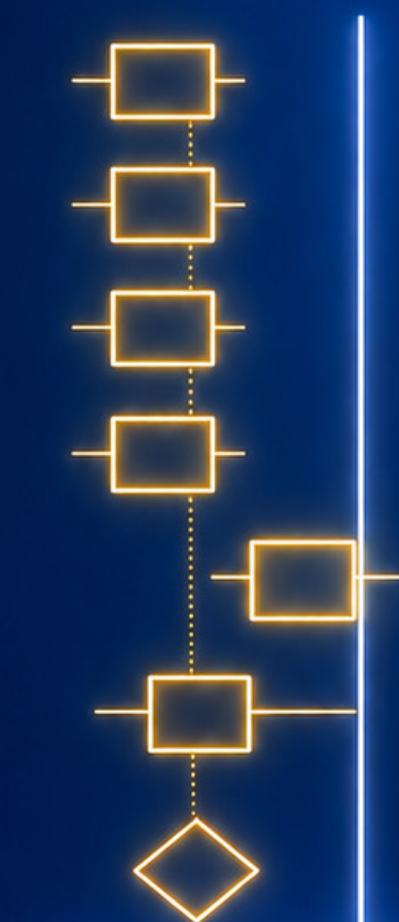


CVCT

December 7 - 9, 2026
The Mayflower Hotel, Washington DC



**SCIENTIFIC
PROGRAM**

**23rd Global Cardio Vascular
Clinical Trialists Forum**

FACULTY

ACADEMY

1. William Abraham (Columbus, OH, USA)
2. Rahul Aggarwal (Boston, MA, USA)
3. Gorav Ailawadi (Ann Arbor, MI, USA)
4. Alberto Aimo (Pisa, IT)
5. Ziad Ali (New York, NY, USA)
6. Emily Alsentzer (Stanford, CA, USA)
7. Jason Andrade (Vancouver, BC, CAN)
8. Alessia Argirò (Florence, ITA)
9. Suzanne Arnold (Kansas City, MO, USA)
10. Garima Arora (Birmingham, AL, USA)
11. Clare Arnott (Sydney, AU)
12. Deborah Ascheim (Boston, MA, USA)
13. Michel Azizi (Paris, FRA)
14. Andrew Baker (Edinburgh, GBR)
15. Suzanne Baron (Boston, MA, USA)
16. Wayne Batchelor (Orlando, FL, USA)
17. Tina Baykaner (Stanford, CA, USA)
18. Jeroen Bax (Leiden, NED)
19. Ankeet S. Bhatt (San Francisco, CA, USA)
20. Ami Bhatt (Boston, MA, USA)
21. Jan Biegus (Wrocław, POL)
22. Erin Bohula (Boston, MA, USA)
23. Biykem Bozkurt (Houston, TX, USA)
24. Jenifer Brown (Boston, MA, USA)
25. Dan Burkhoff (New York, NY, USA)
26. Javed Butler (Dallas, TX, USA)
27. Robert Califf (Durham, NC, USA)
28. Francesco Cappelli (Florence, ITA)
29. Ediina Cenko (Bologna, IT)
30. Rishi Chandiramani (Baltimore, USA)
31. Kelly Chin (Dallas, TX, USA)
32. Leslie Cho (Cleveland, OH, USA)
33. Clara Chow (Sydney, AUS)
34. Heidi Christ (Basel, CHE)
35. Brian Claggett (Boston, MA, USA)
36. Caroline Coats (Glasgow, GBR)
37. David Cohen (Boston, MA, USA)
38. Roisin Colleran (Galway, IRL)
39. Isabella Cooper (Amyloidosis Research Consortium, USA)
40. Philip Croon (Amsterdam, NED)
41. Jonathan Cunningham (Boston, MA, USA)
42. Donald Cutlip (Boston, MA, USA)
43. Issa Dahabreh (Boston, MA, USA)
44. Zainab Dakhil (Baghdad, IQ)
45. Stefanie Dimmeler (Frankfurt, GER)
46. John Deanfield (London, GBR)
47. Lovedeep Dhingra (New Haven, CT, USA)
48. Ron Do (New York, NY, USA)
49. Kieran Docherty (Glasgow, GBR)
50. Jessilyn Dunn (Durham, NC, USA)
51. Victor J. Dzau (Boston, MA, USA)
52. Perry Elliott (London, GBR)
53. Mariam Elmegaard (Herlev, DEN)
54. David Erlinge (Lund, SWE)
55. Anthony Etyang (Kilifi, KEN)
56. Hap Farber (Boston, MA, USA)
57. Gemma Figtree (Sydney, AUS)
58. Naomi Fisher (Boston, MA, USA)
59. Mona Fiuzat (Washington, DC, USA)
60. Mariana Fontana (London, UK)
61. Gabrielle Fredman (New York, NY, USA)
62. Marat Fudim (Durham, NC, USA)
63. Valentin Fuster (New York, NY, USA)
64. Karen Gainey (Sydney, AUS)
65. Michael Gibson (Boston, MA, USA)
66. Jason Gill (Glasgow, GBR)
67. Mario Gimona (Salzburg, AUT)
68. Nicolas Girerd (Nancy, FRA)
69. Mardi Gomberg-Maitland (Washington, DC, USA)
70. Sascha Goonewardena (Ann Arbor, MI, USA)
71. John Gregson (London, GBR)
72. Trish Greenhalgh (Oxford, GBR)
73. Martha Gulati (Los Angeles, CA, USA)
74. Aakriti Gupta (New York, NY, USA)
75. Juan Granada (New York, NY, USA)
76. Christopher Granger (Durham, NC, USA)
77. Jennifer Green (Durham, NC, USA)
78. Barry Greenberg (San Diego, CA, USA)
79. Bernard Gersh (Rochester, MN, USA)
80. Roger Hajjar (Boston, MA, USA)
81. Frank Harrell (Nashville, TN, USA)
82. Josephine Harrington (Denver, COL)
83. Jörg Hausleiter (Munich, GER)
84. Anna Hemnes (Nashville, TN, USA)
85. Hiddo Heerspink (Groningen, NED)
86. Adrian Hernandez (Durham, NC, USA)
87. Will Herrington (Oxford, GBR)

88. Nick Hill (Boston, MA, USA)
89. Robert Hinchliffe (Bristol, GBR)
90. Carolyn Ho (Boston, MA, USA)
91. Mark Huffman (St Louis, MO, USA)
92. Marc Humbert (Paris, FRA)
93. Borja Ibanez (Madrid, ESP)
94. Riccardo Inciardi (Brescia, IT)
95. Kiyotake Ishikawa (New York, NY, USA)
96. Samir Kapadia (Cleveland, OH, USA)
97. Naresh Kanumilli (Manchester, GBR)
98. Gemma Figtree (Sydney, AUS)
99. Sanjay Kaul (Los Angeles, CA, USA)
100. Steve Kawut (Philadelphia, PA, USA)
101. Rohan Khera (New Haven, CT, USA),
102. Kamlesh Khunti (Leicester, GBR)
103. Paulus Kirchhof (Hamburg, GER)
104. Lars Kober (Copenhagen, DEN)
105. Mitch Krucoff (Durham, NC, USA)
106. Wolfgang Koenig (Munich, GER)
107. Christina Lalani (Boston, MA, USA)
108. Carolyn Lam (Singapore, SGP)
109. Martin Landray (Oxford, GBR)
110. Martin Leon (New York, NY, USA)
111. Klaus Ley (Augusta, GA, USA)
112. Jianping Li (Beijing, CHN)
113. Peter Libby (Boston, MA, USA)
114. Jennifer Linge (Linköping, SWE)
115. Ildi Lingvay (Dallas, TX, USA)
116. Giovanna Liuzzo (Rome, ITA)
117. Donald Lloyd Jones (AHA, USA)
118. Thomas Lüscher (London, GBR)
119. Michael Mack (Dallas, TX, USA)
120. Karen Joynt Maddox (St. Louis, MO, USA)
121. Ken Mahaffey (Stanford, CA, USA)
122. Martin Maron (Boston, MA, USA)
123. James Martin (Dallas, TX, USA)
124. Ahmad Masri (Portland, USA)
125. Manuel Mayr (London, GBR)
126. Margaret McEntegart (Glasgow, GBR)
127. Darren McGuire (Dallas, TX, USA)
128. Maritza McIntyre (Ex CBER director FDA, USA)
129. John McMurray (Glasgow, GBR)
130. Vallerie McLaughlin (Ann Arbor, MI, USA)
131. Reginald McNulty (Irvine, USA)
132. Alexandre Mebazaa (Paris, FRA)
133. Mandeep Mehra (Boston, MA, USA)
134. Roxana Mehran (New York, NY, USA)
135. Philippe Menasché (Paris, FRA)
136. Guiomar Mendieta-Badimon (Barcelona, ESP)
137. Robert Mentz (Durham, NC, USA)
138. Niekbachsh Mohammadnia (Nijmegen, NED)
139. Javier Morales (New York, N, USA)
140. Marie-Claude Morice (Massy, FRA)
141. Pamela Morris (Mount Pleasant, SC, USA)
142. Paul Muntner (Birmingham, AL, USA)
143. Joseph Musunuru (Philadelphia, PA, USA)
144. Ann Marie Navar (Dallas, TX, USA)
145. Steven Nathan (Falls Church, VA, USA)
146. Stephen Nicholls (Adelaide, AUS)
147. Steven Nissen (Cleveland, OH, USA)
148. Brendon Neuen (Sydney, AUS)
149. Borge Nordestgaard (Copenhagen, DNK)
150. Giovanni Occhipinti (Bologna, IT),
151. Christopher O'Connor (Washington, DC, USA)
152. Michelle O'Donoghue (Boston, MA, USA)
153. Evangelos K Oikonomou (New Haven, CT, USA)
154. Iacopo Olivotto (Florence, ITA)
155. Joanna Osmanska (Glasgow, UK)
156. Anjali Owens (Philadelphia, PA, USA)
157. Neha Pagidipati (Durham, NC, USA)
158. Milton Packer (Dallas, TX, USA)
159. Ambarish Pandey (Dallas, TX, USA)
160. Victoria Parikh (Stanford, CA, USA)
161. Aline Pedroso (New Haven, CT, USA)
162. Michael Pencina (United Health, USA)
163. Emerson Perin (Houston, TX, USA)
164. Divaka Perera (London, GBR)
165. Mark Petrie (Glasgow, GBR)
166. Marc Pfeffer (Boston, MA, USA)
167. Bertram Pitt (Ann Arbor, MI, USA)
168. Jorge Plutzky (Boston, MA, USA)
169. Stuart Pocock (London, GBR)
170. Jeffrey Popma (CRF, USA)
171. Iona Preston (Boston, MA, USA)
172. Silvia Priori (Pavia, ITA)
173. Odayme Quesada (Cincinnati, OH, USA)
174. Rita Redberg (San Francisco, CA, USA)
175. Yogesh Reddy (Rochester, MN, USA)
176. Nathalie Reilly (Leiden, NED)
177. Paul Ridker (Boston, MA, USA)
178. Stuart Rich (Chicago, IL, USA)
179. Frank Rockhold (Durham, NC, USA)
180. Anthony Rodgers (Sydney, AUS)
181. Blanca Rodriguez (Oxford, GBR)
182. Leslie Rosman (Chapel Hill, NC, USA)
183. Robert Rosenson (New York, NY, USA)
184. Joseph Rossano (Philadelphia, PA, USA)
185. Anne-Christine Ruwald (Copenhagen, DK)
186. Marc Sabatine (Boston, MA, USA)
187. Nanette Santoro (Aurora, CO, USA)
188. Naveed Sattar (Glasgow, GBR)
189. Prash Sanders (Adelaide, AUS)

190. Sandeep Sahay (Houston, TX, USA)
191. Suchi Saria (Baltimore, MD, USA)
192. Gianluigi Savarese (Stockholm, SWE)
193. Ben Saville (Austin, TX, USA)
194. Markus Schlaich (Perth, AUS)
195. Roland Schmieder (Erlangen, GER)
196. Greg Schwartz (Denver, CO, USA)
197. Michele Senni (Bergamo, ITA)
198. Nishant Shah (Durham, NC, USA)
199. Abhinav Sharma (Montreal, CAN)
200. Mike Sharma (Hamilton, ON, CAN)
201. Frances Shiely (Cork, GBR),
202. Oksana Shlobin (Falls Church, VA, USA)
203. Tabassome Simon (Paris, FRA)
204. Rouchelle Sriranjani-Rothwell (Cambridge, GBR)
205. Motasim Sirhan (Elixir Medical, USA)
206. Olivier Sitbon (Paris, FRA)
207. Christian Sohns (Hannover, GER)
208. Scott Solomon (Boston, MA, USA)
209. Tor Beiring Sorensen (Copenhagen, DK)
210. John Spertus (Kansas City, MO, USA)
211. Rouchelle Sriranjani (Cambridge, GBR)
212. Gregg Stone (New York, NY, USA)
213. Emma Svennberg (Stockholm, SWE)
214. Ibrahim Halil Tanboga (Istanbul, TUR)
215. Jean Claude Tardiff (Montreal, CAN)
216. Pam Taub (San Diego, CA, USA)
217. Thomas Thum (Hannover, GER)
218. Lale Tokgozoglul (Ankara, TUR)
219. Mark Toshner (Cambridge, GBR)
220. Rhian Touyz (Montreal, CAN)
221. Harriette Van Spall (Hamilton, CAN)
222. Jean-Luc Vachiéry (Brussels, BEL)
223. Anjali Vaidya (Philadelphia, PA, USA)
224. Muthiah Vaduganathan (Boston, MA, USA)
225. Frances Varian (Sheffield, GBR),
226. Sreek Vemulapalli (Durham, NC, USA)
227. Corey Ventetuolo (Providence, RI, USA)
228. Atul Verma (Hamilton, CAN)
229. Subodh Verma (Toronto, CAN)
230. Dennis Villareal (Houston, TX, USA)
231. Vinod Thourani (Atlanta, GA, USA)
232. Rishi Wadhera (Boston, MA, USA)
233. Ron Waksman (Washington, DC, USA)
234. Jian'an Wang (Hangzhou, CHN)
235. Paul Wang (Stanford, CA, USA)
236. Lynne Warner Stevenson (Nashville, TN, USA)
237. Oussama Wazni (Cleveland, OH, USA)
238. Jason Weatherald (Edmonton, CA)
239. Jeffrey Weitz (Hamilton, CAN)

240. Isabella Wiest (Dresden, GER)
241. Bryan Williams (London, GBR)
242. William White (Boca Raton, FL, USA)
243. Michael Wolf (Chicago, IL, USA)
244. Lijing Yan (Beijing, CHN)
245. Seppo Ylä-Herttuala (Kuopio, FIN)
246. Robert Yeh (Boston, MA, USA)
247. Faiez Zannad (Paris, FRA)
248. Andre Zimmerman (Boston, MA, USA)

INDUSTRY

249. William Abraham (V-Wave, ISR)
250. Phillip Adamson (CVRx, USA)
251. Hafid Ait Oufella (Polygon, FRA)
252. David Albert (AliveCor, USA)
253. Alessandro Albuquerque (Recordati, ITA)
254. Yousuf Ali (Boehringer Ingelheim, GER)
255. Peter Altman (BioCardia, USA)
256. Greg Aubert (Lexeo Therapeutics, USA)
257. Puja Banka (Merck, Rahway, USA)
258. Sameer Bansilal (Alnylam, USA)
259. Arnaud Bastien (BMS, USA)
260. Rachel Batterham (Lilly, GBR)
261. David Bauman (Schrodinger, USA)
262. Dietmar Berger (Sanofi, FRA)
263. Mario Berger (Bayer, GER)
264. Scott Berry (Berry Consultants, USA)
265. Narinder Bhalla (Lexeo Therapeutics, USA)
266. Dan Bloomfield (Anthos, USA)
267. Sahar Boostenay (REVAMP, ISR)
268. Maria Borentain (Bayer, GER)
269. Meike Brinker (Bayer, GER)
270. Todd Brinton (Edwards, USA)
271. Martina Brueckmann (Roche, CH)
272. John Brumfield (Berlin Heals, GER)
273. Gabriel Brooks (Solid Biosciences, USA)
274. Brieana Buckley (Editas, Medicine, USA)
275. Chris Cabell (Inhibikase, USA)
276. Hui Cao (Novartis, USA)
277. Rafael Cavalcante (Boston Scientific, USA)
278. Andrew Cheng (NovoNordisk, USA)
279. Mark Chin (Avoro Ventures, USA)
280. Jeff Closs (Ancora, USA)
281. Martine Clozel (Idorsia, CHE)
282. Kevin Costa (Novoheart, USA)
283. Amy Crawford (Berry Consultants, USA)
284. Carlos Cuevas (BMS/J&J, USA)
285. Emil deGoma (BraveHeart, USA)
286. Bjorn Dahlof (Cereno, SWE)
287. Reynolds M. Delgado III (Procyron, USA)

288. Alex DePaoli (Rona Therapeutics, CHN)
289. Mark DiNubile (BioAegis, USA)
290. Jason Duran (CRISPR Therapeutics, USA)
291. Punag Divanji (Cytokinetics, USA)
292. Cord Dohrmann (Evotec, GER)
293. David Drachman (Magenta, ISR)
294. Jay Edelberg (Kardigan, USA)
295. Jennifer Hellawell (Arrowhead pharmaceuticals, USA)
296. Mads Engelmann (NovoNordisk, DEN)
297. Jeff Emmick (Lilly, USA)
298. Odd Erik (Roche, CH)
299. Christopher Fang (Hippocratic AI)
300. Chris Farina (Abcentra, USA)
301. Sergio Fazio (Corsera, USA)
302. Udi Fainberg (Novo Nordisk, DK)
303. Juan Camilo Arjona Ferreira (Organon, COL)
304. Tim Fischell (Ablative Solutions, USA)
305. Monica Florio (Amgen, USA)
306. Amy Ford (Lilly, USA)
307. Folke Folkvaljon (AstraZeneca, SWE)
308. Brandon Fornwalt (Tempus, USA)
309. Kristen Fortney (BioAge, USA)
310. Kevin Friedman (Kelonia, USA)
311. Keiichi Fukuda (Heartseed, JPN)
312. Anders Gabrielsen (Ribocure, SWE), Federica Genovese (Nordic Bioscience, DNK)
313. Jyothis George (NodThera, GBR)
314. George Georges (38 Pharma/GSK, USA)
315. Saar Gill (Interius BioTherapeutics, USA)
316. Justin Godown (Cytokinetics, USA)
317. Thomas Goldin Diness (Pharmacosmos, Denmark/USA)
318. Alexandra Goncalves (BMS, USA),
319. Devi Govender (Abiomed, USA)
320. Christine Guo (Ametris, USA)
321. Chad Grothen (Lilly, USA)
322. Kendra Grubb (Medtronic, USA)
323. András Gruber (Aronora, USA)
324. Finn Gustafsson (Abbott, USA)
325. David Gutstein (Regeneron, USA),
326. Becky Harmon (Eli Lilly, USA)
327. Steve Heitner (Cytokinetics, USA),
328. Graeme Hickey (Medtronic, USA)
329. Laura Higginbotham (IQVIA, USA)
330. Udo Hoffmann (Cleerly / MGH, USA)
331. Stefan Irion (BlueRock Therapeutics/Bayer, GER)
332. Silviu Itescu (Mesoblast, AUS)
333. Filip Janku (Monterosa, USA)
334. Gavin Jeffries (Fluicell, SWE)
335. Per Johannsen (AstraZeneca, SWE)
336. Toby S. Johnson (Band Therapeutics, USA)
337. Amer Joseph (Idorsia, CHE),
338. Ryan Kam (Egnyte, USA)
339. Fred Kamal (Medley Tx)
340. Navin Kapur (Abiomed/JnJ, USA)
341. John Kastelein (New Amsterdam, USA)
342. Sekar Kathiresan (Verve, USA)
343. Amit Khera (Verve Therapeutics, USA)
344. James Kim (Medera, USA)
345. So Young Kim (Tenax, USA)
346. Filip Knop (NovoNordisk, DNK)
347. Mikhail Kosiborod (AstraZeneca, USA)
348. Stanko Skrtic (HeartBeat.bio, AUT)
349. Tenley Kreter (Supira Medical, USA)
350. Jordan Lancaster (Avery Therapeutics, USA)
351. Anastasia Lesogor (Novartis, CHE)
352. Howard Levin (Coridea, USA)
353. Stephen Levine (Dassault, FRA)
354. Henri Lichens (DrugFarm, USA)
355. Li Li (Innovent Biologics, CHN)
356. Dustin Little (Astra Zeneca, USA)
357. Steve Lubitz (Novartis, USA)
358. Christina Mack (IQVIA, USA)
359. Hideo Makimura (Affinia Therapeutics, USA)
360. Craig Markovitz (Magenta Medical, ISR)
361. Ciaran McMullan (Merck, USA)
362. Greg Michaud (Biosense Webster, USA)
363. Ryan Miller (BioVentrix, USA)
364. Michele Mercuri (Alexion, USA)
365. Puneet Mohan (BMS-Pfizer, USA)
366. Gillian Murtagh (Bridgebio, USA)
367. Ashwin Nayak (UpDoc, USA)
368. Yaacov Nitzan (Aquapass, ISR)
369. Chris O'Donnell (Novartis, CH)
370. Nirav Patel (Medtronic, USA)
371. Mahesh Patel (Merck, USA)
372. Natasha Paterson (Tenaya Therapeutics, USA)
373. Shira Perl (AstraZeneca, USA)
374. Garrett Pilcher (Medtronic, USA)
375. Franck Rahaghi (United Therapeutics, USA)
376. Curtis Rambaran (Silence Therapeutics, GBR)
377. Shiv Rao (Abridge, USA)
378. Mark Reisman (Edwards, USA)
379. Helen Reeve-Stoffer (Recor Medical, USA)
380. Marzia Rigolli (Eli Lilly, USA)
381. Maria Sejersten Ripa (Novo Nordisk, DNK)
382. Luke Roberts (Bayer, GER)
383. David Rodman (Mineralys Therapeutics, USA)
384. Lothar Roessig (AskBio, GER)

