

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

CVCT

2-4 December 2021

PRELIMINARY PROGRAM

FACULTY

(All tentative, to be confirmed)

ACADEMY

1. William Abraham (Columbus, USA)
2. Michelle Albert (San Francisco, USA)
3. Stefan Anker (Berlin, GER)
4. Michel Azizi (Paris, FRA)
5. George Bakris (Chicago, USA)
6. Colin Baigent (Oxford, GBR)
7. Antonio Bernabe-Ortiz (Lima, PEN)
8. Deepak Bhatt (Boston, USA)
9. Raymond Benza (Ann Arbor, USA)
10. Ulrika Birgersdotter-Green (San Diego, USA)
11. Barry Borlaug (Rochester, USA)
12. Nadia Bouabdallaoui (Montreal, CAN)
13. Biykem Bozkurt (Houston, USA)
14. Mike Bristow (Denver, USA)
15. Emily Brown (Liverpool, GBR)
16. John Buse (Chapel Hill, USA)
17. Javed Butler (Jackson, USA)
18. Rob Califf (Verily Life Sciences and Google Health, USA)
19. John Camm (London, GBR)
20. Glenn Chertow (Palo Alto, USA)
21. Kelly Chin (Dallas, USA)
22. John Cleland (Glasgow, GBR)
23. Barbara Condorelli (ESC, Oxford, GBR)
24. Joe Coresh (Baltimore, USA)
25. Paul Corris (Newcastle, GBR)
26. Martin Cowie (London, GBR)
27. Marina Cuchel (Philadelphia, USA)
28. Nikolaos Dagres (Leipzig, GER)
29. Thibaut Damy (Creteil, FRA)
30. Thomas Deering (Atlanta, USA)
31. David DeMets (Madison, USA)
32. Murray Epstein (Miami, USA)
33. Brian Ference (Oxford, GBR)
34. Joao Ferreira (Porto, POR)
35. Gerasimos Filippatos (Athens, GRE)
36. Gemma Figtree (Sydney, AUS)
37. Gregg C. Fonarow (San Francisco, USA)
38. Nazzareno Galiè (Bologna, ITA)
39. Peter Ganz (San Francisco, USA)
40. Bernard Gersh (Cleveland, USA)
41. Michael Gibson (Boston, USA)
42. Mardi Gomberg-Maitland (Washington, USA)
43. Sascha Goonewardena (Ann Arbor, USA)
44. Christopher Granger (Durham, USA)
45. Jennifer Green (Durham, USA)
46. John Gregson (London, GBR)
47. Paul Hassoun (Baltimore, USA)
48. Hiddo Heerspink (Groningen, NED)
49. Adrian Hernandez (Durham, USA)
50. Gerhard Hindricks (Leipzig, GER)
51. Ziad Hijazi (Uppsala, SWE)
52. Marius Hoeper (Hannover, GER)
53. Marc Humbert (Paris, FRA)
54. Elaine Hylek (Boston, USA)
55. Pierre Jais (Bordeaux, FRA)
56. Stefan James (Uppsala, SWE)
57. Jim Januzzi (Boston, USA)
58. Shona Kalkman (Utrecht, NED)
59. Steve Kawut (Philadelphia, USA)
60. Paulus Kirchhof (Hamburg, GER)
61. Wolfgang Koenig (Münich, GER)
62. Mikhail Kosiborod (Kansas City, USA)
63. Dipak Kotecha (Birmingham, GBR)
64. Florian Kronenberg (Innsbruck, AUS)
65. Harlan Krumholz (New Haven, USA)
66. Carolyn Lam (Singapore, SIN)
67. David Lanfear (Detroit, USA)
68. Martin Landray (Oxford, GBR)
69. Lisa Lavange (Chapel Hill, USA)
70. Adeera Levin (Vancouver, CAN)
71. Joann Lindenfield (Nashville, USA)
72. Gregory Lip (Liverpool, GBR)
73. Renato Lopez (Durham, USA)
74. Thomas Lüscher (London, GBR)
75. Theresa McDonagh (London, GBR)
76. Darren McGuire (Dallas, USA)
77. Vallerie McLaughlin (Ann Arbor, USA)
78. Elizabeth McNally (Chicago, USA)
79. Ziad Mallat (Cambridge, GBR)
80. Felipe Martinez (Cordoba, ARG)
81. Roxana Mehran (New York, USA)
82. Marco Metra (Brescia, ITA)
83. Jaime J Miranda (Lima, PEN)
84. Eric Muhammad (Inglewood, USA)
85. Finnian Mc Causland (Boston, USA)
86. Dan Mark (Durham, USA)

