijssen (Brussels, BEL)

NIH viewpoint
Ahmed Hasan (NHLBI, USA)

Industry viewpoints
Robert Hillman (Celecor, USA), Dmitry Gryaznov (Viatris, USA)

Regulatory viewpoint
Fortunate Senatore (FDA, USA)

The iCVCT Multi-Stakeholder Think Tank Debate

THROMBOSIS TRIALS – HOW TO TACKLE THE BENEFIT / RISK EQUATION

Chairpersons Michael Gibson (Boston, MA, USA) & Vijay Kunadian (Newcastle upon Tyne, UK)

Panelists : Rishi Chandiramani (Baltimore, MA, USA), Michael Gibson (Boston, MA, USA), Dmitry Gryaznov (Viatris, USA), Edip Gurol (Boston, USA),Ahmed Hasan (NHLBI, USA), Robert Hillman (Celecor, USA), Vijay Kunadian (Newcastle upon Tyne, UK), Janssen Ellen (J&J, USA), Jordan Pomeroy (FDA, USA), Fortunate Senatore (FDA, USA), Jan Tijssen (Brussels, BEL), Christian Ruff (Boston, MA, USA), Gregg Stone (New York, NY, USA), Mellanie True Hills (Stop AFib, USA)

State
Wednesday, December 10, 2025
07:30 -10:00

EVOLUTION OF NEW THERAPIES FOR HYPERTENSION
WHAT IS THEIR PLACE IN MODERN TREATMENT STRATEGIES?
Chairpersons: Katherine Tuttle (Seattle, WA, USA) & Bryan Williams (London, UK)

Aldosterone emerging from the shadows in hypertension
New Endocrine society guidelines – implications for future hypertension trials
Rhian Touyz (Montréal, CAN)

Aldosterone dysregulation – implications for new treatments targeting aldosterone
Jenifer Brown (Boston, MA, USA)

Advances in aldosterone imaging with PET-CT
Erik Arstad (London, UK)

Aldosterone Synthase Inhibitors (ASIs) – Overview of Lorundrostat hypertension trials
Luke Laffin (Cleveland, OH, USA)

ASIs – Overview of Baxdrostat hypertension trials
Bryan Williams (London, UK)

ASIs – Trials of ASI combination with SGLT2is
Katherine Tuttle (Seattle, WA, USA)

Novel MRAs; their role in hypertension along or in combination with ASIs?
Michel Azizi (Paris, FRA)

Are all MRAs alike? The issue of differentiation among MRAs
Bertram Pitt (Ann Arbor, USA)

Targeting the renin angiotensin system with small interfering RNA for hypertension
Review of the Kardia trials programme with Zilebesiran
Christopher Granger (Durham, NC, USA)

Development programme of other siRNA compounds for hypertension
Michael Weber (New York, NY, USA)

Targeting the Natriuretic Peptide system for the treatment of Hypertension

Developments in targeting the natriuretic peptide system for hypertension
John Burnett (Rochester, MN, USA)

How to position novel therapies in the hierarchy of treatment versus established generic treatments for hypertension
Industry viewpoints
Martine Clozel (Idorsia, CH), Tomasz Gasior (Boehringer, GER), Christopher O'Donnell (Novartis, USA), Shira PerL (Astrazeneca, USA)

Regulatory viewpoint
Austin Hu (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

NEW THERAPIES FOR HYPERTENSION. HOW TO ASSESS? HOW TO POSITION?
Chairpersons: Katherine Tuttle (Seattle, WA, USA) & Bryan Williams (London, UK)

Panelists: Erik Arstad, (London, UK), Michel Azizi (Paris, FRA), Vince Benn (KBP, USA), Jenifer Brown (Boston, MA, USA), John Burnett (Rochester, MN, USA), Martine Clozel (Idorsia, CH), Christopher Granger (Durham, NC, USA), Tomasz Gasior (Boehringer, GER), Austin Hu (FDA, USA), Luke Laffin (Cleveland, OH, USA), Christopher O'Donnell (Novartis, USA), Shira PerL (Astrazeneca, USA), Bertram Pitt (Ann Arbor, USA), Rhian Touyz (Montréal, CAN), Katherine Tuttle (Seattle, WA, USA), Michael Weber (New York, NY, USA), Bryan Williams (London, UK)

State
Wednesday, December 10, 2025
11:00 -13:00

GENERATIVE ARTIFICIAL INTELLIGENCE-ENABLED FUTURE OF CARDIOVASCULAR CLINICAL TRIALS
Chairpersons: Folkert Asselbergs (EHJ, NED) & Rohan Khera (JAMA, USA)