385. Campbell Rogers (Heartflow, USA)
386. Rob Roscigno (Gossamer, USA)
387. Martin Rothman (Pulnovo, CHN)
388. Harry D. Rowland (Relief Cardiovascular, USA)
389. Nitin Salunke (Supira Medical, USA)
390. Carlos Sanmarco (Pulmovant, USA)
391. Richard Secer (CeleCor, USA)
392. Monica Shah (Nuevocor, SGP)
393. David Simmons (Launch Therapeutics, USA)
394. Marshelle Smith (Secretome Therapeutics, USA)
395. Derek Solum (United Therapeutics, USA),
396. Luba Soskin (Bayer, CHE)
397. Kenneth Stein (Boston Scientific, USA)
398. Norman Stockbridge (S&S Consulting, USA)
399. Kate Stohlman (Corvia, USA)
400. Howard Surks (Cardurion, USA)
401. Whit Tingley (Tenaya Therapeutics, USA)
402. Noriko Tojo (Otsuka, JPN)
403. Sam Tsimikas (Ionis, USA)
404. Mintu Turakhia (iRhythm / Stanford, USA)
405. Alessia Urbinati (Merck, USA)
406. Muthu Venkateshwaran (BridgeBio, USA)
407. Luke Walker (Umoja Biopharma, USA),
408. Liron Walsh (Intellia, USA)
409. Eugene Wang (HELP Therapeutics, CHN)
410. Anna Windle (Novo Nordisk, USA)
411. Janet Wittes (Wittes LLC, USA)
412. Stephen Wiviott (AstraZeneca, USA)
413. Yong Yue (Laekna Therapeutics, CHN)
414. Rami Younes (Boehringer Ingelheim, USA)
415. Travis Zack (OpenEvidence, USA)
416. Dion Zappe (Alnylam, USA)
417. Cordula Zeller (Boehringer Ingelheim, GER)
418. Jie Zeng (Rona Therapeutics, CHN)
419. Hong Zhao (Abbott, USA)
430. Eileen Craig (FDA, USA)
431. Chad Kliger (FDA, USA)
432. Aneesh Deoras (FDA, USA)
433. Nicole Gillette (FDA, USA)
434. Charu Gandotra (FDA, USA)
435. Jacob George (MHRA, GBR)
436. Lydia Glaw (FDA, USA)
437. Michelle, Jordan (FDA, USA)
438. Laura Helbling (FDA, USA)
439. William Herzog (FDA, USA)
440. Rob Kazmierski (ex FDA, USA)
441. Mori Krantz (FDA, USA)
442. Choong May Ling (HSA, Singapore, SIN)
443. Cheryl Loggins (FDA, USA)
444. Tzu-Yun.McDowell (FDA, USA)
445. April Marrone (FDA, USA)
446. Jan Müller-Berghaus (EMA, GER)
447. Chinwe Okoro (FDA, USA)
448. Rachel Neubrandner (FDA, USA)
449. Julia Parris (MHRA, UK)
450. Bakul Patel (former FDA, USA)
451. Francesco Pignatti (EMA, NED)
452. Ileana Pinea (FDA, USA)
453. Lisa Plummer (FDA, USA)
454. Jordan Pomeroy (FDA, USA)
455. Mitch Psotka (FDA, USA)
456. Ann Punnoose (FDA, USA)
457. Jon Resar (FDA, USA),
458. Brittany Schuck (FDA, USA)
459. Kimberly Selzman (FDA, USA)
460. Fortunato Senatore (FDA, USA)
461. John Sharretts (exFDA, USA)
462. Jeff Shuren (FDA, USA)
463. Raymond Soccio (FDA, USA)
464. Harald Sourij (EMA, AUT)
465. Michelle Tarver (FDA, USA)
466. Laurence Tallon (MHRA, GBR)
467. Aliza Thompson (FDA, USA)
468. James Travis (FDA, USA)
469. Karim Mikhail (FDA, USA)
470. Kaveeta Vasisht (FDA, USA)
471. Changfu Wu (FDA, USA)
472. Siyuan Zhou (NMPA, Beijing, CHN)
473. Bram Zuckerman (FDA, USA)

NIH / NHLBI / NIBSC / Government

420. Janine Clayton (NIH/ OWH, USA)
421. Patrice Desvigne-Nickens (NIH/NHLBI, USA)
422. Cara Lewis (NIH/NHLBI, USA)
423. Eric Leifer (NIH/NHLBI, USA)
424. George Mensah (NIH/NHLBI, USA)
425. Catherine Spong (NIH/NICHD, USA)
426. Haider Warraich (ARPA-H, USA)

REGULATORY

427. Gregory Alexander (FDA, USA)
428. Stephen Browning (FDA, USA)
429. Wilson Bryan (FDA, USA)

PAYERS / INVESTORS

474. Amanda Adler (London, GBR)
475. JoAnna Baldwin (CMS, USA)
476. Hanson Gifford (The Foundry, USA)
477. Craig Gordon (GordonMD Global Investment LP,

USA)

- 478. Niklas Hedberg (TLV, SWE)
- 479. Grace Lin (ICER, USA)
- 480. Josh Makower (Coravin, USA)
- 481. Jaime Murillo (Bogotá, COL)
- 482. Sari Ormstad (EU JCA, NOR)
- 483. Antoine Papiernik (Sofinova Partners, FRA)
- 484. Tamara Syrek Jensen (CMS, USA)
- 485. Sunny Varshney (Broadview Ventures, USA)
- 486. Julie Yoo (Andreessen Horowitz (a16z), USA)

JOURNAL

- 487. Kirsten Bibbins-Domingo (JAMA, USA)
- 488. Barbara Casadei (JAMA Cardiology)
- 489. Filippo Crea (EHJ, ITA)
- 490. Karen Gainey (Sydney, AUS)
- 491. Flavia Geraldes (The Lancet, GBR)
- 492. Harlan Krumholz (JACC, USA)
- 493. Jane Leopold (NEJM, USA)
- 494. Ji-Hyun Lee (Nature Medicine, USA)
- 495. Bradley Maron (Circulation, USA)

PATIENTS

- 496. Marc Bains (HeartLife, CAN)
- 497. Coleen Brunetti (Pulmonary Hypertension Association, USA)
- 498. Emma Doble (BMJ, GBR)
- 499. ShantaQuilette Carter (Pink Peppermint Project, USA)
- 500. Patrick Gee (iAdvocate, USA)
- 501. Pieter Glijnis (Phospholamban Foundation, NED)
- 502. Trudie Lobban (London, GBR)
- 503. Rhonda Monroe (Charlotte, NC, USA)
- 504. Lisa Salberg (HCMA, USA)

MONDAY, DECEMBER 7TH

PALM COURT

8:30 - 10:30

AI MASTER CLASS 1

[view details >>](#)

10:30
11:00



11:00 - 13:00

AI MASTER CLASS 2

[view details >>](#)

13:00
14:00



14:00 - 16:00

AI MASTER CLASS 3

[view details >>](#)

16:00
16:30



16:30 - 19:30

CELL THERAPY

[view details >>](#)

EAST

8:30 - 10:30

AMYLOIDOSIS

[view details >>](#)

10:30
11:00



11:00 - 13:00

HYPERTROPHIC
CARDIOMYOPATHY

[view details >>](#)

13:00
14:00



14:00 - 16:00

PATIENT-REPORTED
OUTCOMES

[view details >>](#)

16:00
16:30



16:30 - 19:30

HYPERTENSION

[view details >>](#)

STATE

8:30 - 10:30

ALDOSTERONE IN
CKM

[view details >>](#)

10:30
11:00



11:00 - 13:00

CKM TRIALS

[view details >>](#)

13:00
14:00



14:00 - 16:00

WOMEN'S HEALTH

[view details >>](#)

16:00
16:30



16:30 - 19:30

RISK OF ASCVD

[view details >>](#)

CHINESE

16:30 - 19:30

PATIENT SESSION

[view details >>](#)

BALLROOM

8:30 - 10:30

LDL CHOLESTEROL

[view details >>](#)

10:30
11:00



11:00 - 13:00

LP (A) TRIALS

[view details >>](#)

13:00
14:00



14:00 - 16:00

iCVCT #5 MEDTECH
STARTUPS

[view details >>](#)

16:00
16:30



16:00 - 19:00

BIOTECH STARTUPS

[view details >>](#)

19:30 - 21:00: RECEPTION OR POSTER WINE AND CHEESE
OR AWARDS

TUESDAY, DECEMBER 8TH

PALM COURT

8:30 - 10:30

**STATS
MASTERCLASS # 1**

[view details >>](#)

10:30
11:00



11:00 - 13:00

**STATS
MASTERCLASS #2**

[view details >>](#)

13:00
14:00



14:30 - 16:30

**STATS
MASTERCLASS #3**

[view details >>](#)

16:30
17:00



17:00 - 19:00

**OBESITY: BODY
COMPOSITION**

[view details >>](#)

EAST

8:30 - 10:30

ZEUS DEEP DIVE

[view details >>](#)

10:30
11:00



11:00 - 13:00

**ANTI-
INFLAMMATORY &
ASCVD**

[view details >>](#)

13:00
14:00



14:30 - 16:30

PAH 1

[view details >>](#)

16:30
17:00



17:00 - 19:00

PAH 2

[view details >>](#)

STATE

8:30 - 10:30

**iCVCT #1
THROMBOSIS**

[view details >>](#)

10:30
11:00



11:00 - 13:00

**iCVCT #2
VENTRICULAR
ASSIST DEVICES**

[view details >>](#)

13:00
14:00



14:30 - 16:30

**iCVCT # 3
IMPLANTABLES FOR
DENOVO PCI**

[view details >>](#)

16:30
17:00



17:00 - 19:00

**iCVCT #4 VALVE
TRIALS**

[view details >>](#)

BALLROOM

8:30 - 10:30

AI MASTER CLASS 4

[view details >>](#)

10:30
11:00



11:00 - 13:00

**INDUSTRY-
ACADEMIA
INTERACTIONS**

[view details >>](#)

13:00
14:00



14:30 - 16:30

OBESITY NEW DATA

[view details >>](#)

16:30
17:00



17:00 - 19:00

GREAT DEBATES

[view details >>](#)

13.30 - 14.20: KEYNOTE LECTURE BY MARC PFEFFER (BOSTON, MA, USA) & VICTOR J. DZAU (BOSTON, MA, USA)
19.30 - 21.00: RECEPTION OR POSTER WINE AND CHEESE OR AWARDS

WEDNESDAY, DECEMBER 9TH

PALM COURT

8:00 - 10:00

LBCT 1

[view details >>](#)

10:00
10:30



10:30 - 12:30

GENE THERAPY

[view details >>](#)

12:30
13:30



13:30 - 16:30

GENETIC MEDICINE

[view details >>](#)

16:30
17:00



17:00 - 19:00

EP STROKE

[view details >>](#)

EAST

8:00 - 10:00

LBCT 2

[view details >>](#)

10:00
10:30



10:30 - 12:30

HF MEETS EP

[view details >>](#)

12:30
13:30



13:30 - 16:30

CHRONIC HEART
FAILURE DEVICES

[view details >>](#)

16:30
17:00



17:00 - 19:00

IMPLEMENTATION
SCIENCE AND
PAYMENT REFORM

[view details >>](#)

STATE

8:00 - 10:00

LBCT 3

[view details >>](#)

12:30
13:30



13:30 - 16:30

WEARABLES

[view details >>](#)

16:30
17:00



17:00 - 19:00

DRIVERS OF HEART
FAILURE

[view details >>](#)

CHINESE

8:00 - 10:00

LBCT 4

[view details >>](#)

10:00
10:30



10:30 - 12:30

IMPLEMENTATION

[view details >>](#)

BALLROOM

8:00 - 10:00

LBCT 5

[view details >>](#)

10:00
10:30



10:30 - 12:30

WHO IS IN THE
COMMAND ROOM?

[view details >>](#)

12:30
13:30



13:30 - 16:30

TRIALS'
PUBLISHING &
ADOPTION

[view details >>](#)

16:30
17:00



17:00 - 19:00

REGULATORY
HARMONIZATION

[view details >>](#)

**Palm court
Monday, December 7, 2026
08:30 -10:30**

**AI MASTER CLASS 1
AI IN CARDIOVASCULAR DEVICES AND HARDWARE
HOW SHOULD EVIDENCE STANDARDS FOR AI-ENABLED DEVICES ALIGN WITH TRADITIONAL DEVICE
EVALUATION?**

**Chairpersons: Kirsten Bibbins-Domingo (JAMA, USA) & Lesley Curtis (Duke Clinical Research
Institute, USA)**

AI in Devices and Hardware. What Evidence Do We Need? Defining future evaluation frameworks
Michelle Tarver (FDA, USA)

Planning an AI in Devices trial: regulatory pathways (510(k), De Novo, PMA) and what each demands
Stephen Browning (FDA, USA)

From bench to bedside: evaluating a locked algorithm across multiple clinical contexts
Udo Hoffmann (Cleerly / MGH, USA)

Prospective validation, real-world evidence, and pragmatic trial designs for device-AI
TBD

Case study: AI-ECG - multiple products, heterogeneous validation, and no head-to-head data
Philip Croon (Amsterdam, NED)

Wearables, arrhythmia algorithms, and post-market performance monitoring after clearance
Mintu Turakhia (iRhythm / Stanford, USA)

Generalizability, dataset shift, and the demographic gap in device-AI validation
TBD

Industry viewpoints
David Albert (AliveCor, USA), Brandon Fornwalt (Tempus, USA), Campbell Rogers (Heartflow, USA)

Investor perspective: how capital is allocated and what signals matter for device-AI
Julie Yoo (a16z, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**AI IN CARDIOVASCULAR DEVICES AND HARDWARE: HOW SHOULD EVIDENCE STANDARDS FOR AI-
ENABLED DEVICES ALIGN WITH TRADITIONAL DEVICE EVALUATION?**

**Chairpersons : Kirsten Bibbins-Domingo (JAMA, USA) & Lesley Curtis (Duke Clinical Research
Institute, USA)**

Panelists: David Albert (AliveCor, USA), Kirsten Bibbins-Domingo (JAMA, USA), Stephen Browning (FDA, USA), Philip Croon (Amsterdam, NED), Lesley Curtis (Durham, NC, USA), Brandon Fornwalt (Tempus, USA), Udo Hoffmann (Cleerly/MGH, USA), Campbell Rogers (HeartFlow, USA), Michelle Tarver (FDA, USA), Mintu Turakhia (iRhythm/Stanford, USA), Julie Yoo (Andreessen Horowitz (a16z), USA)

**Palm court
Monday, December 7, 2026
11:00 -13:00**

**AI MASTER CLASS 2
CLINICAL DECISION SOFTWARE: EVALUATING ADAPTIVE ALGORITHMS AND SaMD
FOR CARDIOVASCULAR RISK PREDICTION, IMAGING DIAGNOSTICS, TRIAGE, AND DECISION
SUPPORT: PREDETERMINED CHANGE CONTROL PLANS, CLINICAL UTILITY VS. ACCURACY, AND THE
SaMD FRAMEWORK**

Chairpersons : Carolyn Lam (Singapore, SGP) & Harlan Krumholz (JACC, USA)

The SaMD evidence framework. What Evidence Do We Need? Defining future evaluation frameworks
Bakul Patel (former FDA, USA)

From risk prediction to clinical action: when does AI improve cardiovascular prevention?
John Deanfield (London, GBR)

Why high AUC does not equal clinical value: decision-consequential endpoints
Ann Marie Navar (Dallas, TX, USA)

Predetermined Change Control Plans: enabling software updates without full re-review
Rob Kazmierski (ex FDA, USA)

Alert fatigue, workflow disruption, clinician trust: the implementation science of CDS
TBD

Can you run a traditional RCT on software that updates quarterly? Adaptive trial designs for SaMD
Harriette Van Spall (Hamilton, ON, CAN)

The CDS exemption boundary: where does decision support end and regulated SaMD begin?
Michelle Tarver (FDA, USA)

What is the appropriate regulatory strategy for generative AI in medicine?
Evangelos K Oikonomou (New Haven, CT, USA)

Industry viewpoints
Shiv Rao (Abridge, USA)

Regulatory viewpoints
Jordan Pomeroy (FDA, USA)

Investor perspective: how capital is allocated and what signals matter for SaMD
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**ADAPTIVE CLINICAL DECISION SOFTWARE: WHAT LEVEL AND TYPE OF EVIDENCE SHOULD BE
REQUIRED FOR CLINICIANS TO TRUST AND ADOPT AI DIAGNOSTIC AND DECISION SUPPORT TOOLS?**

Moderators: Carolyn Lam (Singapore, SGP) & Harlan Krumholz (JACC, USA)

Panelists: Stephen Browning (FDA, USA), John Deanfield (London, GBR), Michelle Jordan (FDA, USA), Harlan Krumholz (JACC, USA), Carolyn Lam (Singapore, SGP), Ann Marie Navar (Dallas, TX, USA), Bakul Patel (former FDA, USA), Jordan Pomeroy (FDA, USA), Rob Kazmierski (ex FDA, USA), Evangelos K Oikonomou (New Haven, CT, USA), Shiv Rao (Abridge, USA), John Spertus (Kansas City, MO, USA), Michelle Tarver (FDA, USA), Harriette Van Spall (Hamilton, ON, CAN)

**Palm court
Monday, December 7, 2026
14:00 -16:00**

**AI MASTER CLASS 3
GENERATIVE AI AND AUTONOMOUS SYSTEMS: EVALUATING THE UNEVALUABLE
CAN EXISTING FRAMEWORKS ASSESS GENERATIVE AI - OR DO WE NEED TO BUILD FROM SCRATCH?
Chairpersons: Rohan Khera (Stanford, USA) & Haider Warraich (ARPA-H, USA)**

Unbiased Evaluation of Generative AI and Autonomous Systems
Emily Alsentzer (Stanford, CA, USA)

Generative AI deployment at the point of care: from accurate answers to adoption and workflow
Travis Zack (OpenEvidence / UCSF, USA)

Generative AI for Implementation of Evidence-Based Cardiovascular Therapies
Lovedeep Dhingra (New Haven, CT, USA)

Red-Teaming and Adversarial Testing AI Before Clinical Deployment
Isabella Wiest (Dresden, GER)

Guardrails and governance: deployment safety, liability frameworks, and institutional oversight
Suchi Saria (Baltimore, MD, USA)

Funder perspective: what should be funded for clinical agentic and autonomous systems?
Haider Warraich (ARPA-H, USA)

Regulatory Perspective
Aneesh Deoras(FDA, USA)

Digital Health Industry Perspectives
Ashwin Nayak (UpDoc, USA)

Investor Perspective
Julie Yoo (a16z, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**GENERATIVE AI IN CLINICAL MEDICINE: CAN EXISTING FRAMEWORKS ASSESS GENERATIVE AI - OR
DO WE NEED TO BUILD FROM SCRATCH?**

Chairpersons: Rohan Khera (Stanford, USA) & Haider Warraich (ARPA-H, USA)

Panelists: Emily Alsentzer (Stanford, CA, USA), Aneesh Deoras (FDA, USA), Lovedeep Dhingra (New Haven, CT, USA), Rohan Khera (Stanford, CA, USA), Ashwin Nayak (UpDoc, USA), Suchi Saria (Baltimore, MD, USA), Haider Warraich (ARPA-H, USA), Isabella Wiest (Dresden, GER), Julie Yoo (Andreessen Horowitz (a16z), USA), Travis Zack (OpenEvidence, USA)

Palm court
Monday, December 7, 2026
16:30 -19:30

CARDIAC TARGETED BIOLOGICS, REGENERATION, REALITY, AND REINVENTION
Chairpersons : Stefanie Dimmeler (Frankfurt, GER) & Emerson Perin (Houston, TX, USA)

Issues related to routes of administration

Mapping-guided catheter delivery of iPSC-derived cardiomyocyte spheroids
Keiichi Fukuda (Heartseed, JAP)

Catheter-based delivery of iPSC-derived cardiomyocytes
Eugene Wang (HELP Therapeutics, CHN)

Regulatory viewpoint
Chinwe Okoro (FDA, USA)

Gene therapy for boosting cardiomyocyte proliferation: the SALVADOR-HF trial
Emerson Perin (Houston, TX, USA)

siRNA for the treatment of heart failure
Thomas Thum (Hannover, GER)

Secretome-based therapy.
Mario Gimona (Salzburg, AUT)

Digital twins in cell therapy clinical trials
Stephen Levine (Dassault, FRA)

Developmental and regulatory enabling aspects of translationally holistic human centric cardiac organoid platform
Stanko Skrtic (HeartBeat.bio, AUT)

Industry briefings (2-3 slides, 5 minutes)

Peter Altman (BioCardia, USA), Cord Dohrmann (Evotec, GER), Stefan Irion (BlueRock Therapeutics/Bayer, GER), Silviu Itescu (Mesoblast, AUS), Gavin Jeffries (Fluicell, SWE), Stanko Skrtic (HeartBeat.bio, AUT), Jordan Lancaster (Avery Therapeutics, USA), Marshelle Smith (Secretome Therapeutics, USA), Eugene Wang (HELP Therapeutics, CHN), Fred Kamal (Medley Tx, USA)

Industry briefings: From in-vivo immune-cell engineering to myocardial precision delivery: can targeted vectors be redirected to the heart?