87. Alexandre Mebazaa (Paris, FR)
88. Bruce Neal (Sydney, AUS)
89. Borge Nordestgaard (Copenhagen, DEN)
90. Christopher O'Connor (Washington, USA)
91. Eileen O'Meara (Montreal, CAN)
92. Suzanne Oparil (Birmingham, USA)
93. Milton Packer (Dallas, USA)
94. Richard Page (Burlington, USA)
95. Ambarish Pandey (Dallas, USA)
96. Vlado Perkovic (Sydney, AUS)
97. Marc Pfeffer (Boston, USA)
98. Ileana Pina (Detroit, USA)
99. Bertram Pitt (Ann Arbor, USA)
100. Stuart Pocock (London, GBR)
101. Piotr Ponikowski (Cracow, POL)
102. Ionna Preston (Boston, USA)
103. Arshed Quyyumi (Atlanta, USA)
104. Kazem Rahimi (Oxford, GBR)
105. Sanjay Rajagopalan (Cleveland, USA)
106. Paul Ridker (Boston, USA)
107. Robert S. Rosenson (New York, USA)
108. Patrick Rossignol (Nancy, FRA)
109. Prabir Roy-Chaudhury (Tucson, USA)
110. Hesham Sadek (Dallas, USA)
111. Furrukh Sana (Boston, USA)
112. Naveed Sattar (Glasgow, GBR)
113. Kimberly Selzman (Salt Lake City, USA)
114. Sanjiv Shah (Chicago, USA)
115. Leslie Shaw (New York, USA)
116. Gérald Simonneau (Paris, FRA)
117. Scott Solomon (Boston, USA)
118. Erik Stroes (Amsterdam, NED)
119. Jesper Hastrup Svendsen (Copenhagen, DEN)
120. Wilson Tang (Cleveland, USA)
121. Jean Claude Tardif (Montreal, CAN)
122. John Teerlink (San Francisco, USA)
123. Lehana Thabane (Hamilton, CAN)
124. Thenappan Thenappan (Minneapolis, USA)
125. Lale Tokgözoğlu (Ankara, TUR)
126. Mintu Turakhia (Stanford, USA)
127. Harriette Van Spall (Hamilton, CAN)
128. Atul Verma (Toronto, CA)
129. Eric Vicaut (Paris, FRA)
130. Pugazhendhi Vijayaraman (Wilkes-Barre, USA)
131. Tina Vilsbøll (Copenhagen, DEN)
132. Adriaan Voors (Groningen, NED)
133. Christoph Wanner (Würzburg, GER)
134. Harriet Washington (New York, USA)
135. David Wheeler (London, GBR)
136. Clyde Yancy (Chicago, USA)
137. Salim Yusuf (Hamilton, CAN)

138. Sarah Zaman (Melbourne, AUS)
139. Roham Zamanian (Stanford, USA)
140. Faiez Zannad (Paris, FRA)

JOURNAL/MEDIA

141. Filippo Crea (EHJ, Rome, ITA)
142. Robert Golub (JAMA, Washington, USA)
143. Joseph Hill (Circulation, Dallas, USA)
144. Larry Husten (CVCTCardiobrief, New York, USA)
145. John Jarcho (NEJM, Boston, USA)
146. Rob Mentz (JCF, Durham, USA)
147. Rita Redberg (JAMA Internal Medicine, USA)
148. Rupa Sarkar (The Lancet Digital Health, GBR)
149. Stuart Spencer (The Lancet, London, GBR)
150. Ron Winslow (Ex Wall Street Journal, Portland, USA)

INDUSTRY

151. Philip Adamson (Abbott, USA)
152. Shazia Ali (Regeneron, USA)
153. Tomas Andersson (AstraZeneca, SWE)
154. Marianne Bach Treppendahl (Novonordisk, DEN)
155. Agim Beshiri (Abbott Dx, USA)
156. Sudhir Borgonha (Capricor, USA)
157. Martina Brueckmann (Boehringer Ingelheim, GER)
158. Kristine Buchholtz (NovoNordisk, DEN)
159. Jim Carr (Stealth, USA)
160. Alan Cheng (Medtronic, USA)
161. Thomas Clozel (Owkin, Paris, FRA)
162. Maggie Cook (Renovacor, USA)
163. Hafun Fridriksdottir (Teva, USA)
164. Al Gianchetti (Xylocor, USA)
165. Ruchira Glaser (Moderna, USA)
166. Fred Grossman (Mesoblast, USA)
167. James Hare (eko-ai, Singapore, SG)
168. Sibylle Hauske (Boehringer Ingelheim, GER)
169. Waheed Jamal (Boehringer Ingelheim, GER)
170. Gerard Kornelis Hovingh (Novonordisk, DEN)
171. Helina Kassahun (Amgen, USA)
172. Sekar Kathiresan (Verve Therapeutics, USA)
173. Frank Kramer (Bayer, GER)
174. Joerg Koglin (Merck, USA)
175. Rob Kowal (Medtronic, USA)
176. Nardev Khurmi (Sanofi, USA)
177. Fouzia Laghrissi (Dalcure, CH)
178. Anna Maria Langkilde (AstraZeneca, SWE)
179. Antonio Lopez (Amgen, USA)
180. Santica Marcovina (MedPace, USA)
181. Debra Marshall (Arca Biopharma, USA)
182. Serge Masson (Roche, CH)
183. Devan Mehrotra (Merck, USA)