Large Language Models for smart clinical trial patient matching
Alexander Blood (Boston, MA, USA)

Clinical outcome assessment using generative AI. Input from eCOA provider
Pamela Tenaerts (Medable, Inc, USA)

Clinical outcome assessment using generative AI. Clinical trialist views.
Jonathan Cunningham (Boston, MA, USA)

Evaluating and Monitoring Health AI tools.
Sneha S Jain (Stanford, CA, USA)

Generative AI for better patient engagement and trial dissemination
Adrian Hernandez (Durham, NC, USA)

Uncovering rare cardiovascular disorders using generative AI applications for the EHR
Evangelos Oikonomou (EHJ, USA)

AI industry Viewpoints: Generating high-fidelity synthetic controls for accelerating clinical trial procedures
Maxime Touzot (Owkin, FRA)

Industry viewpoint on generative AI in clinical research
John Whang (BridgeBio, USA)

Regulatory viewpoint on the role of generative AI in trial design and patient care
Anindita Saha (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate

ARTIFICIAL INTELLIGENCE ENABLING CLINICAL TRIALS
Chairpersons: Folkert Asselbergs (EHJ, NED) & Rohan Khera (JAMA, USA)

Panelists: Sadegh Alikhaani (Los Angeles, CA, USA), Folkert Asselbergs (EHJ, NED), Alexander Blood (Boston, MA, USA), Jonathan Cunningham (Boston, MA, USA), Adrian Hernandez (Durham, NC, USA), Sneha S Jain (Stanford, CA, USA), Rohan Khera (JAMA, USA), Rhonda Monroe (Charlotte, NC, USA), Evangelos Oikonomou (EHJ, USA), Annie Saha (FDA, USA), Pamela Tenaerts (Medable, Inc, USA), Maxime Touzot (Owkin, FRA), John Whang (BridgeBio, USA)

State
Wednesday, December 10, 2025
14:00 -16:00

iCVCT
CLINICAL TRIALS IN STRUCTURAL HEART INTERVENTIONS: CHALLENGES AND OPPORTUNITIES
Chairpersons: David Cohen (Boston, MA, USA) & Sanjay Kaul (Los Angeles, CA, USA)

PART I: HEALTH STATUS AS AN ENDPOINT FOR STRUCTURAL HEART DISEASE

Responder Analyses are useful and essential for interpretation
John Spertus (Kansas City, MO, USA)

Responder Analyses are unnecessary and misleading
Peter Juni (Oxford, UK)

Placebo-Controlled Trials in Valvular Interventions

Placebo-controlled trials of transcatheter valve therapies are more essential than ever
Roxana Mehran (New York, NY, USA)

Placebo-controlled trials of transcatheter valve interventions are ideal, but they are neither practical nor feasible
Jamie McCabe (Rochester, NY, USA)

Regulatory Viewpoints
Changfu Wu (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Debate
ENDPOINTS IN STRUCTURAL HEART TRIALS
Chairpersons: David Cohen (Boston, MA, USA) & Sanjay Kaul (Los Angeles, CA, USA)

Panelists: Rasha Al Lamee (London, UK), David Cohen (Boston, MA, USA), Peter Juni (Oxford, UK), Samir Kapadia (Cleveland, OH, USA), Aaron Kaplan (Lebanon, NH, USA), Sanjay Kaul (Los Angeles, CA, USA), Alexandra Lansky (New Haven, CT, USA), Martin Leon (New York, NY, USA), Stuart Pocock (London, UK), Roxana Mehran (New York, NY, USA), Sam Raben (FDA, USA), Toby Rogers (Bethesda, MD, USA), , John Spertus (Kansas City, MO, USA)), Changfu Wu (FDA, USA)

State
Wednesday, December 10, 2025
14:00 -16:00

iCVCT
CLINICAL TRIALS IN STRUCTURAL HEART INTERVENTIONS: CHALLENGES AND OPPORTUNITIES
Chairpersons: David Cohen (Boston, MA, USA) & Sanjay Kaul (Los Angeles, CA, USA)

PART II: CONTROVERSIES IN CLINICAL TRIAL DESIGN AND USE OF REAL-WORLD EVIDENCE FOR STRUCTURAL HEART INTERVENTIONS

Crossover in Regulatory/Device Approval Trials—When and How Should it be Allowed?
Stuart Pocock (London, UK)