Kevin Friedman (Kelsonia, USA), Saar Gill (Interius BioTherapeutics, USA), Luke Walker (Umoja Biopharma, USA)

Regulatory guidance
Wilson Bryan (CBER/FDA)

Closing remarks
Philippe Menasche (Paris, FRA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

SHOULD CARDIOLOGY ADOPT ACCELERATED PATHWAYS FOR REGENERATIVE THERAPIES?
Chairpersons : Philippe Menasche (Paris, FRA) & Emerson Perin (Houston, TX, USA)

Panelists: Peter Altman (BioCardia, USA), Cord Dohrmann (Evotec, GER), Stefanie Dimmeler (Frankfurt, GER), Kevin Friedman (Kelsonia, USA), Keiichi Fukuda (Heartseed, JPN), , Saar Gill (Interius BioTherapeutics, USA), Mario Gimona (Salzburg, AUT), Stefan Irion (BlueRock Therapeutics/Bayer, GER), Silviu Itescu (Mesoblast, AUS), Gavin Jeffries (Fluicell, SWE), Fred Kamal (Medley Tx, USA), Stanko Skrtic (HeartBeat.bio, AUT), Jordan Lancaster (Avery Therapeutics, USA), Stephen Levine (Dassault Systèmes, FRA), Philippe Menasché (Paris, FRA), Chinwe Okoro (FDA, USA), Emerson Perin (Houston, TX, USA), Marshelle Smith (Secretome Therapeutics, USA), Thomas Thum (Hannover, GER), Luke Walker (Umoja Biopharma, USA), Eugene Wang (HELP Therapeutics, CHN)

East
Monday, December 7, 2026
08:30 -10:30

CARDIAC AMYLOIDOSIS TRIALS CHANGING LANDSCAPE AND IMPLEMENTATION ISSUES
Chairpersons: Mariana Fontana (London, UK) and Iacopo Olivotto (Florence, ITA)

Diagnosis of cardiac amyloidosis—the tip of an iceberg?
Mariana Fontana (London, UK)

Should we systematically screen for ATTR?
Francesco Cappelli (Florence, Italy)

The role of transthyretin: stabilize, knock out, or both?

What should future control groups in future trials look like in an era of acoramidis/tafamidis + silencers?
TBD

Innovative trial design options.
Mariana Fontana (London, UK)

Regulatory viewpoint: Approvability issues
Karim Mikhail (FDA, USA)

What are my thoughts on the future treatment landscape including CRISPR based, other long term silencer– stabilizer therapies, and depleters
Isabella Cooper (Amyloidosis Research Consortium, USA)

What are the financial realities for ATTR management?
TBD

What does holistic care look like for people with ATTR-CM?
TBD

Industry Viewpoints

Sameer Bansilal (Alnylam, USA), Michele Mercuri (Alexion, USA), Gillian Murtagh (Bridgebio, USA), Liron Walsh (Intellia, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**TAKING ATTR-CARDIOMYOPATHY TREATMENT TO THE NEXT LEVEL: IDENTIFYING PATIENTS,
ASSESSING FRAILTY, INTEGRATING THERAPIES.**

Chairpersons: Mariana Fontana (London, UK) and Iacopo Olivotto (Florence, ITA)

Panelists: Alberto Aimo (Pisa, IT), Sameer Bansilal (Alnylam, USA), Francesco Cappelli (Florence, ITA), Isabella Cooper (Amyloidosis Research Consortium, Boston, MA, USA), Mori Krantz (FDA, USA), Michele Mercuri (Alexion, Boston, MA, USA), Karim Mikhail (FDA, USA), Gillian Murtagh (BridgeBio, Palo Alto, CA, USA), Iacopo Olivotto (Florence, ITA), Liron Walsh (Intellia, USA)

East
Monday, December 7, 2026
11:00 -13:00

THE END OF THE BEGINNING: WHAT NEXT FOR DRUG TRIALS IN HYPERTROPHIC CARDIOMYOPATHY?

Chairpersons: Perry Elliott (London, GBR) and Iacopo Olivotto (Florence, ITA)

Myosin inhibitors in obstructive HCM: a class effect?
Carolyn Ho (Boston, MA, USA)

Lessons from ODYSSEY and ACACIA -HCM.
Differences in molecule, design, execution, or chance in non-obstructive HCM?
Anjali Owens (Philadelphia, PA, USA)

Do we need 'next (third) generation' myosin modulators?
Martin Maron (Boston, MA, USA)

Metabolic modulators and mitotropes: We've been here before—so what is new this time?
Caroline Coats (Glasgow, GBR)

Is it possible to do hard end-point trials in hypertrophic cardiomyopathy?
Ahmad Masri (Portland, USA)

The case of pediatric trials
Joseph Rossano (Philadelphia, PA, USA)

Industry perspectives
Arnaud Bastien (BMS, USA), Gabriel Brooks (Solid Biosciences, USA), Justin Godown (Cytokinetics, USA), Emil deGoma (BraveHeart, USA), Natasha Paterson (Tenaya Therapeutics, USA)

Regulatory viewpoints
Laura Helbling (FDA, USA)
Fortunato Senatore (FDA, USA)
Ann Punnoose (FDA, USA)

Patient viewpoints
Lisa Salberg (HCMA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HYPERTROPHIC CARDIOMYOPATHY TRIALS. THE SURROGATE vs. HARD OUTCOME DILEMMA

Chairpersons: Perry Elliott (London, GBR) and Iacopo Olivotto (Florence, ITA)

Panelists: Arnaud Bastien (BMS, USA), Gabriel Brooks (Solid Biosciences, USA), Caroline Coats (Glasgow, GBR), Emil deGoma (BraveHeart, USA), Perry Elliott (London, GBR), Justin Godown (Cytokinetics, USA), Laura Helbling (Silver Spring, MD, USA), Carolyn Ho (Boston, MA, USA), Martin Maron (Boston, MA, USA), Ahmad Masri (Portland, OR, USA), Iacopo Olivotto (Florence, ITA), Anjali Owens (Philadelphia, PA, USA), Natasha Paterson (Tenaya Therapeutics, USA), Ann Punnoose (FDA, USA), Joseph Rossano (Philadelphia, PA, USA), Lisa Salberg (HCMA, Denville, NJ, USA), Fortunato Senatore (FDA, USA)

East
Monday, December 7, 2026
14:00 -16:00

**CVCT - HEART FAILURE Collaboratory joint session
PATIENT-REPORTED OUTCOMES – ESSENTIAL, BUT HOW?**

Chairpersons: Mona Fiuzat (Washington, DC, USA) & Chris O'Connor (Washington, DC, USA)

History And Challenges with Current PRO Endpoints
Javed Butler (Dallas, TX, USA)

What Is an Anchor and Minimally Clinically Important Difference, and How To Assess It?
Folke Folkvaljon (AstraZeneca, SWE)

Population Mean Difference and Responder Analysis
Mitch Psotka (FDA, USA)

Does Distribution-Based Analysis Solve the Problem?
Cordula Zeller (Boehringer Ingelheim, GER)

Do We Need Pros? NYHA Class as Endpoint? How to use Anchor?
Charu Gandotra (FDA, USA)

PROs in Win Ratio and in Open-Label Trials
Eric Leifer (NIH/NHLBI, USA)

Regulatory Viewpoint
Charu Gandotra (FDA, USA)
Lisa Plummer (FDA, USA)

Industry Viewpoints
Phillip Adamson (CVRx, USA), Lothar Roessig (AskBio, GER)

Patient viewpoint
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

REFINING PATIENT-REPORTED OUTCOMES USE IN CLINICAL TRIALS.

Chairpersons: Mona Fiuzat (Washington, DC, USA) & Chris O'Connor (Washington, DC, USA)

Panelists: Phillip Adamson (CVRx, USA), Martina Brueckmann (Roche, CH), Javed Butler (Dallas, TX, USA), Mona Fiuzat (Washington, DC, USA), Folke Folkvaljon (AstraZeneca, SWE), Charu Gandotra (FDA, USA), Eric Leifer (NIH, USA), Christopher O'Connor (Washington, DC, USA), Lisa Plummer (FDA, USA), Mitch Psotka (FDA, USA), Lothar Roessig (AskBio, GER), Frances Varian (Sheffield, GBR), Cordula Zeller (Boehringer Ingelheim, GER), Bram Zuckerman (FDA, USA)

East
Monday, December 7, 2026
16:30 -19:30

**HYPERTENSION TRIALS
PART I**

NOVEL TARGETED THERAPEUTICS —NAVIGATING THE OPPORTUNITIES AND OBSTACLES

Chairpersons: Jenifer Brown (Boston, MA, USA) & Neha Pagidipati (Durham, NC, USA)

Are all forms of difficult-to-control or resistant hypertension caused by aldosterone dysregulation?

Jenifer Brown (Boston, MA, USA)

Acute Severe Hypertension: Disease? Target? Bystander?

Jay Edelberg (Kardigan, USA)

Aldosterone Synthase Inhibitors (ASIs): Will they transform hypertension management?

Bryan Williams (London, GBR)

Small Interfering RNA (siRNA) Against Angiotensinogen: Going Beyond Conventional RAS Blockade for Hypertension Treatment and CVD Prevention?

Neha Pagidipati (Durham, NC, USA)

Have Endothelin Receptor Antagonists Finally Found Their Place in Resistant Hypertension?

Markus Schlaich (Perth, AUS)

Industry Viewpoints

Martine Clozel (Idorsia, CHE), Shira Perl (AstraZeneca, USA), David Rodman (Mineralys Therapeutics, USA)

Panel Discussion & Q&A

HAVE WE REACHED PEAK INNOVATION IN HYPERTENSION THERAPIES?

Chairpersons: Jenifer Brown (Boston, MA, USA) & Neha Pagidipati (Durham, NC, USA)

Panelists: Michel Azizi (Paris, FRA), Jenifer Brown (Boston, MA, USA), Martine Clozel (Idorsia, CHE), Jay Edelberg (Kardigan, USA), Tim Fischell (Ablative Solutions, USA), Naomi Fisher (Boston, MA, USA), William Herzog (FDA, USA), Neha Pagidipati (Durham, NC, USA), Shira Perl (AstraZeneca, USA), Garrett Pilcher (Medtronic, USA), Helen Reeve-Stoffer (Recor Medical, USA), David Rodman (Mineralys Therapeutics, USA), Anthony Rodgers (Sydney, AUS), Markus Schlaich (Perth, AUS), Roland Schmieder (Erlangen, GER), Laurence Tallon (MHRA, GBR), Noriko Tojo (Otsuka, JPN), William White (Boca Raton, FL, USA), Bryan Williams (London, GBR), Dion Zappe (Alnylam, USA)

East
Monday, December 7, 2026
16:00 -19:00

HYPERTENSION TRIALS PART II

ARE STANDARD RCT DESIGNS KILLING POTENTIALLY EFFECTIVE ANTI-HYPERTENSIVE DRUGS AND DEVICE-BASED THERAPY?

Chairpersons: Michel Azizi (Paris, FRA) & Bryan Williams (London, GBR)

Learning from Recent Failures of Novel Drug and Device Development for Hypertension. How would I design my next trial?

Drug Therapy
William White (Boca Raton, FL, USA)

Device-based therapy
Roland Schmieder (Erlangen, GER)

Navigating Regulatory Guidelines: Where Does RDN Stand in 2026 in an Era of Novel Approaches To Treatment?
Naomi Fisher (Boston, MA, USA)

Ubiquitous Single-Pill multidrug combination therapy for hypertension: Multiple drugs or better-targeted therapy?
Anthony Rodgers (Sydney, AUS)

Industry Viewpoints
Tim Fischell (Ablative Solutions, USA), Helen Reeve-Stoffer (Recor Medical, USA), Noriko Tojo (Otsuka, JPN), Dion Zappe (Alnylam, USA)

Cheap daily generics versus one-shot or biannual injectable therapies?

Regulatory viewpoints
Laurence Tallon (MHRA, GBR), Aliza Thompson (FDA, USA)
William Herzog (FDA, USA)

Payers' viewpoint
TBD

The CVCT Multi-Stakeholder Think Tank Debate

BRIDGING THE GAP BETWEEN INNOVATION AND IMPLEMENTATION: CAN CHEAP, GENERIC POLYPILLS FOR THE MASSES COEXIST WITH INNOVATIVE TARGETED THERAPIES?

Chairpersons: Michel Azizi (Paris, FRA) & Bryan Williams (London, GBR)

Panelists: Michel Azizi (Paris, FRA), Jenifer Brown (Boston, MA, USA), Martine Clozel (Idorsia, CHE), Tim Fischell (Ablative Solutions, USA), Naomi Fisher (Boston, MA, USA), William Herzog (FDA, USA), Neha Pagidipati (Durham, NC, USA), Shira Perl (AstraZeneca, USA), Garrett Pilcher (Medtronic, USA), Helen Reeve-Stoffer (Recor Medical, USA), David Rodman (Mineralys Therapeutics, USA), Anthony Rodgers (Sydney, AUS), Markus Schlaich (Perth, AUS), Roland Schmieder (Erlangen, GER), Laurence Tallon (MHRA, GBR), Aliza Thompson (FDA, USA), Noriko Tojo (Otsuka, JPN), William White (Boca Raton, FL, USA), Bryan Williams (London, GBR), Dion Zappe (Alnylam, USA)

State
Monday, December 7, 2026
08:30 -10:30

**ALDOSTERONE IN CARDIOVASCULAR-KIDNEY-METABOLISM DISEASES
ENDURING AND EMERGING SCIENCE, NEW OPPORTUNITIES AND CLINICAL TRIALS LANDSCAPE**
Chairpersons: Bertram Pitt (Ann Arbor, MI, USA) & Faiez Zannad (Paris, FRA)

Prevalence and Clinical Impact of Hyperaldosteronism and Hypercortisolism in CKM disease
Anand Vaidya (Boston, MA, USA)

How far can we suppress maladaptive mineralocorticoid biology without toxicity. How translational science may inform clinical trials.
TBD

Is aldosterone level the wrong target, and MR overactivation the real disease biology?
Bertram Pitt (Ann Arbor, MI, USA)

sMRA, nsMRA, MRM, and ASi: Will anyone ever measure aldosterone before treatment?
Mario Berger (Bayer, GER)

ASI trials update
Javed Butler (Dallas, TX, USA)

nsMRA trials update
Scott Solomon (Boston, MA, USA)

Primary care physician viewpoint. Why are we failing to detect hyperaldosteronism in routine CKM care?"
Javier Morales (New York, NY, USA)

Industry viewpoints
Alessandro Albuquerque (Recordati, ITA), Maria Borentain (Bayer, GER), Mikhail Kosiborod (AstraZeneca, USA), David Rodman (Mineralys Therapeutics, USA)

What level of incremental benefit justifies premium pricing?
Tamara Syrek Jensen (CMS, USA), Niklas Hedberg (TLV, SWE)

The CVCT Multi-Stakeholder Think Tank Debate

**ALDOSTERONE IN CARDIOVASCULAR-KIDNEY-METABOLISM DISEASES
ENDURING AND EMERGING SCIENCE, NEW OPPORTUNITIES AND CLINICAL TRIALS LANDSCAPE**
Chairpersons: Bertram Pitt (Ann Arbor, MI, USA) & Faiez Zannad (Paris, FRA)

Panelists: Alessandro Albuquerque (Recordati, ITA), Mario Berger (Bayer, GER), Maria Borentain (Bayer, GER), Javed Butler (Dallas, TX, USA), Niklas Hedberg (TLV, SWE), Mikhail Kosiborod (AstraZeneca, USA), John McMurray (Glasgow, GBR), Javier Morales (New York, NY, USA), Bertram Pitt (Ann Arbor, MI, USA), David Rodman (Mineralys Therapeutics, USA), Scott Solomon (Boston, MA, USA), Tamara Syrek Jensen (CMS, USA), Anand Vaidya (Boston, MA, USA)

State
Monday, December 7, 2026
11:00 -13:00

CARDIO-KIDNEY-METABOLIC TRIALS. HOW TO COPE WITH MULTIPLE DRUGS, MULTI-ORGAN COMPOSITE ENDPOINTS AND MULTIPLE SOURCES OF EVIDENCE.

Chairpersons: Hidido L Heerspink (Groningen, NED) & Clare Arnott (Sydney, AU)

Targeting combined multiorgan cardiovascular and kidney benefits. Rationale and opportunities

Nephrologist viewpoint
Hidido L Heerspink (Groningen, NED)

Cardiologist viewpoint
Faiez Zannad (Paris, FRA)

Primary Care Physician viewpoint
Naresh Kanumilli (Manchester, GBR)

How to select the right patient population in multiorgan cardio-kidney-metabolic clinical trials?
Brendon Neuen (Sydney, AUS)

Hitting multiple birds with a single stone

Virtues and limitations of composite endpoints. Statistician viewpoints.
Heidi Christ (Basel, CHE)

Can dual indications be claimed with a single trial? Regulatory viewpoint.
Aliza Thompson (FDA, USA)

How may payers value single drug multi-organ benefits?
Amanda Adler (London, GBR)

Trials investigating multidrug CKM stack. Add-on, vs. head-to-head, vs. non-inferiority trial designs.