184. Masahiro Murakami (Eli Lilly, USA)
185. Gillian Murtagh (Abbott Dx, USA)
186. Richard Nkulikiyinka (Bayer, GER)
187. David Platt (Novartis, USA)
188. Manish Ponda (Regeneron, USA)
189. Emma Raderschadt (Boehringer Ingelheim, GER)
190. Jérôme Rossert (AstraZeneca, USA)
191. Natalie Cheung Rotelli (Eli Lilly, USA)
192. Giacomo Ruotolo (Eli Lilly, USA)
193. David Soergel (Novartis, USA)
194. Jennifer Stacey (TriNetx, USA)
195. Kenneth Stein (Boston Scientific, USA)
196. James Strait (Merck, USA)
197. Thomas Thum (Cardior Pharmaceuticals, GER)
198. Thomas Thuren (Novartis, USA)
199. Whittemore Tingley (Tenaya Therapeutics, USA)
200. Sotirios Tsimikas (Akcea, USA)
201. Johan van Hylckama Vlieg (Kaleido, USA)
202. John Vest (Alnylam, USA)
203. John Wagner (Cygnal Therapeutics, USA)
204. Steve Williams (Somalogic, USA)
205. Janet Wittes (StatCollaborative, USA)
206. Samuel Wright (CSL Behring, USA)
207. Fred Yang (KBP, USA)
208. Nadim Yared (CVRx, USA)
209. Yinong Zhou (Novartis, USA)
210. André Ziegler (Roche, GER)

REGULATORY

211. Angeles Alonso (MHRA, GBR)
212. Kristina Dunder (EMA, SWE)
213. Preston Dunnmon (FDA, USA)
214. Andrew Farb (FDA, USA)
215. Alan Fraser (Cardiff, GBR)
216. Charu Gandotra (FDA, USA)
217. Peter Mol (EMA, NED)
218. Dan O'Connor (MHRA, GBR)
219. Bakul Patel (FDA, USA)
220. Mitch Psotka (FDA, USA)
221. Krishna Prasad (MHRA, GBR)
222. Fred Senatore (FDA, USA)
223. John Sharretts (FDA, USA)
224. Jeff Siegel (FDA, USA)
225. Norman Stockbridge (FDA, USA)
226. Bob Temple (FDA, USA)
227. Aliza Thompson (FDA, USA)
228. Ellis Unger (FDA, USA)
229. George Van Hare (FDA, USA)
230. Emmanouil Zouridakis (MHRA, GBR)
231. Bram Zuckerman (FDA, USA)

NIH

232. Marie Bernard (NIH, USA)
233. Patrice Desvigne-Nickens (NIH, USA)
234. Kathleen Fenton (NIH/CTSN, USA)
235. Lawrence Fine (NHLBI, USA)
236. Erin Iturriaga (NIH, NHLBI, USA)
237. Jonathan Kaltman (NIH, USA)
238. Paul Kimmel (NIH, USA)
239. Ellen Leschek (NIH, USA)
240. Yves Rosenberg (NIH, USA)
241. Wendy Weber (NIH, NCCIH, USA)

PATIENTS

242. Bill Adams (Erhard, USA)
243. Jacqueline Alikhaani (Los Angeles, USA)
244. Sadegh Alikhaani (Los Angeles, USA)
245. Marc Bains (Vancouver, CAN)
246. Cynthia Chauhan (Wichita, USA)
247. Jillianne Code (Vancouver, CAN)
248. Pat Furlong (Parent Project Muscular Dystrophy, USA)
249. Patrick Gee (Chesterfield, USA)
250. Penilla Gunther (Stockholm, SWE)
251. Nick Harshorne-Evans (London, GBR)
252. Trudie Lobban (London, GBR)
253. Steven Macari (Poitiers, FRA)
254. Robin Martinez (Denver, USA)
255. Greg Merritt (Brighton, USA)
256. Wanda F Moore (Arizona, USA)
257. Mellanie True Hills (Stop AFib, Greenwood, USA)
258. Marilena Vrana (Brussels, BEL)

LAWYERS & ETHICISTS

259. Mark DuVal (DuVal & Associates, Minneapolis, USA)

PAYER / ECONOMISTS

260. Meindert Boysen (NICE, London, GBR)
261. Joseph Chin (Medicare, USA)
262. Steven Farmer (CMS, USA)
263. Tamara Sysek Jensen (CMS, USA)
264. Piotr Szymański (Warsaw, POL)



THURSDAY, DECEMBER 2ND

THEATRE

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**SGLT2i and GLP1RA
CARDIOMETABOLIC TRIALS**

[view details >>](#)

**HEART FAILURE WITH
PRESERVED EJECTION
FRACTION LIGHT AT THE END
OF THE TUNNEL?**
Part I. Understanding and
Interpreting the results of
EMPEROR-PRESERVED

[view details >>](#)

**HEART FAILURE WITH
PRESERVED EJECTION
FRACTION. LIGHT AT THE END
OF THE TUNNEL?**
Part II. Implementing
the results of EMPEROR-
PRESERVED

[view details >>](#)

**TAILORING MEDICAL
THERAPY TO HEART FAILURE
CLINICAL PROFILES**

[view details >>](#)

BALLROOM

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**THE RAPIDLY CHANGING
LANDSCAPE OF CARDIO
KIDNEY TRIALS Part 1**

[view details >>](#)

**THE RAPIDLY CHANGING
LANDSCAPE OF
CARDIOKIDNEY Part 2**

[view details >>](#)

**THE RAPIDLY CHANGING
LANDSCAPE OF
CARDIOKIDNEY Part 3**

[view details >>](#)

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

[view details >>](#)

TOCQUEVILLE

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

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

[view details >>](#)

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

[view details >>](#)