Surrogates vs. Outcomes in Cerebral Protection: The Sentinel Saga
Samir Kapadia (Cleveland, OH, USA)

Surrogate Outcomes are the Only Way Forward
Alexandra Lansky (New Haven, CT, USA)

Evaluating Leaflet Modification Devices: Who Needs a Control Group?
Toby Rogers (Bethesda, MD, USA)

Surrogates aren't enough: Outcomes are all that Matter
Sanjay Kaul (Los Angeles, CA, USA)

Outcomes trials are a fantasy: The entrepreneur's perspective
Aaron Kaplan (Lebanon, NH, USA)

Regulatory Viewpoints
Mark Da Costa (TUV Sud, IRE)

The iCVCT Multi-Stakeholder Think Tank Debate
HOW TO SECURE EVIDENCE BASED STRUCTURAL HEART INTERVENTIONS
Chairpersons: David Cohen (Boston, MA, USA) & Sanjay Kaul (Los Angeles, CA, USA)

Panelists: Rasha Al Lamee (London, UK), Javed Butler (Boston, MA, USA), Rishi Chandiramani (Baltimore, MA, USA), David Cohen (Boston, MA, USA), Mark Da Costa (TUV Sud, IRE), Samir Kapadia (Cleveland, OH, USA), Aaron Kaplan (Lebanon, NH, USA), Sanjay Kaul (Los Angeles, CA, USA), Alexandra Lansky (New Haven, CT, USA), Jamie McCabe (Rochester, NY, USA) , Stuart Pocock (London, UK), Toby Rogers (Bethesda, MD, USA)

State
Wednesday, December 10, 2025
16:30 -18:30

CONTEMPORARY CHRONIC KIDNEY DISEASE TRIALS CRITICAL APPRAISAL

Chairpersons: Jennifer Green (Durham, NC, USA) & TBD

Clinical Trials Update in Diabetes and Chronic Kidney Disease

Targeting The Mineralocorticoid Pathway
Peter Rossing (Copenhague, DEN)

Endothelin Receptor Antagonism
Jennifer Green (Durham, NC, USA)

GLP-1 Receptor Agonism (SURPASS CVOT; SOUL Updates)
Darren McGuire (Dallas, TX, USA)

Anti-Inflammatory Targeted Therapies (FRONTIER; TNF Alpha, PUFA)
Paul Ridker (Boston, MA, USA)

Issues In Contemporary Clinical Trials Design

What Is The Expected Standard Of Care In Trials Of CKD? Are Placebo Controls Still Appropriate?
Brendon Neuen (Sydney, AUS)

Should combinations of therapies for CKD be specifically tested in clinical trials?
TBD

Statistical viewpoint
Frank Rockhold (Durham, NC, USA)

Industry Viewpoints
Mathijs Bunck (Eli Lilly, USA)
Meike Brinker (Bayer, GER)
Anissa Lamarque (Olink, SWE)

Regulatory Viewpoints
Rekha Kambhampati (FDA, USA)

Patients' Viewpoint
Patrick Gee (iAdvocate, USA)

The CVCT Multi-Stakeholder Think Tank Debate

CONTEMPORARY CHRONIC KIDNEY DISEASE CRITICAL APPRAISAL

Chairpersons: Jennifer Green (Durham, USA) & TBD

Panelists : Meike Brinker (Bayer, GER), Mathijs Bunck (Eli Lilly, USA), Patrick Gee (iAdvocate, USA), Jennifer Green (Durham, NC, USA), Hiddo L Heerspink (Groningen, NED), Thomas Idorn (Novo Nordisk, DEN), Meg Jardine (Sydney, AUS), Anissa Lamarque (Olink, SWE), Darren McGuire (Dallas, TX, USA), Kaitlin Mayne (Glasgow, UK), Brendon Neuen (Sydney, AUS), Paul Ridker (Boston, MA, USA), Frank Rockhold (Durham, NC, USA), Peter Rossing (Copenhague, DEN), Naveed Sattar (Glasgow, UK), Marvin Sinsakul (AstraZeneca, USA), Aliza Thompson (FDA, USA)

Chinese
Wednesday, December 10, 2025
07:30 -10:30

GENE-BASED CARDIAC THERAPY.
PART 2. THE TRIALS AND BEYOND
Chairpersons: Roger Hajjar (Boston, MA, USA) & Silvia Priori (Pavia, ITA)

Who should be targeted for gene therapy?
Roger Hajjar (Boston, MA, USA)

Rare Cardiomyopathies and cardio-neuro diseases (HCM, Danon, Friedrich Ataxia). :
Iacopo Olivotto (Florence, ITA)

Industry viewpoint :
Eric Adler (Lexeo Therapeutics, USA)

Pre-Clinical development of a gene-therapy strategy for patients with catecholaminergic polymorphic Ventricular Tachycardi
Silvia Priori (Pavia, ITA)

Industry viewpoint :
Gabriel Brooks (Solid Biosenses, USA)

Heart failure.