Clinical viewpoint
Will Herrington (Oxford, GBR)

Statistical viewpoint
Brian Claggett (Boston, MA, USA)

Regulatory viewpoints
Aliza Thompson (FDA, USA)

Industry viewpoints.
Meike Brinker (Bayer, GER), Martina Brueckmann (Roche, CH), Dustin Little (Astra Zeneca, USA), Becky Harmon (Eli Lilly, USA),
TBD (Novo-Nordisk)

Patient viewpoint.
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

CARDIO-KIDNEY-METABOLIC TRIALS. HOW TO COPE WITH MULTIPLE DRUGS, MULTI-ORGAN COMPOSITE ENDPOINTS AND MULTIPLE SOURCES OF EVIDENCE

Chairpersons: Hidido Heerspink (Groningen, NED) & Clare Arnott (Sydney, AU)

Panelists: Amanda Adler (London, GBR), Clare Arnott (Sydney, AU), Martina Brueckmann (Roche, CH), Meike Brinker (Bayer, GER), Heidi Christ (Basel, CHE), Brian Claggett (Boston, MA, USA), Jennifer Green (Durham, NC, USA), Becky Harmon (Eli Lilly, USA), Hidido L. Heerspink (Groningen, NED), Will Herrington (Oxford, GBR), Naresh Kanumilli (Manchester, GBR), Dustin Little (AstraZeneca, USA), Brendon Neuen (Sydney, AUS), Norman Stockbridge (S&S Consulting, USA), Aliza Thompson (FDA, USA), Faiez Zannad (Paris, FRA)

State
Monday, December 7, 2026
14:00 -16:00

CVCT-NIH-WOMEN AS ONE JOINT SESSION
BEYOND REPRESENTATION: DESIGNING CARDIOVASCULAR TRIALS AROUND WOMEN'S BIOLOGY AND LIFE COURSE

Chairpersons: Robert Califf (Durham, NC, USA) & Martha Gulati (Los Angeles, CA, USA)

Cardiovascular disease (CVD) in women evolves across the lifespan, shaped by reproductive biology, hormonal transitions, and social and environmental influences. A life-course framework highlights pregnancy and menopause as two critical points where cardiovascular risk is either revealed or accelerated. These windows provide important opportunities for early detection, targeted prevention, and improved clinical trial design. However, significant gaps persist, including the underrepresentation of pregnant and perimenopausal women in trials, limited randomized evidence, and a lack of longitudinal studies that track risk across decades.

Reframing lifespan transitions as strategic opportunities for detection and intervention can enable a proactive, lifespan-based approach to prevention and improve cardiovascular outcomes.

Current and future unmet needs in women's cardiovascular health research
Martha Gulati (Los Angeles, CA, USA)

Global priorities and funding opportunities for advancing women's cardiovascular research
Janine Clayton (NIH/ OWH, USA)

Pregnant and lactating individuals in clinical trials: ethical and clinical crossroads
Catherine Spong (NIH/NICHD, USA)

Peripartum and Postpartum interventions to improve short- and long-term maternal and fetal cardiovascular health
Garima Arora (Birmingham, AL, USA)

Trials' opportunities in menopause as a vascular transition.
Nanette Santoro (Aurora, CO, USA)

Ischemia with no obstructive coronary artery disease: A female-enriched phenotypes in HFpEF trials?
Odayme Quesada (Cincinnati, OH, USA)

Obesity-metabolic trials in women
Rachel Batterham (Lilly, GBR)

Regulatory expectations for sex-specific evidence
Kaveeta Vasisht (FDA, USA)

Industry viewpoints
Amy Ford (Lilly, USA), Luba Soskin (Bayer, CHE), Anna Windle (Novo Nordisk, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

SETTING PRIORITIES FOR RESEARCH, POLICY, AND PRACTICE IN WOMEN'S HEALTH
Chairpersons: Robert Califf (Durham, NC, USA) & Martha Gulati (Los Angeles, CA, USA)

Panelists: Garima Arora (Birmingham, AL, USA), Juan Camilo Arjona Ferreira (Organon, COL), Rachel Batterham (Lilly, GBR), Robert Califf (Durham, NC, USA), Ediina Cenko (Bologna, IT), Janine Clayton (NIH/ OWH, USA), Amy Ford (Lilly, USA), Martha Gulati (Los Angeles, CA, USA), Odayme Quesada (Cincinnati, OH, USA), Nanette Santoro (Aurora, CO, USA), Luba Soskin (Bayer, CHE), Catherine Spong (NIH/NICHD, USA), Kaveeta Vasisht (FDA, USA), Anna Windle (Novo Nordisk, USA)

State
Monday, December 7, 2026
16:30 -19:30

STRATEGIES FOR CLINICAL TRIAL DESIGN IN - PATIENTS AT RISK OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE

Part 1

HOW BEST TO DEFINE TARGET POPULATIONS?

Chairpersons: Marc Sabatine (Boston, MA, USA) & Lale Tokgozoglu (Ankara, TUR)

Comparison of guideline recommendations: Sorting out the “at-risk” trial population
Lale Tokgozoglu (Ankara, TUR)

Guiding the next generation of trials in high-risk event-free patients
Erin Bohula (Boston, MA, USA)

Can blood pressure and LDL cholesterol be targeted at once with a single bullet?
Sergio Fazio (Corsera, USA)

Target patient population: Screening of atherosclerosis risk

3-dimensional ultrasonography of carotid and iliofemoral arteries
Valentin Fuster (New York, NY, USA)

CT angiography plaque volume and plaque characteristics
Gemma Figtree (Sydney, AUS)

Genetic instruments
Ron Do (New York, NY, USA)

Proteomic profiling
Sascha Goonewardena (Ann Arbor, MI, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW BEST TO DEFINE TARGET POPULATIONS?

Chairpersons: Marc Sabatine (Boston, MA, USA) & Lale Tokgozoglu (Ankara, TUR)

Panelists: Erin Bohula (Boston, MA, USA), Brian Claggett (Boston, MA, USA), Sergio Fazio (Corsera, USA), Ron Do (New York, NY, USA), Gemma Figtree (Sydney, AUS), Valentin Fuster (New York, NY, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Adrian Hernandez (Durham, NC, USA), Borja Ibanez (Madrid, ESP), Paulus Kirchhof (Hamburg, GER), Guiomar Mendieta-Badimon (Barcelona, ESP), Darren McGuire (Dallas, TX, USA), Marc Sabatine (Boston, MA, USA), John Sharretts (FDA, USA), Lale Tokgozoglu (Ankara, TUR), Muthiah Vaduganathan (Boston, MA, USA), Lisa Yanoff (FDA, USA)

State
Monday, December 7, 2026
16:00 -19:00

Part 2
CVCT-DCRI JOINT SESSION
ENDPOINT FOR PREVENTION BEYOND ASCVD

Chairpersons: Adrian Hernandez (Durham, NC, USA) & Guiomar Mendieta-Badimon (Barcelona, ESP)

Heart failure: Hospitalization or outpatient diagnosis?
Muthiah Vaduganathan (Boston, MA, USA)

Atrial fibrillation: Clinically relevant burden?
Paulus Kirchhof (Hamburg, GER)

Diabetes: The prevention vs. masking conundrum and does it matter?
Darren McGuire (Dallas, TX, USA)

Guiding the next generation of trials in high-risk event-free patients
Nishant Shah (Durham, NC, USA)

Statistical viewpoint
Brian Claggett (Boston, MA, USA)

Industry viewpoint
Stephen Wiviott (AstraZeneca, USA)

Regulatory viewpoint
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PREVENTION TRIALS IN AT RISK POPULATIONS – HOW TO ACCELERATE INNOVATION?

Chairpersons: Adrian Hernandez (Durham, NC, USA) & Guiomar Mendieta-Badimon (Barcelona, ESP)

Panelists: Erin Bohula (Boston, MA, USA), Brian Claggett (Boston, MA, USA), Ron Do (New York, NY, USA), Gemma Figtree (Sydney, AUS), Valentin Fuster (New York, NY, USA), Charu Gandotra (FDA, USA), Sascha Goonewardena (Ann Arbor, MI, USA), Adrian Hernandez (Durham, NC, USA), Borja Ibanez (Madrid, ESP), Paulus Kirchhof (Hamburg, GER), Darren McGuire (Dallas, TX, USA), Guiomar Mendieta-Badimon (Barcelona, ESP), Marc Sabatine (Boston, MA, USA), Nishant Shah (Durham, NC, USA), Lale Tokgozogl (Ankara, TUR), Raymond Soccio (FDA, USA), Aliza Thompson (FDA, USA), Muthiah Vaduganathan (Boston, MA, USA), Stephen Wiviott (AstraZeneca, USA)

Chinese
Monday, December 7, 2026
16:30 -19:30

CVCT/PATIENT ADVOCACY CONSORTIUM JOINT SESSION
MAKING CLINICAL TRIAL EVIDENCE UNDERSTANDABLE TO PATIENTS —AND TO EVERYONE OUTSIDE
THE TRIALIST COMMUNITY?

PLAIN-LANGUAGE TRIAL SUMMARIES PUBLICATIONS.
Chairpersons : Marc Bains (HeartLife, CAN) & Faiez Zannad (Paris, FRA)

CVCT is to announce the important CVCT PLSP new initiative
With the participation of patient trialists and journal editors

Plain language summaries for patients sit at the intersection of three otherwise separate problems: widespread, often underestimated gaps in health literacy; a clinical encounter structurally too brief to transmit complex medical information; and the well-documented link between patient understanding and treatment adherence. None of these problems is fully solvable by better bedside manner alone. A well-constructed PLSP — tested for readability, free of unexplained jargon, and ideally reviewed by actual patients before publication — gives people durable, revisitable access to the information a rushed visit cannot fully deliver. As regulators, journals, funders, and pharmaceutical sponsors increasingly require these summaries as a condition of publication, the opportunity is not just to check a compliance box, but to meaningfully close the gap between what medical research knows and what the patients living with that research actually understand.

«Plain language» to change clinical actions and trial implementation in the real world.

The EU perspective
Trish Greenhalgh (Oxford, GBR)

The US perspective
Michael Wolf (Chicago, IL, USA)

No jargon, please. Just tell me what this trial means. What do non-trialists actually want to know?
Rhonda Monroe (Charlotte, NC, USA)
Frances Shiely (Cork, GBR)

Readable is not necessarily understandable: what health-literacy research teaches us
Kamlesh Khunti (Leicester, GBR)

What errors would make a PLS unacceptable—even if patients and non-trialists find it easy to read?
Stuart Pocock (London, GBR)

The Human-AI loop. Responsible use of artificial intelligence in creating plain language summaries
Karen Gainey (Sydney, AUS)

The respective roles of regulatory lay summaries and of citable plain-language summary journal publications.
Emma Doble (BMJ, GBR)

The CVCT PLSP Initiative: From Trial Results to Non-Trialist Understanding
What minimum standard should CVCT adopt today?
Javed Butler (Dallas, TX, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

Making clinical trial evidence understandable for everyone.
Why and how should scientific publication no longer be the final stop?
Chairpersons : Marc Bains (HeartLife, CAN) & Faiez Zannad (Paris, FRA)

Panelists : Marc Bains (London, GBR), Javed Butler (Dallas, TX, USA), Emma Doble (BMJ, GBR), Karen Gainey (Sydney, AUS), Trish Greenhalgh (Oxford, GBR), Kamlesh Khunti (Leicester, GBR), Rhonda Monroe (Charlotte, NC, USA), Stuart Pocock (London, GBR), Frances Shiely (Cork, GBR), Michael Wolf (Chicago, IL, USA), Faiez Zannad (Paris, FRA)

Ballroom
Monday, December 7, 2026
08:30 -10:30

STRATEGIES TO ACHIEVE LDL CHOLESTEROL GOALS MORE EFFECTIVELY AND MORE EFFICIENTLY
Chairpersons: Pamela Morris (Mount Pleasant, SC, USA) & Greg Schwartz (Denver, CO, USA)

Bivalent approaches to achieve LDL cholesterol goals. Building the platform on a PCSK9 inhibitor
Jie Zeng (Rona Therapeutics, CHN)

Oral combinations getting to goal more effectively – trial design considerations for dual targets
Neha Pagidipati (Durham, NC, USA)

Investigating durable solutions with gene/base editing
Sekar Kathiresan (Verve, USA)

Metabolic regulators: Broadening the approach, Hitting multiple birds with a single stone
Jianping Li (Beijing, CHN)

Ethical considerations for placebo-controlled trials with PCSK9 inhibitors
TBD

Industry viewpoints
Puja Banka (Merck, USA), Alex DePaoli (Rona Therapeutics, CHN), Jason Duran (CRISPR Therapeutics, USA), Jennifer Hellawell (Arrowhead pharmaceuticals, USA), Per Johannsen (AstraZeneca, SWE), John Kastelein (New Amsterdam, USA), Anastasia Lesogor (Novartis, CHE)

Regulatory viewpoint
Eileen Craig (FDA, USA)
Jacob George (MHRA, GBR)

Patient viewpoint
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

STRATEGIES TO ACHIEVE POWERFUL AND LONGER DURATION CHOLESTEROL LOWERING
Chairpersons: Pamela Morris (Mount Pleasant, SC, USA) & Greg Schwartz (Denver, CO, USA)

Panelists: Alex DePaoli (Rona Therapeutics, CHN), Puja Banka (Merck, USA), Eileen Craig (FDA, USA), Jason Duran (CRISPR Therapeutics, USA), Jacob George (MHRA, GBR), Jennifer Hellawell (Arrowhead pharmaceuticals, USA), Per Johannsen (AstraZeneca, SWE), John Kastelein (New Amsterdam, USA), Sekar Kathiresan (Verve Therapeutics, USA), Anastasia Lesogor (Novartis, CHE), Jianping Li (Beijing, CHN), Michelle O'Donoghue (Boston, MA, USA), Pamela Morris (Mount Pleasant, SC, USA), Neha Pagidipati (Durham, NC, USA), Greg Schwartz (Denver, CO, USA), Jie Zeng (Rona Therapeutics, CHN)

Ballroom
Monday, December 7, 2026
11:00 -13:00

LP (a) TRIALS. HORIZON AND BEYOND THE HORIZON

Chairpersons: Leslie Cho (Cleveland, OH, USA) & Robert Rosenson (New York, NY, USA)

HORIZON – Main findings
Leslie Cho (Cleveland, OH, USA)

Target patient population, generalizability, and subgroup analyses: To whom do the results apply?
Borge Nordestgaard (Copenhagen, DNK)

Safety results and implementation issues
Robert S. Rosenson (New York, NY, USA)

Statistical viewpoint and the issue of highly skewed continuous variables
Laine Thomas (Durham, NC, USA)

How HORIZON will frame the competing landscape.

Expanded use of pelacarsen beyond the very high-risk patient
Michelle O'Donoghue (Boston, MA, USA)

Are primary prevention trials next?
Sascha N. Goonewardena (Ann Arbor, MI, USA)

Is one-time administration - lifelong Lp(a) suppression next?
Amit Khera (Verve Therapeutics, USA)

Is aortic stenosis next?
TBD

Which should be the preferred approach for patients with ASCVD and elevated Lp(a)? Targeted Lp(a) suppression or PCSK9 inhibition, or both?
Greg Schwartz (Denver, CO, USA)

Industry viewpoints
Hui Cao (Novartis, USA), Jeff Emmick (Lilly, USA), Monica Florio (Amgen, USA), Curtis Rambaran (Silence Therapeutics, GBR), Sam Tsimikas (Ionis, USA).

Regulatory viewpoint
Jacob George (MHRA, GBR), Brittany Schuck (FDA, USA)

Payers' viewpoint
Grace Lin (ICER, USA)

Patient viewpoint
ShantaQuilette Carter (Pink Peppermint Project, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ADOPTION OF HORIZON RESULTS AND ADAPTION OF LP (a) TRIALS.

Chairpersons : Leslie Cho (Cleveland, OH, USA) & Robert Rosenson (New York, NY, USA)

Panelists: Hui Cao (Novartis, USA), ShantaQuilette Carter (Pink Peppermint Project, USA), Leslie Cho (Cleveland, OH, USA), Jeff Emmick (Lilly, USA), Monica Florio (Amgen, USA), Charu Gandotra (FDA, USA), Jacob George (MHRA, GBR), Sascha N. Goonewardena (Ann Arbor, MI, USA), Amit Khera (Verve Therapeutics, USA), Laine Thomas (Durham, NC, USA), Grace Lin (ICER, USA), Børge G. Nordestgaard (Copenhagen, DNK), Michelle O'Donoghue (Boston, MA, USA), Curtis Rambaran (Silence Therapeutics, GBR), Robert Rosenson (New York, NY, USA), Greg Schwartz (Denver, CO, USA), Brittany Schuck (FDA, USA), Tabassome Simon (Paris, FRA), Sam Tsimikas (Ionis, USA)

Ballroom
Monday, December 7, 2026
14:00 -16:00

iCVCT # 5

STRATEGIZING ENTERING THE CLINICAL STAGE FOR HF MEDTECH STARTUPS
Chairpersons: Dan Burkhoff (New York, NY, USA) & Martin Leon (New York, NY, USA)

Overview. The innovation landscape of HF devices

Innovators' viewpoint
Howard Levin (Coridea, USA)

Investors' viewpoints
Josh Makower (Coravin, USA)
Antoine Papiernik (Sofinova Partners, FRA)
Hanson Gifford (The Foundry, USA)

Regulatory viewpoint
Andrew Farb (FDA, USA)

Recent learnings from pilot studies

Devices to treat Heart Failure
Dan Burkhoff (New York, NY, USA)

Devices to treat Structural Heart Disease
Martin Leon (New York, NY, USA)

The competitive landscape. What is in the pipeline? Industry presentations (5min each)

The First-in-Human & Early Feasibility Masters
Sahar Boostenay (REVAMP, ISR), David Drachman (Magenta, ISR), Yaacov Nitzan (Aquapass, ISR))

Shifting from Feasibility to Pivotal Global Trials (Structural & Interatrial Shunts)
William Abraham (V-Wave, ISR), Jeff Closs (Ancora, USA), Kate Stohlman (Corvia, USA).

Navigating Complex Niche Innovations (Neuro, Myocardial, and Pulmonary Targets)
Reynolds M. Delgado III (Procyrion, USA), Howard Levin (Coridea, USA), Ryan Miller (BioVentrix, USA), Martin Rothman (Pulnovo, CHN), Harry D. Rowland (Relief Cardiovascular, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

STRATEGIZING ENTERING THE CLINICAL STAGE FOR HF MEDTECH STARTUPS
Chairpersons: Dan Burkhoff (New York, NY, USA) & Martin Leon (New York, NY, USA)

Panelists: William Abraham (V-Wave, ISR), Sahar Boostenay (REVAMP, ISR), Dan Burkhoff (New York, NY, USA), Jeff Closs (Ancora, USA), Reynolds M. Delgado III (Procyrion, USA), David Drachman (Magenta, ISR), Andrew Farb (FDA, USA), Hanson Gifford (The Foundry, USA), Howard Levin (Coridea, USA), Martin Leon (New York, NY, USA), Josh Makower (Coravin, USA), Ryan Miller (BioVentrix, USA), Yaacov Nitzan (Aquapass, ISR)), Antoine Papiernik (Sofinnova Partners, FRA), Martin Rothman (Pulnovo, CHN), Harry D. Rowland (Relief Cardiovascular, USA), Kate Stohlman (Corvia, USA)

Ballroom
Monday, December 7, 2026
16:30 -19:30

STRATEGIZING ENTERING THE CLINICAL STAGE FOR BIOTECH STARTUPS.