**PUBLISHING AND
AUTHORSHIP OF MAJOR
TRIALS RESULTS**

[view details >>](#)

**MAXIMIZING SCIENTIFIC
KNOWLEDGE PRODUCTION
FROM TRIAL DATA**

[view details >>](#)

FRIDAY, DECEMBER 3RD

THEATRE

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

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

[view details >>](#)

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

[view details >>](#)

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

[view details >>](#)

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

[view details >>](#)

BALLROOM

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**INCREASING EQUITY AND
DIVERSE REPRESENTATION
AMONG PARTICIPANTS IN
CARDIOVASCULAR CLINICAL
TRIALS**

[view details >>](#)

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

[view details >>](#)

**PRIMARY PREVENTION.
RECENT AND ONGOING
TRIALS**

[view details >>](#)

**PROMOTING THE PRIMARY
PREVENTION TRIALS AGENDA**

[view details >>](#)

TOCQUEVILLE

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**DEVELOPMENTS IN
ATHEROSCLEROSIS FAMILIAL
HYPERCHOLESTEROLEMIA
TRIALS**

[view details >>](#)

**DEVELOPMENTS IN
HYPERTRIGLYCERIDEMIA
TRIALS**

[view details >>](#)

**LIPOPROTEIN (a) INHIBITORS
LOWERING DRUGS TRIALS**

[view details >>](#)

**TARGETING HDL AND
INFLAMMATION TRIALS**

[view details >>](#)

LIBRARY

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**INTERVENTIONAL
CARDIOLOGY TRIALS
(ICVCT) 5**

[view details >>](#)

**INTERVENTIONAL
CARDIOLOGY TRIALS
(ICVCT) 6**

[view details >>](#)

**MACHINE LEARNING AND
ARTIFICIAL INTELLIGENCE
APPLIED TO TRIALS**

[view details >>](#)

SATURDAY, DECEMBER 4TH

THEATRE

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**INTERVENTIONAL
CARDIOLOGY TRIALS
(ICVCT) 1**

[view details >>](#)

**INTERVENTIONAL
CARDIOLOGY TRIALS
(ICVCT) 2**

[view details >>](#)

**INTERVENTIONAL
CARDIOLOGY TRIALS
(ICVCT) 3**

[view details >>](#)

**INTERVENTIONAL
CARDIOLOGY TRIALS
(ICVCT) 4**

[view details >>](#)

BALLROOM

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

**PATIENT VOICE IN CLINICAL
TRIAL - GETTING BEYOND
LIP SERVICE**

[view details >>](#)

**IMPLANTABLE DEVICES AND
MONITORING HEART FAILURE
TRIALS**

[view details >>](#)

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

[view details >>](#)

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

[view details >>](#)

TOCQUEVILLE

8:30 - 10:30

11:00 - 13:00

14:00 - 16:00

16:30 - 18:30

DIGITAL HEALTH TRIALS

[view details >>](#)

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

[view details >>](#)

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

[view details >>](#)

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

[view details >>](#)

SGLT2i and GLP1RA CARDIO METABOLIC TRIALS

Chairpersons :TBD

Theatre
Thursday 02 December, 2021
8.30-10.30

Insight from newest trials

Is VERTIS an outlier?
TBD

Is Dual SGLT inhibitor different (SOLOIST and SCORED)?
Deepak Bhatt (Boston, USA)

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

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

GLP1RA in diabetes a diverse family?
Tina Vilsbøll (Copenhagen, DEN)

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

Compare them or combine them? What trials for the future?
TBD

Industry viewpoint
Kristine Buchholtz (NovoNordisk, DEN), Nardev Khurmi (Sanofi, USA), Anna Maria Langkilde (AstraZeneca, SWE), James Strait (Merck, USA)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

SGLT2i and GLP1RA CARDIO METABOLIC TRIALS. WHAT NEXT?

Chairpersons:TBD

Panelists: Deepak Bhatt (Boston, USA); Kristine Buchholtz (NovoNordisk, DEN); Jennifer Green (Durham, USA); Nardev Khurmi (Sanofi, USA); Anna Maria Langkilde (AstraZeneca, SWE); Darren McGuire (Dallas, USA); Naveed Sattar (Glasgow,GBR); James Strait (Merck, USA); Tina Vilsbøll (Copenhagen, DEN)

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

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

Theatre
Thursday 02 December, 2021
11.00-13.00

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

EMPEROR-PRESERVED main renal results
Javed Butler (Jackson, USA)

Patient reported outcomes results
Joao Ferreira (Porto, POR)

Safety considerations
Gerasimos Filippatos (Athens, GRE)

Statistical viewpoint
Stuart Pocock (London, GBR)

Mechanistic insight.
Milton Packer (Dallas, USA) vs. Bertram Pitt (Ann Arbor, USA)

What's next? The consequence of EMPEROR-PRESERVED on the ongoing HFpEF trials.
TBD

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

THE CVCT FORUM Multi-Stakeholder Moderated Debate HEART FAILURE WITH PRESERVED EJECTION FRACTION Part I: Interpreting the results of EMPEROR-PRESERVED Chairpersons : TBD