HFrEF :
Barry Greenberg (San Diego, CA, USA)

HFpEF :
Marat Fudim (Durham, NC, USA)

Non-Ischemic Cardiomyopathy :
Luke Roberts (AskBio, GER)

DMD Cardiomyopathy :
Pradeep Mammen (Kansas City, MO, USA)

Industry viewpoints. IND enabling work (5min each)

Cardiac fibrosis :
Jordan Shin (Haya Therapeutics, USA)

Targeting cardiomyocyte structure : Robin Shaw (TikkunLev Therapeutics, USA)

Gene Editing for Vascular Diseases : Patricia Musolino (Boston, MA, USA)

Clinical Trial Design in Rare or Orphan Cardiac Diseases. Natural history arms, Surrogate endpoints and other design and statistical issues
Janet Wittes (Wittes LLC, USA)

Patients' acceptance of gene therapy
Alessia Argiro (Florence, ITA)

The CVCT Multi-Stakeholder Think Tank Debate

GENE-BASED CARDIAC THERAPY. PART 2.
HOW ARE WE GETTING AROUND SPECIFIC GENE THERAPIES CLINICAL TRIALS CHALLENGES
Chairpersons: Roger Hajjar (Boston, MA, USA), Silvia Priori (Pavia, ITA)

Panelists : Eric Adler (Lexeo Therapeutics (LexeoTx, USA), Alessia Argiro (Florence, ITA), Gabriel Brooks (Solid Biosenses, USA), Marat Fudim (Durham, NC, USA), Barry Greenberg (San Diego, CA, USA), Roger Hajjar (Boston, MA, USA), Pradeep Mammen (Kansas City, MO, USA), Patricia Musolino (Boston, MA, USA), Silvia Priori (Pavia, ITA), Iacopo Olivotto (Florence, ITA), Luke Roberts (AskBio, GER), Robin Shaw (TikkunLev Therapeutics, USA), Jordan Shin (Haya Therapeutics, USA), Megan Sutton (Everygene, USA), Janet Wittes (Wittes LLC, USA)

Chinese
Wednesday, December 10, 2025
11:00 -13:00

NEW TARGETS FOR HFPEF DRUG DEVELOPMENT
THE ADIPOKINE HYPOTHESIS
Chairpersons: Barry Borlaug (Rochester, MI, USA) & Donna Ryan (Baton Rouge, LA, USA)

Importance of Adiposity in HFpEF
Barry Borlaug (Rochester, MI, USA)

Adipokine Hypothesis of HFpEF
Milton Packer (Dallas, TX, USA)

Extracardiac Signaling in Heart Failure
Douglas Mann (St Louis, MI, USA)

Drug Repurposing for HFpEF: Metformin and Fenofibrate
Joao Ferreira (Porto, POR)

Reorientation of Anti-Cytokine Drug Development to HFpEF
Mark Petrie (Glasgow, UK)

Activin Receptor Ligand Trapping for HFpEF
Maureen O'Connor (35Pharma, USA), Alessia Urbinati (Merck, USA)

New trial strategy for HFpEF trials based on the Adipokine Hypothesis
Milton Packer (Dallas, TX, USA)

Regulatory viewpoint
Jordan Pomeroy (FDA, USA)

The NIH viewpoint (HeartShare)
William Chutkow (FNIH, Novartis, USA)

Industry viewpoints
Lisette Koeneman (Lilly, USA), Judy Meadows (Regeneron, USA)

The CVCT Multi-Stakeholder Think Tank Debate
NEW TARGETS FOR HFPEF DRUG DEVELOPMENT. THE ADIPOKINE HYPOTHESIS
Chairpersons: Barry Borlaug (Rochester, MI, USA) & Donna Ryan (Baton Rouge, LA, USA)

Panelists: Barry Borlaug (Rochester, MI, USA), William Chutkow (FNIH, Novartis, USA), Joao Ferreira (Porto, POR), Riccardo Inciardi (Brescia, ITA), Lisette Koeneman (Lilly, USA), Douglas Mann (St Louis, MI, USA), Judy Meadows (Regeneron, USA), Maureen O'Connor (35Pharma, USA), Milton Packer (Dallas, TX, USA), Alexander Peikert (Graz, AUT), Mark Petrie (Glasgow, UK), Jordan Pomeroy (FDA, USA), Donna Ryan (Baton Rouge, LA, USA), Alessia Urbinati (Merck, USA)