Part 1: HEART FAILURE

Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

The innovation landscape: Regulatory viewpoints
Robert Califf (Durham, NC, USA)
Jacob George (MHRA, GBR)

The innovation landscape: Investors' viewpoints
Craig Gordon (GordonMD Global Investment LP, USA)

What de-risking do investors expect?
Mark Chin (Avaro Ventures, USA)

Recent conceptual advances and Heart failure phase 2 trials
Milton Packer (Dallas, TX, USA)

The competitive landscape. What is in the heart failure pipeline? Industry presentations

Activin type II receptor antagonists-1
Yong Yue (Laekna Therapeutics, CHN)

Activin type II receptor antagonists-2
George Georges (38 Pharma/GSK, USA)

Activin signaling inhibitors
Alessia Urbinati (Merck, USA)

Endotrophin antagonists
Federica Genovese (Nordic Bioscience, DNK)

FGF21 Receptor Agonists
Andrew Cheng (NovoNordisk, USA)

PDE9 inhibitors
Howard Surks (Cardurion, USA)

Actin-related antibodies
Mark DiNubile (BioAegis, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

Part 1: Heart Failure

Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

Panelists: Hafid Ait-Oufella (Polygon, FRA), David Bauman (Schrödinger, USA), Brieana Buckley (Editas Medicine, USA), Robert Califf (Durham, NC, USA), Andrew Cheng (Novo Nordisk, USA), Mark Chin (Avaro Ventures, USA), Mark DiNubile (BioAegis, USA), Chris Farina (Abcentra, USA), Federica Genovese (Nordic Bioscience, DNK), George Georges (38 Pharma/GSK, USA), Jacob George (MHRA, GBR), Craig Gordon (GordonMD Global Investment LP, USA), Filip Janku (Monterosa, USA), Henri Lichens (DrugFarm, USA), Peter Libby (Boston, MA, USA), Ciaran McMullan (Merck, USA), Milton Packer (Dallas, TX, USA), Howard Surks (Cardurion, USA), Alessia Urbinati (Merck, USA), Yong Yue (Laekna Therapeutics, CHN)

Ballroom
Monday, December 7, 2026
16:00 -19:00

STRATEGIZING ENTERING THE CLINICAL STAGE FOR BIOTECH STARTUPS.
Part 2: INFLAMMATION ATHEROSCLEROSIS
Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

Recent conceptual advances and phase 2 inflammation Atherosclerosis Trials (10 min)
Peter Libby (Boston, MA, USA)

The competitive landscape. What is in the inflammation pipeline? Industry presentations

What is new in computational drug design
David Bauman (Schrodinger, USA)

Targeted Protein Degradation in Therapeutics
Filip Janku (Monterosa, USA)

A Novel Anti-inflammatory Approach with a Companion Diagnostic
Henri Lichens (DrugFarm, USA)

Immunological Targets in Cardiac Disease
Hafid Ait Oufella (Polygon, FRA)

Plaque-targeted Anti-Inflammatory Therapy: Targeting Oxidized LDL
Chris Farina (Abcentra, USA)

Repairing Broken Genes with CRISPR
Brieana Buckley (Editas, Medicine, USA)

Oral NLRP3 inflammasome inhibition
Jyothis George (NodThera, GBR)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

Part 2: inflammation Atherosclerosis
Chairpersons: Peter Libby (Boston, MA, USA) & Milton Packer (Dallas, TX, USA)

Panelists: Hafid Ait-Oufella (Polygon, FRA), David Bauman (Schrödinger, USA), Brieana Buckley (Editas Medicine, USA), Robert Califf (Durham, NC, USA), Andrew Cheng (Novo Nordisk, USA), Mark DiNubile (BioAegis, USA), Chris Farina (Abcentra, USA), Federica Genovese (Nordic Bioscience, DNK), Jyothis George (NodThera, GBR), George Georges (38 Pharma/GSK, USA), Jacob George (MHRA, GBR), Craig Gordon (GordonMD Global Investment LP, USA), Filip Janku (Monterosa, USA), Henri Lichens (DrugFarm, USA), Peter Libby (Boston, MA, USA), Ciaran McMullan (Merck, USA), Milton Packer (Dallas, TX, USA), Howard Surks (Cardurion, USA), Alessia Urbinati (Merck, USA), Yong Yue (Laekna Therapeutics, CHN)

**Palm court
Tuesday, December 8, 2026
08:30 -10:30**

**Statistics Master Class # 1:
SOME PERENNIAL CHALLENGES IN TRIAL DESIGN AND ANALYSIS
Chairpersons: Frank Rockhold (Durham, NC, USA) & Gregg Stone (New York, NY, USA)**

In this session, we cover these topical themes:

Per protocol analyses, as usually done, are viewed skeptically as potentially biased, whereas the instrumental variable approach provides greater insight.

Randomized trials often lack power and generalizability, and incorporating external data can enhance both. The non-inferiority design remains common but can be a cumbersome, underpowered tool asking the wrong question. Is there a better way forward?

Instrumental Variables in Randomized Trials

Robert Yeh (Boston, MA, USA)

David Cohen (Boston, MA, USA)

Discussion

Augmenting Power in Randomized Trials Using External Data

Issa Dahabreh (Boston, MA, USA)

Gregory Alexander (FDA, USA)

Discussion

Non-inferiority trials: Their use, misuse, and possible alternatives.

Stuart Pocock (London, GBR)

Javed Butler (Dallas, TX, USA)

Discussion

**Palm court
Tuesday, December 8, 2026
11:00 -13:00**

Bayesian Statistics Masterclass #2

BAYESIAN STATISTICS IN CARDIOVASCULAR TRIALS: FOUNDATIONS, GUIDANCE, AND EVOLVING PERSPECTIVES

Chairpersons: Frank Harrell (Nashville, TN, USA) & Norman Stockbridge (S&S Consulting, USA)

Bayesian statistics is gaining renewed attention in cardiovascular trials, offering a framework for integrating prior knowledge, accumulating evidence, and supporting clinically meaningful decision-making. This masterclass will introduce Bayesian concepts for clinicians, explore how Bayesian thinking differs from traditional frequentist approaches, and examine how it reframes evidence thresholds, multiplicity, and interpretation of trial results. It will also review the draft Bayesian guidance and consider what doors it may open for trial design, regulatory considerations, and future cardiovascular evidence generation. The session will close with reflections on how views of Bayesian methods have evolved, from skepticism to recognition of their potential role in modernizing cardiovascular trials.

**A Primer on What Bayes Offers to Randomized Clinical Trials
Scott Berry (Berry Consultants, USA)**

Discussion

**The Essence of Bayesian Statistics
Frank Harrell (Nashville, TN, USA)**

Discussion

**A Review of the Draft Bayesian Guidance and its Impacts
James Travis (FDA, USA)**

Discussion

**Evolving Views on Bayes
Norman Stockbridge (S&S Consulting, USA)**

Discussion

The CVCT Multi-Stakeholder Think Tank Moderated Debate

UNDERSTANDING BAYESIAN STATISTICS

Chairpersons: Frank Harrell (Nashville, TN, USA) & Norman Stockbridge (S&S Consulting, USA)

**Panelists: Scott Berry (Berry Consultants, USA), Frank Harrell (Nashville, TN, USA), Norman Stockbridge (S&S Consulting, USA),
James Travis (FDA, USA)**

**Tuesday, December 8, 2026
13:30 - 14:20**

KEYNOTE LECTURE

**Marc Pfeffer (Boston, MA, USA)
Victor J. Dzau (Boston, MA, USA)**

**Palm court
Tuesday, December 8, 2026
14:30 -16:30**

**Statistics Masterclass #3
BAYESIAN DESIGNS IN ACTION: LEARNING, BORROWING, AND ADAPTING
Chairpersons: Scott Berry (Berry Consultants) & Stuart Pocock (London, GBR)**

Bayesian methods offer a flexible framework for clinical trial design, allowing studies to learn and adapt as evidence accumulates. Beyond familiar uses such as interim monitoring, early stopping, and sample size selection, Bayesian approaches can support borrowing from historical or external data, adaptive enrichment of trial populations, and more flexible approaches to complex or multiple endpoints, while also offering powerful tools for earlier-phase questions such as dose selection. Through real-world trial examples, this masterclass will illustrate how Bayesian designs can use accumulating evidence to guide trial decisions, focus enrollment on populations most likely to benefit, and create more flexible and efficient cardiovascular trials.

**ICONIC-HF: Dynamic Borrowing in Practice
Thomas Goldin Diness (Pharmacosmos, DNK/USA)**

Discussion

**RESPONDER-HF: Fixed Borrowing with a Hierarchical Endpoint
Amy Crawford (Berry Consultants, USA)**

Discussion

**ENRICH: Adaptive Enrichment of the Trial Population
Ben Saville (Austin, TX, USA)**

Discussion

**CATALYST: Adaptive Sample Size and Follow-up with Multiple Endpoints
Hong Zhao (Abbott, USA)**

Discussion

Palm court
Tuesday, December 8, 2026
17:00 -19:00

OBESITY MEDICINES: BODY COMPOSITION, ASSESSMENTS, TARGETS AND CONCERNS
Chairpersons: Pam Taub (San Diego, CA, USA) & Subodh Verma (Toronto, CAN)

How to assess body composition and muscle function before and after interventions
Dennis Villareal (Houston, TX, USA)

Body composition changes in health and disease, and association with outcomes
Jason Gill (Glasgow, GBR)

Body composition changes with obesity medicines and surgery
Jennifer Linge (Linköping, SWE)

Beyond weight loss: Muscle and bone preservation with GLP-1 RAs, and will they translate into better functionality?
TBD

What target should we treat to: a certain weight, resolution of comorbidities, or both
TBD

Weight loss concerns: potential for too much weight loss in some and rapid regain post cessation / weight cycling?
Naveed Sattar (Glasgow, GBR)

Primary care physician viewpoint: What should tell my obese patients about their muscles?
Javier Morales (Bew York, NY, USA)

Industry talks
Yousuf Ali (Boehringer Ingelheim, GER)
Chad Grothen (Lilly, USA)

Regulatory Perspective : Reflections on muscle- building agents PLUS need for trials with weight loss targets
Raymond Soccio (FDA, USA)
Julia Parris (MHRA, GBR)

Patient viewpoint
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW TO DESIGN OBESITY MEDICINES TRIALS BEYOND WEIGHT LOSS
Chairpersons: Pam Taub (San Diego, CA, USA) & Subodh Verma (Toronto, CAN)

Panelists: Yousuf Ali (Boehringer Ingelheim, GER), Jason Gill (Glasgow, GBR), Chad Grothen (Lilly, USA), Jennifer Linge (Linköping, SWE), Julia Parris (MHRA, GBR), Naveed Sattar (Glasgow, GBR), Thomas Seck (Lilly, USA), Raymond Soccio (FDA, USA), Pam Taub (San Diego, CA, USA), Subodh Verma (Toronto, CAN), Dennis Villareal (Houston, TX, USA)

East
Tuesday, December 8, 2026
08:30 -10:30

ZEUS TRIAL DEEP DIVE : UNDERSTANDING AND INTERPRETING THE RESULTS OF ZEUS
Chairpersons: Paul Ridker (Boston, MA, USA) & Jean Claude Tardiff (Montreal, CAN)

ZEUS rationale and primary results
Paul Ridker (Boston, MA, USA)

The consequence of ZEUS on the ongoing inflammation trials
Wolfgang Koenig (Munich, GER)

What populations are most appropriate targets in cardio-immunology trials:

Is CKD an appropriate target population.
Hiddo Heerspink (Groningen, NLD)

Post-MI inflammation-enriched patients
Adrian Hernandez (Durham, NC, USA)

Heart failure: ATHENA and HERMES
Guiomar Mendieta Badimon (Madrid, ESP)

Peripheral artery disease: LEADER-PAD
Robert Hinchliffe (Bristol, GBR)

Therapeutic window and safety issues in cardiovascular inflammation trials
Jean Claude Tardiff (Montreal, Canada)

Industry viewpoint
Andres Hvelplund (Novo Nordisk, DEN)

Regulatory viewpoints
Aliza Thompson (FDA, USA)

Regulatory Issues: Labeling and Safety
Mads Engelmann (NovoNordisk, DEN)

Patient viewpoint
Patrick Gee (iAdvocate, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ZEUS TRIAL DEEP DIVE: IMPLICATIONS FOR CKM TRIALS

Chairpersons: Paul Ridker (Boston, MA, USA) & Jean Claude Tardiff (Montreal, CAN)

Panelists: Mads Engelmann (Copenhagen, DEN), Patrick Gee (iAdvocate, USA), Hiddo Heerspink (Groningen, NED), Adrian Hernandez (Durham, NC, USA), Robert Hinchliffe (Bristol, GBR), Andres Hvelplund (Novo Nordisk, DEN), Wolfgang Koenig (Munich, GER), Guiomar Mendieta Badimon (Madrid, ESP), Paul Ridker (Boston, MA, USA), Jean Claude Tardiff (Montreal, CAN), Aliza Thompson (FDA, USA)

East
Tuesday, December 8, 2026
11:00 -13:00

ANTI-INFLAMMATORY TREATMENT OF ASCVD: BEYOND ZEUS, WHAT IS NEXT?
Chairpersons: Wolfgang Koenig (Munich, GER) & Giovanna Liuzzo (Rome, IT)

Reverse translation: What have we learned from completed trials?
Peter Libby (Boston, MA, USA)

Targeted immune modulation for atherosclerosis
Klaus Ley (Augusta, GA, USA)

Can proteomics/multiomics provide novel insights into the best targets?
Manuel Mayr (London, GBR)

Could trials investigating an anti-inflammatory transcriptome in T-cells mediated by EPA finally solve the controversy?
Nathalie Reilly (Leiden, NED)

T reg cell-based therapies—how can we identify the immunotolerant patients with the best benefit/risk ratio
Rouchelle Sriranjana-Rothwell (Cambridge, GBR)

Specialized pro-resolving lipid mediators (SPM) implications for trial design
Gabrielle Fredman (New York, NY, USA)

IL-1 β , direct NLRP3 inhibitors – Offsetting risk versus benefit.
Reginald McNulty (Irvine, USA)

Industry Viewpoints
Chris O'Donnell (Novartis, CH), Kristen Fortney (BioAge, USA), Jyothis George (Nodthera, GBR), Maria Sejersten Ripa (Novo Nordisk, DNK), Marzia Rigolli (Eli Lilly, USA)

Regulatory Viewpoint
Mori Krantz (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ANTI-INFLAMMATORY TREATMENT OF ASCVD: WHAT HAVE WE LEARNED FROM RECENT TRIALS? HOW TO TEST NEW TARGETS IN TRIALS?

Chairpersons: Wolfgang Koenig (Munich, GER) & Giovanna Liuzzo (Rome, ITA)

Panelists: Chris O'Donnell (Novartis, CH), Gabrielle Fredman (New York, NY, USA), Kristen Fortney (BioAge, USA), Jyothis George (Nodthera, GBR), Wolfgang Koenig (Munich, GER), Mori Krantz (FDA, USA), Klaus Ley (Augusta, GA, USA), Peter Libby (Boston, MA, USA), Giovanna Liuzzo (Rome, ITA), Manuel Mayr (London, GBR), Reginald McNulty (Irvine, CA, USA), Niek Baksh Mohammadnia (Nijmegen, NED), Jorge Plutzky (Boston, MA, USA), Nathalie Reilly (Leiden, NED), Marzia Rigolli (Eli Lilly, USA), Maria Sejersten Ripa (Novo Nordisk, DNK), Fortunato Senatore (FDA, USA), Rouchelle Sriranjana-Rothwell (Cambridge, GBR)

East
Tuesday, December 8, 2026
14:30 -16:30

PULMONARY ARTERIAL HYPERTENSION
PULMONARY ARTERIAL HYPERTENSION INNOVATIVE TRIALS DESIGNS
Chairpersons: Marc Humbert (Paris, FRA) & Vallerie McLaughlin (Ann Arbor, MI, USA)

PDGF as a target in PAH: lessons from IMPRESS, IMPAHCT and PROSERA
Olivier Sitbon (Paris, FRA)

PDGF as a target in PAH: design of IMPROVE-PAH
Kelly Chin (Dallas, TX, USA)

Sotatercept in PAH: central, hematologic, and peripheral mechanisms of benefit
Yogesh Reddy (Rochester, MN, USA)

Activin signaling inhibitors safety signals in PAH trials
Iona Preston (Boston, MA, USA)

Drug development on top of drugs targeting four pathways: how?
Anna Hemnes (Nashville, TN, USA)

Investigator Viewpoints
Nick Hill (Boston, MA, USA)
Anjali Vaidya (Philadelphia, PA, USA)

Patient Viewpoint
Coleen Brunetti (Pulmonary Hypertension Association, USA)

Industry Viewpoints
Chris Cabell (Inhibikase, USA)
Ciaran McMullan (Merck, USA)
Franck Rahaghi (United Therapeutics, USA)
Rob Roscigno (Gossamer, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PULMONARY ARTERIAL HYPERTENSION INNOVATIVE DESIGNS
Chairpersons: Marc Humbert (Paris, FRA) & Vallerie McLaughlin (Ann Arbor, MI)

Panelists: Coleen Brunetti (Pulmonary Hypertension Association), Kelly Chin (Dallas, TX, USA), Chris Cabel (Inhibikase, USA), Bjorn Dahlof (Cereno, SWE), Hap Farber (Boston, MA, USA), Mardi Gomberg-Maitland (Washington, DC, USA), Anna Hemnes (Nashville, TN), Nick Hill (Boston, MA, USA), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PA, USA), Bradley Maron (Circulation, USA), Vallerie McLaughlin (Ann Arbor, MI, USA), Ciaran McMullan (Merck, USA), Mahesh Patel (Merck, USA), Iona Preston (Boston, MA, USA), Mitch Psotka (FDA, USA), Franck Rahaghi (United Therapeutics, USA), Yogesh Reddy (Rochester, MN, USA), Rob Roscigno (Gossamer, USA), Carlos Sanmarco (Pulmovant, USA), Oksana Shlobin (Falls Church, VA, USA), Olivier Sitbon (Paris, FRA), Derek Solum (United Therapeutics, NC), Mark Toshner (Cambridge, GBR), Anjali Vaidya (Philadelphia, PA, USA), Jean-Luc Vachiéry (Brussels, BE), Corey Ventetuolo (Providence, RI), Jason Weatherald (Edmonton, CA)

East
Tuesday, December 8, 2026
17:00 -19:00

PULMONARY HYPERTENSION NEXT FRONTIERS

Chairpersons: Mardi Gomberg-Maitland (Washington, DC) & Bradley Maron (Circulation, USA)

Concept of urgency in treatment of patients with pulmonary hypertension
Mardi Gomberg-Maitland (Washington, DC, USA)

Survival discrepancy between PAH patients eligible for clinical trials and clinical reality
Mark Toshner (Cambridge, GBR)

Heterogeneity of treatment effect in patients with PAH and co-existing mild lung diseases participating in randomized clinical trials
Steve Kawut (Philadelphia, PA, USA)

Remission as a goal in PAH
Jason Weatherald (Edmonton, CA)

Predictors of pulmonary hypertension in patients with interstitial lung disease
Corey Ventetuolo (Providence, RI, USA)

Pulmonary hypertension associated with interstitial lung diseases: Is it time to consider a morbidity and mortality primary endpoint?
Oksana Shlobin (Falls Church, VA, USA)

Pulmonary hypertension associated with left heart disease: Is it time to consider a morbidity and mortality primary endpoint?
Jean-Luc Vachiéry (Brussels, BE)

Investigator Viewpoints
Hap Farber (Boston, MA, USA)
Sandeep Sahay (Houston, TX, USA)

Patient Viewpoint
Coleen Brunetti (Pulmonary Hypertension Association, USA)

Industry Viewpoints
Mahesh Patel (Merck, USA), Carlos Sanmarco (Pulmovant, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PULMONARY HYPERTENSION NEXT FRONTIERS

Chairpersons: Mardi Gomberg-Maitland (Washington, DC) & Bradley Maron (Circulation, USA)

Panelists: Coleen Brunetti (Pulmonary Hypertension Association), Kelly Chin (Dallas, TX, USA), Chris Cabel (Inhibikase, USA), Bjorn Dahlof (Cerenio, SWE), Hap Farber (Boston, MA, USA), Mardi Gomberg-Maitland (Washington, DC), Anna Hemnes (Nashville, TN), Nick Hill (Boston, MA, USA), Marc Humbert (Paris, FRA), Steve Kawut (Philadelphia, PA, USA), Bradley Maron (Circulation, USA), Vallerie McLaughlin (Ann Arbor, MI, USA), Ciaran McMullan (Merck, USA), Mahesh Patel (Merck, USA), Iona Preston (Boston, MA, USA), Mitch Psotka (FDA, USA), Franck Rahaghi (United Therapeutics, USA), Yogesh Reddy (Rochester, MN, USA), Rob Roscigno (Gossamer, USA), Sandeep Sahay (Houston, TX, USA), Carlos Sanmarco (Pulmovant, USA), Oksana Shlobin (Falls Church, VA, USA), Olivier Sitbon (Paris, FRA), Derek Solum (United Therapeutics, NC), Mark Toshner (Cambridge, GBR), Anjali Vaidya (Philadelphia, PA, USA), Jean-Luc Vachiéry (Brussels, BE), Corey Ventetuolo (Providence, RI), Jason Weatherald (Edmonton, CA)

State
Tuesday, December 8, 2026
08:30 -10:30

iCVCT #1

THROMBOSIS TRIALS. CAN WE UNCOUPLE THROMBOSIS FROM BLEEDING? **Chairpersons: Michael Gibson (Boston, MA, USA) & Carolyn Lam (Singapore, SGP)**

From neutral OCEANIC AF to positive OCEANIC-Stroke trial. Clot mechanics, active drug comparator, and levels of target inhibition.