Panelists: Angeles Alonso (MHRA, GBR); Stefan Anker (Berlin, GER); Javed Butler (Jackson, USA); Joao Ferreira (Porto, POR); Gerasimos Filippatos (Athens, GRE); Milton Packer (Dallas, USA); Bertram Pitt (Ann Arbor, USA); Stuart Pocock (London, GBR); Bob Temple (FDA, USA); Faiez Zannad (Paris, FRA)

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

Part II. Implementing the results of EMPEROR-PRESERVED Chairpersons : TBD

Theatre
Thursday 02 December, 2021
14.00-16.00

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

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

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

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

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

Payers viewpoint
Piotr Szymański (Warsaw, POL)

Patient viewpoint
Cynthia Chauhan (Wichita, USA); Nick Harshorne-Evans (London, GBR)

THE CVCT FORUM Multi-Stakeholder Moderated Debate HEART FAILURE WITH PRESERVED EJECTION FRACTION. LIGHT AT THE END OF THE TUNNEL? Part II. Implementing the results of EMPEROR-PRESERVED Chairpersons : TBD

Panelists: Tomas Andersson (AstraZeneca, SWE); Martina Brueckmann (Boehringer Ingelheim, GER); Cynthia Chauhan (Wichita, USA); Nick Harshorne-Evans (London, GBR); Milton Packer (Dallas, USA); David Platt (Novartis, USA); Krishna Prasad (MHRA, GBR); Scott Solomon (Boston, USA); Piotr Szymański (Warsaw, POL); Bob Temple (FDA, USA)

TAILORING MEDICAL THERAPY TO HEART FAILURE CLINICAL PROFILES

Chairpersons : TBD

Theatre
Thursday 02 December, 2021
16.30-18.30

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

Inpatients acute decompensated and outpatient worsening heart failure.
John Teerlink (San Francisco, USA)

Worsening chronic heart failure
TBD

Ischemic heart failure
Adriaan Voors (Groningen, NED)

Diabetic cardiomyopathy
Ambarish Pandey (Dallas, USA)

Amyloidosis heart failure
Thibaut Damy (Creteil, FRA)

Would a universal definition of heart failure be more appropriate for future trials?
John Cleland (Glasgow, GBR)

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

What would it take to approve phenotype-based heart failure indications? Regulatory viewpoint
Robert Temple (FDA, USA)
TBD (EMA, xxx)

Patient Viewpoint
Trudie Lobban (London, GBR), Marc Bains (Vancouver, CAN)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

OPPORTUNITIES AND CHALLENGES OF HEART FAILURE STRATIFIED MEDICINE TRIALS

Chairpersons: TBD

Panelists: Marc Bains (Vancouver, CAN); John Cleland (Glasgow, GBR); Thibaut Damy (Creteil, FRA); Trudie Lobban (London, GBR); Ambarish Pandey (Dallas, USA); Marc Pfeffer (Boston, USA); Sanjiv Shah (Chicago, USA); John Teerlink (San Francisco, USA); Robert Temple (FDA, USA); Adriaan Voors (Groningen, NED); Janet Wittes (StatCollaborative, USA)

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS

Part 1.

Chairpersons :TBD

Ballroom
Thursday 02 December, 2021
8.30-10.30

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

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

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

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

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

non-steroidal MRAs trials
Bertram Pitt (Ann Arbor, USA)

SGLT2is trials
David Wheeler (London, GBR)

GLP1RA trials
John Buse (Chapel Hill, USA)

Renal outcomes in heart failure trials

Sacubutril valsartan trials
Finnian Mc Causland (Boston, USA)

SGLT2i trials
Milton Packer (Dallas, USA)

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

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS

Chairpersons: TBD

Panelists: George Bakris (Chicago, USA); John Buse (Chapel Hill, USA); Hiddo Heerspink (Groningen, NED) ;
Finnian Mc Causland (Boston, USA); Milton Packer (Dallas, USA); Vlado Perkovic (Sydney, AUS); Bertram Pitt
(Ann Arbor, USA); Paul Ridker (Boston, USA); David Wheeler (London, GBR)

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS

Part 2.

Chairpersons :TBD

Ballroom

Thursday 02 December, 2021

11.00-13.00

The case of end stage renal disease.

Patrick Rossignol (Nancy, FRA)

Resistant hypertension, CKD, and opportunities with novel MRAs (KBP, esaxerinone)

Bertram Pitt (Ann Arbor, USA)

IV iron in CKD and heart failure trials

Piotr Ponikowski (Cracow, POL)

Treating anemia in CKD. Lessons from the recent Vadadustat PRO2TECT and INNO2VATE trials

Glenn Chertow (Palo Alto, USA)

Potassium binders trials enabling cardiokidney protective therapy.

Marc Pfeffer (Boston, USA)

Practical use of potassium binders

Murray Epstein (Miami, USA)

NIH/NIDDK viewpoint

Paul Kimmel (NIH, USA)

Regulatory expectations for the future cardio kidney trials.