Chinese
Wednesday, December 10, 2025
14:00 -16:00

DESIGNING EFFICACY-IMPLEMENTATION HYBRID TRIALS: ACCELERATING TRANSLATION OF FINDINGS FROM CARDIOVASCULAR CLINICAL TRIALS

Chairpersons: Shahnaz Khan (Washington, DC, USA) & Cara Lewis (NHLBI, USA)

Introductory Remarks by Co-Chairs
Shahnaz Khan (Washington, DC, USA)
Cara Lewis (NHLBI, USA)

Rethinking the endgame of implementation science (15 min)
Elvin Geng (St. Louis, MO, USA)

Accelerating research to practice by designing rigorous type 1 hybrid efficacy and effectiveness-implementation studies
Kathryn Hyzak (Ohio, OH, USA)

Type 1 efficacy-implementation hybrid trial on cardiovascular disease

Heart failure with reduced ejection fraction (HFrEF) polypill implementation strategy in Sri Lanka Anubha Agarwal (St Louis, MI, USA)

I-TRANSFER-HF study
Madeline Sterling (New York, NY, USA)

Editors'viewpoints
Harlan Krumholz (JACC, USA)

The CVCT Multi-Stakeholder Think Tank Debate

HOW TO ACCELERATE TRANSLATION OF EVIDENCE GENERATED IN CARDIOVASCULAR CLINICAL TRIALS THROUGH EFFICACY-IMPLEMENTATION HYBRID TRIALS

Chairpersons: Shahnaz Khan (Washington, DC, USA) & Cara Lewis (NHLBI, USA)

Panelists : Anubha Agarwal (St Louis, MI, USA), Safia Chatur (Boston, MA, USA), Elvin Geng (St. Louis, MO, USA), Kathryn Hyzak (Ohio, OH, USA), Shahnaz Khan (Washington, DC, USA), Harlan Krumholz (JACC, USA), Cara Lewis (NHLBI, USA), George Mensah (NHLBI, USA), Yves Rosenberg (NHLBI, USA), Madeline Sterling (New York, NY, USA), Harriette Van Spall (Hamilton, CAN)

Chinese
Wednesday, December 10, 2025
16:30 -18:30

CKLM BIOLOGICS : FROM CONCEPT TO CLINIC
OVERCOMING TRANSLATIONAL AND REGULATORY BARRIERS
Chairpersons: Karine Bourgeois (4Teen4, GER) & Thomas Thum (Hannover, GER)

Cardiogenic shock & inflammation. Lessons on timing, trial logistics in acute syndromes, and regulatory considerations for high-risk patients.
Alexandre Mebazaa (Paris, FRA)
Karine Bourgeois (4Teen4, GER)

Tailored-therapy in heart failure subpopulations, endpoint selection, and future use of AI in imaging.
Jonathan Cunningham (Boston, USA)

Biomarker-guided recruitment, use of intermediate endpoints, and long-term outcome planning in immunotherapy and RNA-based anti-inflammatory trials.
Paul Ridker (Boston, MA, USA)

From platform to multinational trials: Cardior experience as blueprint for cardiovascular RNA therapeutic development
Thomas Thum (Hannover, GER)

Industry viewpoints
Christian Medom Madsen (NovoNordisk, DEN)
Pierluigi Tricoci (Lilly, USA)

Regulatory science and innovation in CV biologics. Fast-track pathways, Surrogate endpoints, and harmonizing trial expectations between FDA/EMA.
Vinay Prasad (CBER, FDA)

The CVCT Multi-Stakeholder Think Tank Debate
ACCELERATING CARDIOVASCULAR BIOLOGICS APPROVAL
Chairpersons Karine Bourgeois (4Teen4, GER) & Thomas Thum (Hannover, GER)

Panelists: Karine Bourgeois (4Teen4, GER), Jonathan Cunningham (Boston, USA), Alexandre Mebazaa (Paris, FRA) , Christian Medom Madsen (NovoNordisk, DEN), Alexander Peikert (Graz, AUT), Vinay Prasad (CBER, FDA), Paul Ridker (Boston, MA, USA), , Thomas Thum (Hannover, GER), Pierluigi Tricoci (Lilly, USA)