Mike Sharma (Hamilton, ON, CAN)

Regeneron FXI inhibition AF trials.

How to move from phase II less bleeding results to Phase III non-inferiority / superiority stroke prevention trial?"
TBD

What comparator(s) and what endpoints in FXI VAD trials?"
Mandeep Mehra (Boston, MA, USA)

Mechanistic insights from the ROXI-CATH tests REGN9933 and REGN7508 contact activation (pic lines and indwelling catheters) trials
Jeff Weitz (Hamilton, CAN)

Are current trial well designed to figure whether FXIa inhibition is a new anticoagulant class — or a precision antithrombotic for selected thrombo-inflammatory vascular beds
Ken Mahaffey (Stanford, CA, USA)

Speed versus diagnostic certainty — Add-on versus replacement strategies?
Michael Gibson (Boston, MA, USA)

Industry viewpoints

Dietmar Berger (Sanofi, FRA), Dan Bloomfield (Anthos, USA), Carlos Cuevas (BMS/J&J, USA), Anders Gabrielsen (Ribocure, SWE), Amer Joseph (Idorsia, CHE), David Gutstein (Regeneron, USA), András Gruber (Aronora, USA), Toby S. Johnson (Band Therapeutics, USA), Richard Secer (CeleCor, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

THE FUTURE OF THROMBOSIS INNOVATION. LARGE TARGETS VS. PRECISION-BIOLOGY BIOTECH ECOSYSTEMS?"

Chairpersons: Michael Gibson (Boston, MA, USA) & Carolyn Lam (Singapore, SGP)

Panelists: Dietmar Berger (Sanofi, FRA), Dan Bloomfield (Anthos, USA), Carlos Cuevas (BMS/J&J, USA), Anders Gabrielsen (Ribocure, SWE), Michael Gibson (Boston, MA, USA), András Gruber (Aronora, USA), David Gutstein (Regeneron, USA), Toby S. Johnson (Band Therapeutics, USA), Amer Joseph (Idorsia, CHE), Carolyn Lam (Singapore, SGP), Ken Mahaffey (Stanford, CA, USA), Mandeep Mehra (Boston, MA, USA), Richard Secer (CeleCor, USA), Mike Sharma (Hamilton, ON, CAN), Jeffrey Weitz (Hamilton, CAN)

State
Tuesday, December 8, 2026
11:00 -13:00

iCVCT # 2

PERCUTANEOUS VENTRICULAR ASSIST DEVICES TRIALS.

HIGH-RISK PCI , CARIOGENIC SHOCK AND UNANSWERED QUESTIONS

Part #1: Percutaneous Mechanical Circulatory Support Devices for High-Risk PCI

Chairpersons: Mitch Krucoff (Durham, NC, USA) & Marie-Claude Morice (Massy, FRA)

Randomized Evidence Evaluating Percutaneous MCS for High-Risk PCI
Divaka Perera (London, GBR)

MCS for High-Risk PCI – What the Evidence Tells Us
Suzanne Baron (Boston, MA, USA)

Regulatory viewpoint
William Herzog (FDA, USA)

Industry viewpoint
Devi Govender (Abiomed, USA)

Update on Percutaneous Ventricular Assist Devices Academic Research Consortium. Endpoint and other trial design issues.
Jeffrey Popma (CRF, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT DEVICES FOR HIGH-RISK PCI

Chairpersons: Mitch Krucoff (Durham, NC, USA) & Marie-Claude Morice (Massy, FRA)

Panelists: Suzanne Baron (Boston, MA, USA), Dan Burkhoff (New York, NY, USA), Rafael Cavalcante (Boston Scientific, USA) , Devi Govender (Abiomed, USA), William Herzog (FDA, USA), Navin Kapur (Abiomed/InJ, USA), Mitch Krucoff (Durham, NC, USA), Christina Lalani (Boston, MA, USA), Craig Markovitz (Magenta Medical, ISR), Roxana Mehran (New York, NY, USA) , Marie-Claude Morice (Massy, FRA), Mauro Moscucci (FDA, USA), Divaka Perera (London, GBR), Jeffrey Popma (CRF, USA), Jon Resar (FDA, USA), Nitin Salunke (Supira Medical, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

State
Tuesday, December 8, 2026
11:00 -13:00

iCVCT # 2
PERCUTANEOUS VENTRICULAR ASSIST DEVICES TRIALS
Part #2. Mechanical Circulatory Support Devices for Cardiogenic Shock
Chairpersons: Roxana Mehran (New York, NY, USA) & Robert Yeh (Boston, MA, USA)

Benefit/Risk of MCS In Stable Patients: The Critical Difference Defining «High Risk PCI» vs.»SCAI A (Pre-shock) CAD Phenotype
Michell Krucoff (Durham, NC, USA)

Clinical Trial Designs to Support Approval of New Shock Devices
Christina Lalani (Boston, MA, USA)

Pumps and Pills in Parallel: The INTeGRATE Trial in HF-Cardiogenic Shock
Alexandre Mebazaa (Paris, FRA)

Regulatory viewpoint
Jon Resar (FDA, USA)

Industry viewpoints
Navin Kapur (Abiomed/JnJ, USA), Craig Markovitz (Magenta Medical, ISR), Nitin Salunke (Supira Medical, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HIGH-RISK PCI , CARDIOGENIC SHOCK AND UNANSWERED QUESTIONS
Chairpersons: Roxana Mehran (New York, NY, USA) & Robert Yeh (Boston, MA, USA)

Panelists: Suzanne Baron (Boston, MA, USA), Dan Burkhoff (New York, NY, USA), Rafael Cavalcante (Boston Scientific, USA) , Nicole Gillette (FDA, USA), Devi Govender (Abiomed, USA), William Herzog (FDA, USA), Navin Kapur (Abiomed/JnJ, USA), Tenley Kreter (Supira Medical, USA), Mitch Krucoff (Durham, NC, USA), Christina Lalani (Boston, MA, USA), Craig Markovitz (Magenta Medical, ISR), Alexandre Mebazaa (Paris, FRA), Roxana Mehran (New York, NY, USA), Marie-Claude Morice (Massy, FRA), Divaka Perera (London, GBR), Jeffrey Popma (CRF, USA), Jon Resar (FDA, USA), Nitin Salunke (Supira Medical, USA), Robert Yeh (Boston, MA, USA)

State
Tuesday, December 8, 2026
14:30 -16:30

iCVCT # 3

**PCI WITHOUT PERMANENT CAGING - NEW DEVICES FOR DE NOVO CORONARY ARTERY
REVASCLARIZATION**

**Part 1: WILL A LEAVE-NOTHING-BEHIND STRATEGY FOR DE NOVO PCI IMPROVE LATE OUTCOMES
AFTER FIRST DES?**

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Coronary disease: have we finally learned whom to revascularize?
Bernard Gersh (Rochester, MN, USA)

Avoiding first DES in favor of a nothing-behind strategy will improve late outcomes after PCI.
Gregg Stone (New York, NY, USA)

Late outcomes after PCI are unlikely to improve with a leave nothing behind strategy.
Ziad Ali (New York, NY, USA)

FDA viewpoint
Lydia Glaw (FDA, USA)

Industry viewpoint
Rafael Cavalcante (Boston Scientific, USA)

Patient viewpoint
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

LEAVE-NOTHING-BEHIND STRATEGY

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Panelists: Ziad Ali (New York, NY, USA), Rafael Cavalcante (Boston Scientific, USA), Roisin Colleran (Galway, IRL), David Cohen (Boston, MA, USA), Donald Cutlip (Boston, MA, USA), David Erlinge (Lund, SWE), Andrew Farb (FDA, USA), Lydia Glaw (FDA, USA), Bernard Gersh (Rochester, MN, USA), Margaret McEntegart (Glasgow, GBR), Roxana Mehran (New York, NY, USA), Giovanni Occhipinti (Bologna, IT), Motasim Sirhan (Elixir Medical, USA), Gregg Stone (New York, NY, USA), Ron Waksman (Washington, DC, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

State
Tuesday, December 8, 2026
14:30 -16:30

iCVCT # 3

**PCI WITHOUT PERMANENT CAGING - NEW DEVICES FOR DE NOVO CORONARY ARTERY
REVASCULARIZATION**

Part 2: LEAVE LESS BEHIND STRATEGIES: COST, BENEFIT, INNOVATION AND SUSTAINABILITY

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Drug-coated balloons for de novo lesions. Review of current clinical trial designs and future utilization.
Roisin Colleran (Galway, IRL)

Beyond the permanent cage: Can “uncaging devices” overcome the late failure of DES without repeating the bioresorbable-
scaffold experience..
David Erlinge (Lund, SWE)

Health system viewpoint – Why Should We Pay for New Balloons/Stents/Scaffolds When DES Are So Affordable
Ron Waksman (Washington, DC, USA)

Industry viewpoint
Motasim Sirhan (Elixir Medical, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

LEAVE-NOTHING VS. LEAVE LESS BEHIND STRATEGIES

Chairpersons: Donald Cutlip (Boston, MA, USA) & Robert Yeh (Boston, MA, USA)

Panelists: Ziad Ali (New York, NY, USA), Rafael Cavalcante (Boston Scientific, USA), Roisin Colleran (Galway, IRL), David Cohen (Boston, MA, USA), Donald Cutlip (Boston, MA, USA), David Erlinge (Lund, SWE), Andrew Farb (FDA, USA), Lydia Glaw (FDA, USA), Bernard Gersh (Rochester, MN, USA), Mitchell Krucoff (Durham, NC, USA), Margaret McEntegart (Glasgow, GBR), Roxana Mehran (New York, NY, USA), Giovanni Occhipinti (Bologna, IT), Motasim Sirhan (Elixir Medical, USA), Gregg Stone (New York, NY, USA), Ron Waksman (Washington, DC, USA), Robert Yeh (Boston, MA, USA), Bram Zuckerman (FDA, USA)

State
Tuesday, December 8, 2026
17:00 -19:00

**iCVCT # 4
VALVE TRIALS**

Part #1 ARE OUR CURRENT TRIAL DESIGNS “FIT FOR PURPOSE”?

Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

Device vs. device Trials: Considerations for endpoint selection
Chad Kliger (FDA, USA)

Quality of Life is the Main Benefit of TTVI—Why not Make it the Primary Endpoint of Device vs. Device Trials?
Suzanne Arnold (Kansas City, MO, USA)

Statistician viewpoint: Multiple Comparators, Crossover and Bayesian issues
Ben Saville (Austin, TX, USA)

Are Device vs. Device trials even Appropriate?
Juan Granada (New York, NY, USA)

Should Cardiac Surgery be in the Mix? The Case for Trials vs. Surgery
Gorav Ailawadi (Ann Arbor, MI, USA)

Panel Discussion

ARE OUR CURRENT TRIAL DESIGNS “FIT FOR PURPOSE”?

Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

Panelists: Gorav Ailawadi (Ann Arbor, MI, USA), Suzanne Arnold (Kansas City, MO, USA), Suzanne Baron (Boston, MA, USA), Wayne Batchelor (Orlando, FL, USA), Todd Brinton (Edwards, USA), Rishi Chandiramani (Baltimore, MD, USA), David Cohen (Boston, MA, USA), John Gregson (London, GBR), Juan Granada (New York, NY, USA), Kendra Grubb (Medtronic, USA), Aakriti Gupta (New York, NY, USA), Jörg Hausleiter (Munich, GER), Sanjay Kaul (Los Angeles, CA, USA), Samir Kapadia (Cleveland, OH, USA), Chad Kliger (FDA, USA), Michael Mack (Dallas, TX, USA), Roxana Mehran (New York, NY, USA), Marie-Claude Morice (Massy, FRA), Mark Reisman (Edwards, USA), Ben Saville (Austin, TX, USA), Sreek Vemulapalli (Durham, NC, USA), Vinod Thourani (Atlanta, GA, USA), Changfu Wu (FDA, USA)

State
Tuesday, December 8, 2026
17:00 -19:00

iCVCT # 4
TRICUSPID VALVE INNOVATION
Part #2 THE TVT REGISTRY AT THE CROSSROADS
Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

The TVT Registry- Lessons from the First 15 Years.
Michael Mack (Dallas, TX, USA)

A View from the Trenches— What I Wish we Had Done Differently.
Sreek Vemulapalli (Durham, NC, USA)

Are EHR-Based Solutions a Viable Alternative?
TBD

Industry viewpoints
Todd Brinton (Edwards, USA), Kendra Grubb (Medtronic, USA)

Regulatory viewpoint
Changfu Wu (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate
TRICUSPID VALVE INNOVATION – LESSONS FROM TRIALS AND REGISTRIES
Chairpersons : David Cohen (Boston, MA, USA) & Vinod Thourani (Atlanta, GA, USA)

Panelists: Gorav Ailawadi (Ann Arbor, MI, USA), Suzanne Arnold (Kansas City, MO, USA), Suzanne Baron (Boston, MA, USA), Wayne Batchelor (Orlando, FL, USA), Todd Brinton (Edwards, USA), Rishi Chandiramani (Baltimore, MD, USA), David Cohen (Boston, MA, USA), John Gregson (London, GBR), Juan Granada (New York, NY, USA), Kendra Grubb (Medtronic, USA), Aakriti Gupta (New York, NY, USA), Jörg Hausleiter (Munich, GER), Sanjay Kaul (Los Angeles, CA, USA), Samir Kapadia (Cleveland, OH, USA), Chad Kliger (FDA, USA), Michael Mack (Dallas, TX, USA), Roxana Mehran (New York, NY, USA), Marie-Claude Morice (Massy, FRA), Mark Reisman (Edwards, USA), Ben Saville (Austin, TX, USA), Sreek Vemulapalli (Durham, NC, USA), Vinod Thourani (Atlanta, GA, USA), Changfu Wu (FDA, USA)

**Ballroom
Tuesday, December 8, 2026
08:30 -10:30**

**ACC-CVCT JOINT SESSION
AI MASTER CLASS 4
AI FOR CLINICAL TRIALS**

**IF AI GENERATES THE EVIDENCE — THROUGH SYNTHETIC CONTROL ARMS, AUTOMATED ANALYSIS,
AND AI-DERIVED ENDPOINTS — CAN REGULATORS AND CLINICIANS STILL TRUST IT?**

Chairpersons: Rohan Khera (New Haven, CT, USA) & Harlan Krumholz (New Haven, CT, USA)

Framework for Regulatory/Community Acceptance of AI-Generated Data: Context of Use, Model Influence, and Decision
Consequence

Jonathan Cunningham (Boston, MA, USA)

Digital Twins and In Silico Control Arms: When Are They Valid?

Blanca Rodriguez (Oxford, GBR)

Synthetic and external control arms: when real-world data replaces placebo

Lesley Curtis (Durham, NC, USA)

9:00-9:10

AI-read imaging, automated endpoint adjudication, and sensor-derived outcomes

Jeroen Bax (Leiden, NED)

EHR-based eligibility surveillance and automated patient recruitment

Michael Gibson (Boston, MA, USA)

Conversational AI for Participant Engagement and Follow-up in Clinical Trials

Christopher Fang (Hippocratic AI, USA)

Human-in-the-Loop AI for CV Trials: What Is Meaningful Human Oversight?

TBD

Industry Perspective

Alexandra Goncalves (BMS, USA)

Regulatory Perspective

Anindita Saha (FDA, USA)

Investor Perspective

Sunny Varshney (Broadview Ventures, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**AI FOR CLINICAL TRIALS: WHEN AI GENERATES THE EVIDENCE
WITHIN 10 YEARS, AI-GENERATED EVIDENCE WILL BE ACCEPTED AS EQUIVALENT TO TRADITIONAL
TRIAL EVIDENCE — AND THIS IS A GOOD THING. DEBATE.**

Chairpersons : Rohan Khera (New Haven, CT, USA) & Harlan Krumholz (New Haven, CT, USA)

Panelists: Jeroen Bax (Leiden, NED), Jonathan Cunningham (Boston, MA, USA), Lesley Curtis (Durham, NC, USA), Christopher Fang (Hippocratic AI, USA), Michael Gibson (Boston, MA, USA), Alexandra Goncalves (BMS, USA), Rohan Khera (New Haven, CT, USA), Harlan Krumholz (New Haven, CT, USA), Carolyn Lam (Singapore, SGP), Blanca Rodriguez (Oxford, GBR), Anindita Saha (FDA, USA), John Spertus (Kansas City, MO, USA), Sunny Varshney (Broadview Ventures, USA)

Ballroom
Tuesday, December 8, 2026
11:00 -13:00

INDUSTRY-ACADEMIA TRIALISTS' INTERACTIONS

Chairpersons: Biykem Bozkurt (Houston, TX, USA) & Scott Solomon (Boston, MA, USA)

Innovation and Excellence - The Importance of Industry-Academic Collaborations
Rob Califf (Durham, NC, USA)

Safeguarding the Industry-Academic Relationship
Marc Pfeffer (Boston, MA, USA)

Investigator Access to Data
Scott Solomon (Boston, MA, USA)

Use of biosamples and the Investigators' Access to biobanks
Faiez Zannad (Paris, FRA)

Journal Editors' Viewpoints
Barbara Casadei (JAMA Cardiology)
Filippo Crea (EHJ, IT)
Flavia Geraldès (The Lancet, GBR)
Bradley Maron (Circulation, USA)
Jane Leopold (NEJM, USA)

Ensuring Trust in Clinical Trials – Patient Perspective
TBD

Industry Viewpoints
Sameer Bansilal (Alnylam, USA), Maria Borentain (Bayer, GER), Steve Heitner (Cytokinetics, USA), Rami Younes (Boehringer Ingelheim, GER), Mahesh Patel (Merck, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

INDUSTRY-ACADEMIA TRIALISTS' INTERACTIONS: SHARING IS TRUST!