Kristina Dunder (EMA, SWE)

Aliza Thompson (FDA, USA)

Patients viewpoints

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

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

**CARDIOKIDNEY PROTECTIVE STRATEGIES.
IMPLEMENTING THE ACCUMULATING EVIDENCE**

Chairpersons: TBD

Panelists : Glenn Chertow (Palo Alto, USA); Kristina Dunder (EMA, SWE); Cynthia Chauhan (Wichita, USA); Murray Epstein (Miami, USA); Patrick Gee (Chesterfield , USA); Paul Kimmel (NIH, USA); Marc Pfeffer (Boston, USA); Bertram Pitt (Ann Arbor, USA); Piotr Ponikowski (Cracow, POL); Patrick Rossignol (Nancy, FRA); Aliza Thompson (FDA, USA)

THE RAPIDLY CHANGING LANDSCAPE OF CARDIOKIDNEY TRIALS

Part 3. Renal endpoint issues in cardio kidney trials

Chairpersons :TBD

Ballroom
Thursday 02 December, 2021
14.00-16.00

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

Nephrology viewpoint.

Christoph Wanner (Wurzburg, GER)

Cardiology viewpoint.

Javed Butler (Jackson, USA)

Is albuminuria a valid surrogate endpoint?

TBD

KHI clinical trial outcomes for kidney failure. Any need for an update?

Adeera Levin (Vancouver, CAN)

Reporting and adjudication of kidney safety endpoints.

Prabir Roy-Chaudhury (Tucson, USA)

Regulatory comments about endpoints in cardio kidney trials

Peter Mol (EMA, NED)

Aliza Thompson (FDA, USA)

Navigating the cardiokidney metabolic space. Industry viewpoints

Marianne Bach Treppendahl (NovoNordisk, DEN); Sibylle Hauske (Boehringer Ingelheim, GER); Richard Nkulikiyinka (Bayer, GER); Jérôme Rossert (AstraZeneca, USA); Thomas Thuren (Novartis, USA); Fred Yang (KBP, USA)

Patients viewpoints

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

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

REASSESSING ENDPOINT SIGNIFICANCE IN CARDIOKIDNEY TRIALS.

Chairpersons: TBD

Panelists : Marianne Bach Treppendahl (NovoNordisk, DEN); Javed Butler (Jackson, USA); Cynthia Chauhan (Wichita, USA); Patrick Gee (Chesterfield , USA); Sibylle Hauske (Boehringer Ingelheim, GER); Adeera Levin (Vancouver, CAN); Peter Mol (EMA, NED); Richard Nkulikiyinka (Bayer, GER); Jérôme Rossert (AstraZeneca, USA); Prabir Roy-Chaudhury (Tucson, USA); Aliza Thompson (FDA, USA); Thomas Thuren (Novartis, USA); Christoph Wanner (Wurzburg, GER); Fred Yang (KBP, USA); Faiez Zannad (Paris, FRA)

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

Chairpersons :TBD

**Ballroom
Thursday 02 December, 2021
16.30-18.30**

**Obesity GLP1RA trials: weight loss and CV prevention
Emily Brown (Liverpool, GBR)**

Obesity in HFpEF patients

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

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

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

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

**Industry viewpoint
Kristine Buchholtz (NovoNordisk, DEN), Masahiro Murakami (Eli Lilly, USA), Yinong Zhou (Novartis, USA)**

**The NIH viewpoint
Ellen Leschek (NIH, USA)**

**Regulatory viewpoint
John Sharretts (FDA, USA)
Emmanouil Zouridakis (MHRA, GBR)**

THE CVCT FORUM Multi-Stakeholder Moderated Debate OBESITY TRIALS : WEIGHT LOSS AND CARDIOVASCULAR OUTCOME TRIALS WITH GIP AND/OR GLP-1 RECEPTOR AGONISTS Chairpersons: TBD

Panelists: Barry Borlaug (Rochester, USA); Emily Brown (Liverpool, GBR); Kristine Buchholtz (NovoNordisk, DEN), John Gregson (London, GBR); Mikhail Kosiborod (Kansas City, USA); Ellen Leschek (NIH, USA); Masahiro Murakami (Eli Lilly, USA); Milton Packer (Dallas, USA); John Sharretts (FDA, USA); Yinong Zhou (Novartis, USA); Emmanouil Zouridakis (MHRA, GBR)

THE INNOVATION LANDSCAPE
Part 1: BIOTECH RAPID FIRE AND READINESS FOR TRANSLATION
Chairpersons: Gemma Figtree (Sydney, AUS), Joseph Hill (Dallas, USA)

Tocqueville
Thursday 02 December, 2021
8.30-10.30

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

Base editing
Sekar Kathiresan (Verve, USA)

Microbiome and Cardiometabolic disease
Wilson Tang (Cleveland, USA)
Johan van Hylckama Vlieg (Kaleido, USA)

The therapeutic potential of cardio-immunology
Ziad Mallat (Cambridge, GBR)

Antisense Oligonucleotides - siRNA
Thomas Thum (Hannover, GER)

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

RNA Interference (RNAi) Therapeutic Targeting Angiotensinogen in Hypertensive Patients
John Vest (Alnylam, USA)

Myocardial cell therapy: is there realistic hope for the future?
Hesham Sadek (Dallas, USA)

Mesoblast: DREAM-HF and AMICI cell therapy trials
Fred Grossman (Mesoblast, USA)

MetCela: VCAM-1-positive cardiac fibroblast for cardiac cell therapy
TBD

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

Venturis: Therapeutic potential of angiogenesis
TBD

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
THE INNOVATION LANDSCAPE
Part 1: BIOTECH READINESS FOR TRANSLATION.
Chairpersons: Gemma Figtree (Sydney, AUS), Joseph Hill (Dallas, USA)