Chairpersons: Biykem Bozkurt (Houston, TX, USA) & Scott D. Solomon (Boston, MA, USA)

Panelists: Sameer Bansilal (Alnylam, USA), Maria Borentain (Bayer, GER), Biykem Bozkurt (Houston, TX, USA), Robert Califf (Durham, NC, USA), Barbara Casadei (JAMA Cardiology), Filippo Crea (EHJ, IT), Mariana Fontana (London, GBR) Flavia Geraldès (The Lancet, GBR), Steve Heitner (Cytokinetics, USA), Jane Leopold (NEJM, USA), Bradley Maron (Circulation, USA), John McMurray (Glasgow, GBR), Mahesh Patel (Merck, USA), Marc Pfeffer (Boston, MA, USA), Scott D. Solomon (Boston, MA, USA), Rami Younes (Boehringer Ingelheim, GER), Faiez Zannad (Paris, FRA)

Ballroom
Tuesday, December 8, 2026
14:30 -16:30

OBESITY MEDICINE: NEW DATA AND BIG QUESTIONS

Chairpersons: Ildi Lingvay (Dallas, TX, USA) & Naveed Sattar (Glasgow, GBR)

Known and recent cardiovascular outcome data from incretin-based CVOTs
Ildi Lingvay (Dallas, TX, USA)

PRO and non-cardiovascular benefits in incretin CVOTs: some surprises?
Stephen Nicholls (Adelaide, AUS)

Ongoing CVOTs of obesity medicines: what gaps in knowledge will they fill?
Jennifer Green (Durham, NC, USA)

To what extent is weight loss the mechanism of CV and other benefits: what do we really know?
Naveed Sattar (Glasgow, GBR)

How to investigate the anti-inflammatory effects of GLP-1 agonists in clinical trials?
Jorge Plutzky (Boston, MA, USA)

Do incremental MOAs for weight loss really make a difference?
Javed Butler (Dallas, TX, USA)

The Death of the Pure Placebo? Navigating GLP-1 Cross-Over in Future Outcome Trials
Odd Erik (Roche, CH)

Industry talks : What future CVOTs design would companies like FDA to consider
Filip Knop (NovoNordisk, DNK), Li Li (Innovent Biologics, CHN)

FDA/EMA: What future CVOTs design would regulator be willing to accept?
Cheryl Loggins (FDA, USA)
Harald Sourij (EMA, AUT)

Patient viewpoint: What do patients wish to see in future trials?
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

NEXT FRONTIERS FOR OBESITY TRIALS

Chairpersons: Ildi Lingvay (Dallas, TX, USA) & Naveed Sattar (Glasgow, GBR)

Panelists: Javed Butler (Dallas, TX, USA), Odd Erik (Roche, CH), Jennifer Green (Durham, NC, USA), Filip Knop (NovoNordisk, DNK), Ildiko Lingvay (Dallas, TX, USA), Li Li (Innovent Biologics, CHN), Cheryl Loggins (FDA, USA), Stephen Nicholls (Adelaide, AUS), Steven Nissen (Cleveland, OH, USA), Jorge Plutzky (Boston, MA, USA), Naveed Sattar (Glasgow, GBR), Raymond Soccio (FDA, USA), Harald Sourij (EMA, AUT), Faiez Zannad (Paris, FRA)

Ballroom
Tuesday, December 8, 2026
17:00 -19:00

CVCT GREAT DEBATES
Chairpersons: Faiez Zannad (Paris, FRA) & TBD

Debate 1

Oral diuretic intensification should be included in the composite endpoint for HF failure
Pro: Harriette Van Spall (Hamilton, CAN)
Con: Javed Butler (Dallas, TX, USA)

Debate 2

It is time to have multi-organ multi-endpoint composites for cardiovascular trials
Pro: Faiez Zannad (Paris, FRA)
Con: Milton Packer (Dallas, TX, USA)

Debate 3

Device trials should be judged differently than drug trials due to size/design limitations
Pro: William Abraham (Columbus, OH, USA)
Con: Mark Petrie (Glasgow, GBR)

Debate 4

Coronary revascularization should be included in expanded MACE endpoint
Pro: Roxana Mehran (New York, NY, USA)
Con: Scott Solomon (Boston, MA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

CVCT GREAT DEBATES
Chairpersons: Faiez Zannad (Paris, FRA) & TBD

Panelists: William Abraham (Columbus, OH, USA), Javed Butler (Dallas, TX, USA), Roxana Mehran (New York, NY, USA), Milton Packer (Dallas, TX, USA), Mark Petrie (Glasgow, GBR), Scott D. Solomon (Boston, MA, USA), Harriette Van Spall (Hamilton, CAN), Faiez Zannad (Paris, FRA)

**Palm court
Wednesday, December 9, 2026
08:00 -10:00**

**ESC-CVCT JOINT SESSION
LBCT 1
Chairpersons: TBD**

Session under construction

**The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 1
Chairpersons: TBD**

Palm court
Wednesday, December 9, 2026
10:00 -12:00

CARDIOVASCULAR GENE THERAPY TRIALS: WHY IS TRANSLATION SO DIFFICULT?
Chairpersons : Deborah Ascheim (Boston, MA, USA) & Andrew Baker (Edinburgh, GBR)

Contrasting irreversible genomic intervention with the conservative cardiovascular outcomes trial culture.
Deborah Ascheim (Boston, MA, USA)

Target patient populations

Who should receive an irreversible therapy?
Chad Grothen (Lilly, USA)

Gene therapy for prevention of vein graft failure
Andrew Baker (Edinburgh, GBR)

What duration is sufficient for approval in the context of durability—reversibility of expression?
Roger Hajjar (Boston, MA, USA)

How and how long to monitor the safety of irreversible overexpression and DSMB-related issues.
Kiran Musunuru (Philadelphia, PA, USA)

Gene therapy for rare diseases (5min each)

Danon Disease and Rare Disease Clinical Translation
Barry Greenberg (San Diego, CA, USA)

Rare Cardio-Neuro Disorders and Precision Cardiomyopathies
Alessia Argirò (Florence, ITA)

LMNA Cardiomyopathy and Mechanobiology
Monica Shah (Nuevocor, Singapore, SGP)

Genetic Therapies for Inherited Life-Threatening Arrhythmias: From CPVT to LQT8
Silvia Priori (Pavia, ITA)

Duchenne muscular dystrophy
Gabriel Brooks (Solidbio, USA)

Statistical viewpoint. Challenges in Rare Cardiovascular Disease. How much evidence-flexibility is acceptable?
Janet Wittes (Wittes LLC, USA)

Patient Perspectives and Acceptance of an irreversible therapy.
Pieter Glijnis (Phospholamban Foundation, NED)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

CREATIVE CLINICAL TRIALS SOLUTIONS FOR ADVANCING GENE THERAPY
Chairpersons: Deborah Ascheim (Boston, MA, USA) & Andrew Baker (Edinburgh, GBR)

Panelists : Alessia Argirò (Florence, ITA), Deborah Ascheim (Boston, MA, USA), Andrew Baker (Edinburgh, GBR), Gabriel Brooks (Solidbio, USA), Barry Greenberg (San Diego, CA, USA), Pieter Glijnis (Phospholamban Foundation, NED), Roger Hajjar (Boston, MA, USA), Kiran Musunuru (Philadelphia, PA, USA), Chad Grothen (Eli Lilly, USA), Monica Shah (Nuevocor, SGP), Silvia Priori (Pavia, ITA), Janet Wittes (Wittes LLC, USA),

**Palm court
Wednesday, December 9, 2026
13:30 -16:30**

THE NEXT GENERATION OF CARDIOVASCULAR GENETIC MEDICINE

Part 1

Chairpersons: Roger J. Hajjar (Boston, MA, USA) & Seppo Ylä-Herttuala (Kuopio, FIN)

Where Cardiovascular Gene Therapy Becomes Clinical Reality.

To this purpose, the CVCT Gene Therapy Trials sessions will explore the transition from first-generation AAV cardiac gene therapy toward scalable cardiovascular genetic medicine. This includes

- Convergence of gene therapy, gene editing, RNA therapeutics, and engineered delivery systems
- Rare monogenic cardiomyopathies versus broad, high-prevalence heart failure indications.
- Clinical trial design evolution in advanced therapeutics
- Regulatory acceleration pathways and “plausible mechanism” frameworks
- Cardiovascular inflammation, fibrosis, and precision endotyping
- Next-generation vector engineering and repeat dosing strategies
- Real-world translational lessons from active clinical programs
- The emergence of gene editing in cardiovascular disease

Opening Perspective. Cardiovascular Genetic Medicine Has Entered Its Second Era
Roger Hajjar (Boston, MA, USA)

Disease Mechanisms and Precision Endotyping.
Victoria Parikh (Stanford, CA, USA)

Cardiac Angiogenesis and Therapeutic Vascular Gene Transfer
Seppo Ylä-Herttuala (Kuopio, FIN)

Cardiac Regeneration in the Clinic
James Martin (Dallas, TX, USA)

PART 1 DISCUSSION

Panelists : Narinder Bhalla (Lexeo Therapeutics, USA), Gabriel Brooks (Solid Biosciences, USA), Roger Hajjar (Boston, MA, USA), Kiyotake Ishikawa (New York, NY, USA), James Kim (Medera, USA), Kevin Costa (Novoheart, CAN), James Martin (Dallas, TX, USA), Hideo Makimura (Affinia Therapeutics, USA), Maritza McIntyre (Former CBER Director, FDA, USA), Victoria Parikh (Stanford, CA, USA), Luke Roberts (Bayer, GER), Lothar Roessig (AskBio, GER), Whit Tingley (Tenaya Therapeutics, USA), Seppo Ylä-Herttuala (Kuopio, FIN)

**Palm court
Wednesday, December 9, 2026
13:30 -16:30**

**THE NEXT GENERATION OF CARDIOVASCULAR GENETIC MEDICINE
PART 2 : DELIVERY: ARE WE TESTING THE GENE OR THE PROCEDURE? OUTCOMES MAY DEPEND MORE
ON DELIVERY SUCCESS THAN BIOLOGICAL CONSTRUCT QUALITY**

Chairpersons: Roger J. Hajjar (Boston, MA, USA) & Seppo Ylä-Herttuala (Kuopio, FIN)

Advanced Cardiac Gene Delivery Platforms
Kiyotake Ishikawa (New York, NY, USA)

Cardiac gene delivery and next-generation capsids.
Gabriel Brooks (Solid Bio, USA)

Precision cardiac gene delivery & Hemodynamic Endpoints in heart failure
James Kim (Medera, USA)

Human Engineered Tissue and IND-Enabling Translation
Kevin Costa (Novoheart, USA)

Neutralizing Antibodies and the GENEPHIT Experience
Luke Roberts (Bayer, GER)

Large-Scale Translation of Cardiovascular Gene Therapy
Lothar Roessig (Askbio, GER)

Hypertrophic Cardiomyopathy Programs
Whit Tingley (Tenaya Therapeutics, USA)

BAG3 Cardiomyopathy and the UPBEAT Trial
Hideo Makimura (Affinia Therapeutics, USA)

Friedreich Ataxia Cardiomyopathy and Rare Disease Translation
Greg Aubert (Lexeo Therapeutics, USA)

Regulatory Viewpoints
Maritza McIntyre (Ex CBER director FDA, USA)
Jan Müller-Berghaus (EMA, GER)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

GENE THERAPY TRANSLATABILITY AND READINESS FOR CLINICAL STAGE

Chairpersons: Roger J. Hajjar (Boston, MA, USA) & Seppo Ylä-Herttuala (Kuopio, FIN)

Panelists : Greg Aubert (Lexeo Therapeutics, USA), Gabriel Brooks (Solid Biosciences, USA), Roger Hajjar (Boston, MA, USA), Kiyotake Ishikawa (New York, NY, USA), James Kim (Medera, USA), Kevin Costa (Novoheart, CAN), James Martin (Dallas, TX, USA), Hideo Makimura (Affinia Therapeutics, USA), Maritza McIntyre (Former CBER Director, FDA, USA), Jan Müller-Berghaus (EMA, GER), Victoria Parikh (Stanford, CA, USA), Luke Roberts (Bayer, GER), Lothar Roessig (AskBio, GER), Whit Tingley (Tenaya Therapeutics, USA), Seppo Ylä-Herttuala (Kuopio, FIN)

Palm court
Wednesday, December 9, 2026
17:00 -19:00

ELECTROPHYSIOLOGY WILL BE PART OF STROKE PREVENTION IN 2030
Chairpersons: Paulus Kirchhof (Hamburg, GER) & Ken Mahaffey (Stanford, CA, USA)

PFA at Five: The Energy Source That Changed AF Ablation
Prash Sanders (Adelaide, AUS)

AF Burden and Stroke Risk: Can we measure more to treat less?
Lindsay Rosman (Chapel Hill, NC, USA)

EAST-AFNET 4, OCEAN, ALONE, OPTION: Is rhythm control a stroke-prevention therapy?
Jason Andrade (Vancouver, CAN)

Debate: "Ready or Reckless: Are left atrial occluders a valid replacement for oral anticoagulation?"

PRO: Oussama Wazni (Cleveland, OH, USA)
CON: Atul Verma (Hamilton, CAN)

Better stroke prevention with novel drugs: Factor XI antagonists for stroke prevention
Ken Mahaffey (Stanford, CA, USA)

The 'EP Collaboratory' proposal: addressing systemic challenges in clinical trials
Paul Wang (Stanford, CA, USA)

NIH Viewpoint
Patrice Desvigne-Nickens (NIH/NHLBI, USA)

Industry Viewpoint: "Can Industry Build Comparative Evidence Without Killing Innovation?"
Greg Michaud (Biosense Webster, USA)

Industry Viewpoint: "Anticoagulation in 2030: A Pharma Perspective on the Patients We Still Aren't Reaching"
Carlos Cuevas (BMS, USA)

Industry Viewpoint: "Beyond Anticoagulation: A Biotech Perspective on Residual Stroke Risk in AF"
David Gutstein (Regeneron, USA)

Industry Viewpoint: "Rhythm control and LAAO. A Medtech perspective on stroke prevention"
Kenneth Stein (Boston Scientific, USA)

Patient Viewpoint: "Stroke and bleeds: What matters for AF patients"
Trudie Lobban (London, GBR)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW ELECTROPHYSIOLOGY MAY BE PART OF STROKE PREVENTION IN 2030?
Chairpersons: Paulus Kirchhof (Hamburg, GER) & Ken Mahaffey (Stanford, CA, USA)

Panelists : Jason Andrade (Vancouver, BC, CAN), Carlos Cuevas (BMS, USA), Patrice Desvigne-Nickens (NIH/NHLBI, USA), David Gutstein (Regeneron, USA), Paulus Kirchhof (Hamburg, DEU), Trudie Lobban (London, GBR), Kenneth Mahaffey (Stanford, CA, USA), Greg Michaud (Biosense Webster, USA), Puneet Mohan (BMS-Pfizer, USA), Yogesh Reddy (Rochester, MN, USA), Lindsay Rosman (Chapel Hill, NC, USA), Prash Sanders (Adelaide, AUS), Kimberly Selzman (FDA, USA), Kenneth Stein (Boston Scientific, USA), Atul Verma (Hamilton, CAN), Oussama Wazni (Cleveland, OH, USA), Paul Wang (Stanford, CA, USA),

East
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 2
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 2
Chairpersons: TBD

East
Wednesday, December 9, 2026
10:30 -12:30

HEART FAILURE MEETS ELECTROPHYSIOLOGY: THE QUESTIONS THAT WON'T GO AWAY **Chairpersons: Javed Butler (Dallas, TX, USA) & Tina Baykaner (Stanford, CA, USA)**

AF ablation outcome trials: The EP community is growing up
Emma Svennberg (Stockholm, SWE)

Debate: "AF ablation in HFrEF: The question is answered!"
PRO: Christian Sohns (Hannover, GER)
CON: Mark Petrie (Glasgow, GBR)

Why opposing signals can be expected from small trials: the case for sufficiently powered trials.
TBD

Bidirectional effects of cardiometabolic drugs on atrial and ventricular function.
Anne-Christine Ruwald (Copenhagen, DK)

Beyond the Primary Endpoint: Can Atrial Fibrillation Be Better Tracked in Heart Failure Trials?
Nicolas Girerd (Nancy, FRA)

AF burden and heart failure trajectories: Known unknowns.
Paulus Kirchhof (Hamburg, GER)

Industry Viewpoint: "Measuring More, Treating Smarter": Industry View of HF-EP Trial Design"
Nirav Patel (Medtronic, USA)

Industry Viewpoint: Entresto and Beyond: Reimagining Disease Modification Across the HF-AF Continuum
Steve Lubitz (Novartis, USA)

Industry Viewpoint: "Connecting HF and AF: A Pharma Perspective on Anticoagulation, Cardioresenal Protection, and Trial Design"
Maria Borentain (Bayer, GER)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

ROADMAP FOR HEART FAILURE & ELECTROPHYSIOLOGY TRIALISTS COLLABORATIONS **Chairpersons: Javed Butler (Dallas, TX, USA) & Tina Baykaner (Stanford, CA, USA)**

Panelists : Tina Baykaner (Stanford, CA, USA), Maria Borentain (Bayer, GER), Javed Butler (Dallas, TX, USA), Kieran Docherty (Glasgow, GBR), Nicolas Girerd (Nancy, FRA), Paulus Kirchhof (Hamburg, GER), Steve Lubitz (Novartis, USA), Nirav Patel (Medtronic, USA), Mark Petrie (Glasgow, GBR), Anne-Christine Ruwald (Copenhagen, DNK), Christian Sohns (Hannover, GER), Emma Svennberg (Stockholm, SWE)

East
Wednesday, December 9, 2026
13:30 -16:30

**CVCT-THT JOINT SYMPOSIUM
DEVICE THERAPIES FOR HEART FAILURE
SLOW DEVELOPMENT AND SLOW ADOPTION
WHAT IS THE PROBLEM AND WHAT CAN WE DO?**

Chairpersons: Dan Burkhoff (New York, NY, USA) & Faiez Zannad (CVCT, Paris, FRA)

Should devices always follow failure of comprehensive drug therapy?
Finn Gustafsson (Abbott, USA)

What is the development and adoption landscape?
Marat Fudim (Durham, NC, USA)

Impediments and solutions to more sham control trials
Rita Redberg (San Francisco, CA, USA)

Why not more event driven trials? When and how
Robert Mentz (Durham, NC, USA)

Maximizing follow-up, OLE, and RWE
TBD

Diuretic intensification and GDMT change – endpoints?
Javed Butler (Dallas, TX, USA)

PRO assessment, sham, blinding and placebo adjustment
Gregg Stone (New York, NY, USA)

Endpoints – hierarchical, Bayesian – what will work and what will be believe in?
Graeme Hickey (Medtronic, USA)

What evidence is needed for payer?
JoAnna Baldwin (CMS, USA)
Sari Ormstad (EU JCA, NOR)

Industry Perspective
Philip Adamson (CVRx, USA), Navin Kapur (Abiomed/JnJ, USA), John Brumfield (Berlin Heals, GER)

FDA Perspective
Ileana Pinea (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

**DEVICE THERAPIES FOR HEART FAILURE. SLOW DEVELOPMENT AND SLOW ADOPTION
WHAT IS THE PROBLEM AND WHAT CAN WE DO?**

Chairpersons: Dan Burkhoff (New York, NY, USA) & Faiez Zannad (CVCT, Paris, FRA)

Panelists : Philip Adamson (CVRx, USA), JoAnna Baldwin (CMS, USA), John Brumfield (Berlin Heals, GER), Dan Burkhoff (New York, NY, USA), Javed Butler (Dallas, TX, USA), Andrew Farb (FDA, USA), Marat Fudim (Durham, NC, USA), Finn Gustafsson (Abbott, USA), Graeme Hickey (Medtronic, USA), Navin Kapur (Abiomed/JnJ, USA), Robert Mentz (Durham, NC, USA), Sari Ormstad (EU JCA, NOR), Ileana Pinea (FDA, USA), Rita Redberg (San Francisco, CA, USA), Gregg Stone (New York, NY, USA), Faiez Zannad (CVCT, Paris, FRA).

East
Wednesday, December 9, 2026
17:00 -19:00

**FROM EVIDENCE GENERATION TO UPTAKE
IMPLEMENTATION SCIENCE AND PAYMENT REFORM IN CARDIOMETABOLIC MEDICINE**
Chairpersons: Ankeet S. Bhatt (San Francisco, CA, USA) and Neha Pagidipati (Durham, NC, USA)

Why positive CV trials still fail at uptake
Ankeet S. Bhatt (San Francisco, CA, USA)

Designing phase 3 trials for implementation from day 1
Harriette Van Spall (Hamilton, CAN)

Can pragmatic health-system trials help?
Tor Beiring Sorenson (Copenhagen, DEN)

FDA's Total Life Cycle Advisory Program (TAP)
April Marrone (FDA, USA)

Implementation of science for equity in HF and cardiometabolic care
Mariam Elmegaard (Herlev, DEN)

Financial Toxicity
Karen Joynt Maddox (St. Louis, MO, USA)

Payment reform and New Models
Rishi Wadhera (Boston, MA USA)

How to use AI in the health plan setting.
Michael Pencina (United Health, USA)

Payer/HTA perspective: coverage, affordability, and access after positive trials
Jaime Murillo (Bogotá, COL)

Industry Perspectives
Udi Fainberg (Novo Nordisk, DNK)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

IMPLEMENTATION-READY EVIDENCE GENERATION
Chairpersons: Ankeet S. Bhatt (San Francisco, CA, USA) & Neha Pagidipati (Durham, NC, USA)

Panelists : Ankeet S. Bhatt (San Francisco, CA, USA), Mariam Elmegaard (Herlev, DEN), Udi Fainberg (Novo Nordisk, DNK), Karen Joynt Maddox (St. Louis, MO, USA), April Marrone (FDA, USA), Jaime Murillo (Bogotá, COL), Neha Pagidipati (Durham, NC, USA), Michael Pencina (United Health, USA), Tor Beiring Sørensen (Copenhagen, DNK), Harriette Van Spall (Hamilton, ON, CAN), Rishi Wadhera (Boston, MA, USA)

State
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 3
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 3
Chairpersons: TBD

State
Wednesday, December 9, 2026
13:30 -16:30

WEARABLES IN CARDIOVASCULAR CLINICAL TRIALS: FROM SIGNAL TO ENDPOINT PART 1: FROM MEASURE TO ENDPOINT

Chairpersons: Jessilyn Dunn (Durham, NC, USA) & Abhinav Sharma (Montreal, CAN)

The 2025 CVCT wearables session ("Wearables for CV Trials") and AI Masterclass established that wearables are ready to participate in trials. The 2026 session advances the conversation by committing to a single, narrow question: how do we take a signal off a wrist and make it count as an endpoint. The structure is pipeline-based rather than stakeholder-based, and the case-study arc deliberately includes the one wearable-derived primary endpoint qualified anywhere in the world (SV95C in DMD) alongside a cardiovascular-adjacent pivotal trial that missed on a wearable endpoint (REBUILD). The cross-cutting payer and statistical perspectives are new.

Setting the frame: from signal to endpoint in cardiovascular trials
Abhinav Sharma (Montreal, CAN)

Analytical validation: turning sensor signals into trustworthy digital measures
Jessilyn Dunn (Durham, NC, USA)

Clinical validation case studies: from measure to endpoint

Stride Velocity 95th Centile in Duchenne Muscular Dystrophy Trials
TBD

Wearable activity monitoring in HF rehabilitation trials (REHAB-HF and beyond)
Ambarish Pandey (Dallas, TX, USA)

AFib burden
Jason Andrade (Vancouver, CAN)

Ambulatory / nocturnal BP– Cuffless devices
Paul Muntner (Birmingham, AL, USA)

Novel biomarkers: sleep, HRV, respiratory rate
Mintu Turakhia (iRhythm / Stanford, USA)

REBUILD MVPA endpoint: lessons from a negative trial
Steven Nathan (Falls Church, VA, USA)

Safety monitoring: wearables as pharmacovigilance tools

Remote detection of decompensation and SAEs
Michael Gibson (Boston, MA, USA)

Regulatory qualification pathways
Stephen Browning (FDA, USA)

Part 1 DISCUSSION

Panelists : Marc Bains (HeartLife, CAN), JoAnna Baldwin (CMS, USA), Jason Andrade (Vancouver, BC, CAN), Ami Bhatt (Boston, MA, USA), Stephen Browning (FDA, USA), Lesley Curtis (Duke, NC, USA), Punag Divanji (Cytokinetics, USA), Jessilyn Dunn (Durham, NC, USA), Michael Gibson (Boston, MA, USA), Christine Guo (Ametris, USA), Steven Lubitz (Novartis, USA), Paul Muntner (Birmingham, AL, USA), Steven Nathan (Falls Church, VA, USA), Ambarish Pandey (Dallas, TX, USA), Abhinav Sharma (Montreal, CAN), Mintu Turakhia (iRhythm / Stanford, USA), Sari Ormstad (EU JCA, NOR)

State
Wednesday, December 9, 2026
13:30 -16:30

**WEARABLES IN CARDIOVASCULAR CLINICAL TRIALS: FROM SIGNAL TO ENDPOINT
PART 2: FROM TRIAL VALIDATION TO CLINICAL PRACTICE**

Chairpersons: Jessilyn Dunn (Durham, NC, USA) & Abhinav Sharma (Montreal, CAN)

From trial to clinic: translating digital endpoints into practice
Ami Bhatt (Boston, MA, USA)

Statistician viewpoint. Digital endpoints.
Lesley Curtis (Duke, NC, USA)

Industry and CROs viewpoints
Punag Divanji (Cytokinetics, USA), Christine Guo (Ametris, USA), Steven Lubitz (Novartis, USA), Laura Higginbotham (IQVIA, USA)

Will Payers Trust Digitally Derived Endpoints? From Validation to Coverage and Reimbursement
JoAnna Baldwin (CMS, USA)
Sari Ormstad (EU JCA, NOR)

Patient viewpoint: adherence, burden, and equity
Marc Bains (HeartLife, CAN)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

WEARABLES IN CARDIOVASCULAR CLINICAL TRIALS. READY FOR MAINSTREAM?

Chairpersons: Jessilyn Dunn (Durham, NC, USA) & Abhinav Sharma (Montreal, CAN)

Panelists : Gregory Alexander (FDA, USA), Marc Bains (HeartLife, CAN), JoAnna Baldwin (CMS, USA), Jason Andrade (Vancouver, BC, CAN), Ami Bhatt (Boston, MA, USA), Stephen Browning (FDA, USA), Lesley Curtis (Duke, NC, USA), Punag Divanji (Cytokinetics, USA), Jessilyn Dunn (Durham, NC, USA), Andrew Farb (FDA, USA), Charu Gandotra (FDA, USA), Michael Gibson (Boston, MA, USA), Christine Guo (Ametris, USA), Laura Higginbotham (IQVIA, USA), Steven Lubitz (Novartis, USA), Paul Muntner (Birmingham, AL, USA), Steven Nathan (Falls Church, VA, USA), Ambarish Pandey (Dallas, TX, USA), Abhinav Sharma (Montreal, CAN), Sari Ormstad (EU JCA, NOR)

State
Wednesday, December 9, 2026
17:00 -19:00

DRIVERS OF HEART FAILURE: WHERE ARE WE?

Chairpersons: Lynne Warner Stevenson (Nashville, TN, USA) & Mark Petrie (Glasgow, GBR)

Overview of residual risk in heart failure.
Michele Senni (Bergamo, ITA)

Is pulmonary hypertension a treatment target in HFpEF?
Milton Packer (Dallas, TX, USA)

Hemodynamics as potential mechanistic target in pulmonary hypertension related heart failure
Stuart Rich (Chicago, IL, USA)

Device therapy trials in pulmonary hypertension associated with left heart disease
Gegg Stone (New York, NY, USA)

Decompensated Heart Failure Trials. Where are we?
Jan Biegus (Wraclaw, POL)

Is there any value to singling out HFmrEF?
Gianluigi Savarese (Stockholm, SWE)

Racing the remodeling clock: Rapid fire communications

Ghrelin for fast remodeling/recovery:
Lars Lund (Stockholm, SWE)

Fast full GDMT for fast remodeling/recovery
Alexandre Mebazaa (Paris, FRA)

Industry viewpoints
Francis Duhay (Pulnovo, CHN), Mahesh Patel (Merck, USA), So Young Kim (Tenax, USA)

Regulatory viewpoints
Charu Gandotra (FDA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

WHAT ARE THE NEXT HEART FAILURE TRIALS TARGET PATIENT POPULATIONS?

Chairpersons: Lynne Warner Stevenson (Nashville, TN, USA) & Mark Petrie (Glasgow, GBR)

Panelists: Jan Biegus (Wrocław, POL), Javed Butler (Dallas, TX, USA), Maria Rosa Costanzo (Naperville, IL, USA), Kieran Docherty (Glasgow, GBR), Francis Duhay (Pulnovo, CHN), Charu Gandotra (FDA, USA), Josephine Harrington (Denver, CO), Riccardo Inciardi (Brescia, IT), So Young Kim (Tenax, USA), Lars Lund (Stockholm, SWE), Alexandre Mebazaa (Paris, FRA), Rachel Neuberger (FDA, USA), Milton Packer (Dallas, TX, USA), Mahesh Patel (Merck, USA), Mark Petrie (Glasgow, GBR), Stuart Rich (Chicago, IL, USA), Gianluigi Savarese (Stockholm, SWE), Michele Senni (Bergamo, ITA), Gregg Stone (New York, NY, USA), Rhian Touyz (Montreal, CAN), Lynne Warner Stevenson (Nashville, TN, USA)

Chinese
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 4
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 4
Chairpersons: TBD

Chinese
Wednesday, December 9, 2026
10:30 -12:30

CVCT-NIH/NHLBI joint session
THE TRIAL YOU DIDN'T KNOW YOU WERE RUNNING: IMPLEMENTATION PROBLEMS AS
CARDIOVASCULAR SCIENCE

Chairpersons: Cara Lewis (NIH/NHLBI, USA) & Harriette Van Spall (Hamilton, CAN)

Some of the most consequential cardiovascular research of the past two decades didn't start with a molecule or a device — it started with a clock. When door-to-balloon time got attention, something deceptively radical occurred: treating the process of care delivery as a scientific problem worthy of rigorous investigation. The result was a body of evidence that changed how hospitals are organized, not just what drugs or devices they use.

This session invites cardiovascular trialists to look at their own work through the same lens: within or alongside the trials you are already running, what are the implementation problems hiding in plain sight?

Welcome and framing: What the clock taught us — the door-to-balloon story as a model for cardiovascular science
George Mensah (NIH/NHLBI, USA)

From trialist to implementation scientist: Rethinking what counts as a research question
Muthiah Vaduganathan (Boston, MA, USA)

The evidence-practice gap: When the evidence is sufficient, but the system is not
Christopher Granger (Durham, NC, USA)

Delivery as intervention: Designing trials around the prevention gap
Clara Chow (Sydney, AUS)

Where the gap is widest: Implementation science in low- and middle-income country cardiovascular care
TBD

The methodological toolkit: How to turn a care delivery problem into a rigorous trial
Mark Huffman (St Louis, MO, USA)

Journal Editors' Viewpoint: What journals need to see — making implementation science publishable in high-impact cardiovascular medicine
Flavia Geraldès (The Lancet, GBR)

Should implementation outcomes be co-primary endpoints in phase 3 cardiovascular trials?
Harriette Van Spall (Hamilton, CAN)

Who is responsible for closing the evidence-to-practice gap — trialists, health systems, regulators, or journals?
Filippo Crea (ESC, London, GBR)

Global perspective and implementation large scale.
Christina Mack (IQVIA, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

IF THE GAP BETWEEN EVIDENCE AND PRACTICE IS THE HIGHEST-YIELD TARGET IN CARDIOVASCULAR
MEDICINE, WHAT IS STOPPING US?

Chairpersons: Cara Lewis (NIH/NHLBI, USA) & Harriette Van Spall (Hamilton, CAN)

Panelists : Clara Chow (Sydney, AUS), Filippo Crea (ESC, London, UK), Anthony Etyang (Kilifi, KEN), Flavia Geraldès (The Lancet, GBR), Christopher Granger (Durham, NC, USA), Mark Huffman (St. Louis, MO, USA), Cara Lewis (NIH/NHLBI, USA), Christina Mack (IQVIA, USA), George Mensah (NIH/NHLBI, USA), Muthiah Vaduganathan (Boston, MA, USA), Harriette van Spall (Hamilton, ON, CAN)

Ballroom
Wednesday, December 9, 2026
08:00 -10:00

ESC-CVCT JOINT SESSION
LBCT 5
Chairpersons: TBD

Session under construction

The CVCT Multi-Stakeholder Think Tank Moderated Debate
LBCT 5
Chairpersons: TBD

Ballroom
Wednesday, December 9, 2026
10:30 -12:30

WHO IS IN THE COMMAND ROOM?
HOW BIG PHARMA, CROs, AROs AND REGULATORY BODIES ARE RESHAPING THE FUTURE OF CV INNOVATION.

Chairpersons : Robert Califf (Durham, NC, USA) & Thomas Lüscher (London, GBR)

Oncology, Device and rare disease have become the prototype ecosystem for accelerated innovation (surrogate endpoints, precision medicine, adaptive approvals, companion diagnostics, payer tolerance for uncertainty), whereas cardiovascular medicine remains more conservative, outcomes-driven, reimbursement-constrained, and operationally expensive. Has cardiovascular innovation become economically unviable? Are regulators slowing innovation — or protecting science? Did oncology “win” because it accepted uncertainty? Are heavy mega-trials now unsustainable?

Why oncology moves faster than cardiovascular medicine?

Donald Lloyd Jones (AHA, USA)
Francesco Pignatti (EMA, NED)

Are rare diseases the oncology-ization of cardiovascular medicine?

Muthu Venkateshwaran (BridgeBio, USA)

Why do cardiovascular devices and drugs follow different evidence pathways?

Roxana Mehran (New York, NY, USA)
Robert Califf (Durham, NC, USA)

Are we spending billions measuring things that no longer matter?

Martin Landray (Oxford, GBR)
David Simmons (Launch Therapeutics, USA)

The CVCT Multi-Stakeholder Think Tank Moderated Debate

HOW CAN BIG PHARMA, CROs, AROs AND REGULATORY BODIES ALIGN TO IMPROVE THE RATE OF CV DRUG INNOVATION?

Chairpersons : Robert Califf (Durham, NC, USA) & Thomas Lüscher (London, GBR)

Panelists : Robert Califf (Durham, NC, USA), Martin Landray (Oxford, GBR), Donald Lloyd Jones (AHA, USA), Thomas Lüscher (London, GBR), Roxana Mehran (New York, NY, USA), Rita Redberg (San Francisco, CA, USA), David Simmons (Launch Therapeutics, USA), Tabassome Simon (Paris, FRA) , Muthu Venkateshwaran (BridgeBio, USA)

PUBLISHING TRIAL RESULTS AND ADOPTION BY GUIDELINES. WHAT WOULD IT TAKE FOR JOURNALS AND GUIDELINES COMMITTEES TO NOT GIVE TRIALISTS A HARD TIME?

Chairpersons: Filippo Crea (EHJ, ITA) & Harlan Krumholz (JACC, USA) & Bradley Maron (Circulation, USA)

Editorial difficulties do not usually arise because journals want to be obstructive. They often arise because authors and journals approach the trial report with different priorities. Authors want to communicate the importance of the study; journals need to protect interpretability, proportionality, and trust. Guidelines are not simply a pass-through mechanism for positive trials or regulatory approvals. Guideline committees need to judge certainty, applicability, clinical priority, feasibility, and how new evidence fits within an existing therapeutic landscape.

Before the results: trial design choices that later determine editorial scrutiny.

Stuart Pocock (London, UK), Ji-Hyun Lee (Nature Medicine, USA)

Endpoint hierarchy, composite outcomes, estimands, multiplicity, non-inferiority margins, subgroup plans, missing data, interim analyses, external validity, and whether the trial can answer the clinical question it claims to address.

After the results: how to report positive, neutral, or mixed findings avoiding interpretive tensions.

Sanjay Kaul (Los Angeles, CA, USA), Flavia Geraldes (The Lancet, GBR)

Discordant components of composite outcomes, positive secondary outcomes after neutral primary outcomes, underpowered safety findings, subgroup "signals", effect sizes versus p values, and statistical versus clinical importance.

The editor/statistical reviewer perspective: what makes a trial paper easier or harder to accept?

Issa Dahabreh (JAMA, USA), Jane Leopold (NEJM, USA)

Protocol and SAP transparency, CONSORT adherence, completeness of reporting, sponsor role, data access, patient-relevant outcomes, and whether the interpretation is proportionate to the data.

Case Studies

- VICTOR a neutral primary outcome with an important mortality signal.

Faiez Zannad (Paris, FRA), Flavia Geraldes (The Lancet, GBR)

- SELECT a trial with a broad claim but narrow population

John Deanfield (London, GBR), Jane Leopold (NEJM, USA)

When is one positive trial enough?

Ibrahim Halil Tanboga (Istanbul, TUR)

Strength of evidence, replication, internal validity, magnitude and consistency of benefit, patient-centred outcomes, safety, totality of evidence, and how committees think about class and level of recommendation.

From trial population to guideline population.

Lars Kober (Copenhagen, DEN)

Heart Failure guidelines: Applicability across sex, age, geography, comorbidity, kidney function, frailty, background therapy, under-represented groups, and whether subgroup evidence should narrow or broaden recommendations

When evidence, approval, and guidelines move at different speeds.

Isabelle Van Gelder (Groningen, NED)

Conflicting trials, rapid therapeutic innovation, surrogate versus clinical outcomes, neutral or mixed trials, changing standards of care, and whether guidelines should lead, follow, or wait.

Case Studies

- BAROSTIM and BEAT-HF: Approved interventions without formal guideline recommendations

William Abraham (Columbus, OH, USA), Bram Zuckerman (FDA, USA)

- PARTNER 3 plus NOTION-2. TAVR versus surgery: sequencing an irreversible intervention.

Michael Mack (Dallas, TX, USA), Andrew Farb (FDA)

A class-effect question: a positive trial with limited generalizability; or a treatment whose uptake depends on sequencing with existing therapies.

The CVCT Multi-Stakeholder Think Tank Moderated Debate

PUBLISHING TRIAL RESULTS AND ADOPTION BY GUIDELINES. WHAT WOULD IT TAKE FOR JOURNALS AND GUIDELINES COMMITTEES TO NOT GIVE TRIALISTS A HARD TIME?

Chairpersons: Filippo Crea (EHJ, ITA) & Harlan Krumholz (JACC, USA) & Bradley Maron (Circulation, USA)

Panelists: William Abraham (Columbus, OH, USA), Filippo Crea (EHJ, ITA), Issa Dahabreh (JAMA, USA), John Deanfield (London, UK), Andrew Farb (FDA, USA), Flavia Geraldes (The Lancet, UK), Sanjay Kaul (Los Angeles, CA, USA), Harlan Krumholz (JACC, USA), Lars Kober (Copenhagen, DEN), Ji-Hyun Lee (Nature Medicine, USA), Jane Leopold (NEJM, USA), Jane Leopold (NEJM, USA), Michael Mack (Dallas, TX, USA), Bradley Maron (Circulation, USA), Stuart Pocock (London, UK), Ibrahim Halil Tanboga (Istanbul, TUR), Rita Redberg (San Francisco, CA, USA), Isabelle Van Gelder (Groningen, NED), Faiez Zannad (Paris, FRA), Bram Zuckerman (FDA, USA)

Ballroom
Wednesday, December 9, 2026
17:00 -19:00

THE MULTI-REGION REGULATORY HARMONIZATION MATRIX: PRAGMATIC REALITIES OF GLOBAL EVIDENCE ACCEPTANCE

Chairpersons: Robert M. Califf (Durham, NC, USA) & Jian'an Wang (Hangzhou, CHN)

The MHRA's Innovative Licensing and Access Pathway (ILAP): Accelerating Multi-Agency Scientific Alignment
Jacob George (MHRA, GBR)

The Mathematical Reality of ICH E17: How the FDA Evaluates Multi-Regional Clinical Trials (MRCTs)
Tzu-Yun McDowell (FDA, USA)

Bridging the Atlantic: Friction and Successes within the EMA-FDA Parallel Scientific Advice Pipeline
TBD

Beyond Border Restrictions: The NMPA's Evolution from Localized Phase 3 Trials to Global Multi-Center Trials
Siyuan Zhou (NMPA, Beijing, CHN)

One Global Trial, Multiple Regulatory Decisions: What Evidence Can Japan Accept—and What Still Needs to Be Local
TBD

Erasing the «Drug Lag»: Operational Mechanics of Simultaneous Global Regulatory Submissions
TBD

Power in Numbers: Reliance-Based Reviews and Unified Decisions within the Access Consortium
Choong May Ling (HSA, Singapore, SIN)

The Practical Bottlenecks of Adaptation: Re-Evaluating FDA/EMA Data within Emerging Market Ecosystems
TBD

The CVCT Multi-Stakeholder Think Tank Moderated Debate

«Friction & Alignment»: Navigating Conflicting Endpoint Requirements, Ethnic Sensitivity Bridging, and the Future of Sovereign Data Acceptance

Chairpersons: Robert M. Califf (Durham, NC, USA) & Jian'an Wang (Hangzhou, CHN)

Panelists: Gregory Alexander (FDA, USA), Stephen Browning (FDA, USA), Robert M. Califf (Durham, NC, USA), Andrew Farb (FDA, USA), Charu Gandotra (FDA, USA), Jacob George (MHRA, GBR), Laura Helbling (FDA, USA), Rob Kazmierski (ex-FDA, USA), Choong May Ling (HSA, Singapore, SGP), Tzu-Yun.McDowell (FDA, USA), Karim Mikhail (FDA, USA), Chinwe Okoro (FDA, USA), Francesco Pignatti (EMA, NED), Mitch Psotka (FDA, USA), Jon Resar (FDA, USA), Christian Schneider (London, GBR), John Sharretts (ex FDA, USA), Jeff Shuren (FDA, USA), Laurence Tallon (MHRA, GBR), Aliza Thompson (FDA, USA), James Travis (FDA, USA), Jian'an Wang (Hangzhou, CHN), Changfu Wu (FDA, USA), Siyuan Zhou (NMPA, Beijing, CHN)