Panelists: Gemma Figtree (Sydney, AUS); Al Gianchetti (Xylocor, USA); Ruchira Glaser (Moderna, USA); Fred Grossman (Mesoblast, USA); Joseph Hill (Dallas, USA); Sekar Kathiresan (Verve, USA); Ziad Mallat (Cambridge, GBR); Hesham Sadek (Dallas, USA); Wilson Tang (Cleveland, USA); Thomas Thum (Cardior Pharmaceuticals, GER); Johan van Hylckama Vlieg (Kaleido, USA); John Vest (Alnylam, USA);

**THE INNOVATION LANDSCAPE
PART 2 : RARE DISEASE CARDIOMYOPATHIES
PATHWAYS FOR APPROVAL
Chairpersons: Wilson Tang (Cleveland, USA), TBD**

**Tocqueville
Thursday 02 December, 2021
11.00-13.00**

**Drug Development in Rare Disease Cardiomyopathies. What is in the pipeline?
Elizabeth McNally (Chicago, USA)**

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

**Omeicos: Targeting mitochondriopathies for heart disease
TBD**

**Genome Biologics for rare mitochondrial diseases
TBD**

**Dinaqor: Adeno-associated virus (AAV) gene cardiomyopathy therapy
TBD**

**Renovacor gene replacement therapy for dilated cardiomyopathies
Maggie Cook (Renovacor, USA)**

**Tenaya: Gene therapy for hypertrophic cardiomyopathy
Whittemore Tingley (Tenaya Therapeutics, USA)**

**Clinical development challenges and need for surrogate endpoints
Investigator viewpoint
TBD**

**Industry viewpoint
Sudhir Borgonha (Capricor, USA); Jim Carr (Stealth, USA); TBD (Pfizer, USA); TBD (Cumberland Pharmaceuticals, USA),**

**Regulatory viewpoint the FDA Orphan Drug Grant Program
Dunnmon Preston (FDA, USA)
Dan O'Connor (MHRA, GBR)**

**The FDA Regenerative Medicine Advanced Therapy (RMAT) designation
TBD**

**The FDA Regeneration gene therapy Orphan Drug Designation
TBD**

**THE CVCT FORUM
Multi-Stakeholder Moderated Debate
THE INNOVATION LANDSCAPE
Part 2: RARE DISEASE CARDIOMYOPATHIES
PATHWAYS FOR APPROVAL
Chairpersons: Wilson Tang (Cleveland, USA), TBD**

Panelists : Sudhir Borgonha (Capricor, USA); Mike Bristow (Denver, USA); Jim Carr (Stealth, USA); Maggie Cook (Renovacor, USA); Preston Dunnmon (FDA, USA); Gemma Figtree (Sydney, AUS); Pat Furlong (Parent Project Muscular Dystrophy, USA); Sekar Kathiresan (Verve, USA); Debra Marshall (Arca Biopharma, USA) ; Elizabeth McNally (Chicago, USA); Ziad Mallat (Cambridge, GBR); Dan O'Connor (MHRA, GBR); Hesham Sadek (Dallas, USA); Wilson Tang (Cleveland, USA); Thomas Thum (Cardior Pharmaceuticals, GER); Whittemore Tingley (Tenaya Therapeutics, USA); Johan van Hylckama Vlieg (Kaleido, USA); John Vest (Alnylam, USA)

PUBLISHING AND AUTHORSHIP OF MAJOR TRIALS RESULTS

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

**Tocqueville
Thursday 02 December, 2021
14.00-16.00**

Publishing the information before the information.

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

Late Breaking Clinical Trials and media coverage at major international meetings
Barbara Condorelli (ESC, Oxford, GBR)

The role of non-reviewed preprints and preprint servers. Lessons from publications of COVID trials.
Harlan Krumholz (New Haven, USA)

Issues with guidelines publications
Robert Golub (JAMA, Washington, USA)
Thomas Lüscher (London, GBR)

Authorship roles, authorship rules.

What deserves authorship?
Stuart Spencer (The Lancet, London, GBR)
Bertram Pitt (Ann Arbor, USA)

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

How to fill the authorship diversity gap?
Harriette Van Spall (Hamilton, CAN)
Rita Redberg (JAMA Internal Medicine, USA)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

**Chairpersons: John Jarcho (NEJM, Boston, USA),
Stuart Spencer (The Lancet, London, GBR)**

Panelists: Barbara Condorelli (ESC, Oxford, GBR); Robert Golub (JAMA, Washington, USA); John Jarcho (NEJM, Boston, USA); Harlan Krumholz (New Haven, USA); Thomas Lüscher (London, GBR); Marc Pfeffer (Boston, USA); Bertram Pitt (Ann Arbor, USA); Rita Redberg (JAMA Internal Medicine, USA); Stuart Spencer (The Lancet, London, GBR); Harriette Van Spall (Hamilton, CAN); Ron Winslow (Ex Wall Street Journal, Portland, USA)

MAXIMIZING SCIENTIFIC KNOWLEDGE PRODUCTION FROM TRIAL DATA.

**Chairpersons: Filippo Crea (EHJ, Rome, ITA),
Joseph Hill (Circulation, Dallas, USA)**

**Tocqueville
Thursday 02 December, 2021
16.30-18.30**

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

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

**The potential of multiple trial database integration
TBD**

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

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

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

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

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

MAXIMIZING SCIENTIFIC KNOWLEDGE PRODUCTION FROM TRIAL DATA.

Chairpersons: Filippo Crea (EHJ, Rome, ITA), Joseph Hill (Dallas, Circulation, USA)

**Panelists: Filippo Crea (EHJ, Rome, ITA); Robert Golub (JAMA, Washington, USA);
Joseph Hill (Circulation, Dallas USA); Larry Husten (CVCTCardiobrief, New York, USA); Jonathan Kaltman (NIH, USA);
Thomas Lüscher (London, GBR); Stuart Pocock (London, GBR); Emma Raderschadt (Boehringer Ingelheim, GER);
Faiez Zannad (Paris, FRA)**

NEW HFrEF GUIDELINES... SO WHAT? IS HFrEF THERAPY BECOMING TOO COMPLICATED, TOO EXPENSIVE?

Chairpersons: TBD

**Theatre
Friday 03 December, 2021
8.30-10.30**

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

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

**Is HF therapy is becoming too expensive?
Pro: Dan Mark (Durham, USA)
Con: Martin Cowie (London, GBR)
Payers' comment :Joseph Chin (Medicare, USA)**

**Will the new HF guidelines only make inertia worse?
Eileen O'Meara (Montreal, CAN)**

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

**Industry viewpoints
Tomas Andersson (AstraZeneca, SWE), Marty Lefkowitz (Novartis, USA), Salim Shah (Sarfez, USA)**

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

THE CVCT FORUM Multi-Stakeholder Moderated Debate NEW HFrEF GUIDELINES... SO WHAT? IS HFrEF THERAPY BECOMING TOO COMPLICATED, TOO EXPENSIVE? Chairpersons: TBD

Panelists: Tomas Andersson (AstraZeneca, SWE); Joseph Chin (Medicare, USA); Jillianne Code (Vancouver, CAN); Martin Cowie (London, GBR); Gregg C. Fonarow (San Francisco, USA); Nick Harshorne-Evans (London, GBR); Marty Lefkowitz (Novartis, USA); Theresa McDonagh (London, GBR); Dan Mark (Durham, USA); Eileen O'Meara (Montreal, CAN); Milton Packer (Dallas, USA); Ileana Pina (Detroit, USA); Salim Shah (Sarfez, USA); Faiez Zannad (Paris, FRA)

SHOULD NOT THE FUTURE HFrEF TRIALS RATHER BE IMPLEMENTATION TRIALS?

Chairpersons: TBD

Theatre
Friday 03 December, 2021
11.00-13.00

Staging individual foundational HFrEF drug drugs.

Biykem Bozkurt (Houston, USA)

How to investigate whether low doses of everything may be an option?

Marco Metra (Brescia, ITA)

Would fixed combinations help, and what trial should be done in this space?

Joao Ferreira (Porto, POR)

Regulatory comments about fixed combination trials

Charu Gandotra (FDA, USA)

Armin Koch (EMA, GER)

The need for implementation strategies trials.

Faiez Zannad (Paris, FRA)

The role of HF Collaboratory

Christopher O'Connor (Washington, USA)

The role of the NIH

Patrice Desvigne-Nickens (NIH, USA)

Industry viewpoints

Salim Shah (Sarfez, USA), Waheed Jamal (Boehringer Ingelheim, GER)

Patients viewpoint

Nick Harshorne-Evans (London, GBR), Jillianne Code (Vancouver, CAN)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

MOVING TOWARDS HEART FAILURE THERAPY IMPLEMENTATION STRATEGIES TRIALS

Chairpersons: TBD

Panelists: Biykem Bozkurt (Houston, USA); Jillianne Code (Vancouver, CAN); Patrice Desvigne-Nickens (NIH, USA); Joao Ferreira (Porto, POR); Charu Gandotra (FDA, USA); Nick Harshorne-Evans (London, GBR); Waheed Jamal (Boehringer Ingelheim, GER); Armin Koch (EMA, GER); Marco Metra (Brescia, ITA); Christopher O'Connor (Washington, USA); Salim Shah (Sarfez, USA); Faiez Zannad (Paris, FRA)

THE EVOLVING LANDSCAPE OF PULMONARY ARTERIAL HYPERTENSION TRIALS

Part 1- PROGRESS IN TRIAL DESIGN

**Chairpersons: Mardi Gomberg-Maitland (Washington, USA);
Marc Humbert (Paris, FRA)**

**Theatre
Friday 03 December, 2021
14.00-16.00**

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

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

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

Time to reassess future PAH approval trial designs?

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

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

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

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

Pragmatic post approval trials and real world data
Kelly Chin (Houston, USA)

Is PAH therapy getting too expensive? Health economics and cost-effectiveness valuation of PAH trials
Paul Corris (Newcastle, GBR)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

REDESIGNING PULMONARY ARTERIAL HYPERTENSION TRIALS

**Chairpersons: Mardi Gomberg-Maitland (Washington, USA);
Marc Humbert (Paris, FRA)**

Panelists: Kelly Chin (Houston, USA); Paul Corris (Newcastle, GBR); Nazzareno Galiè (Bologna, ITA); Mardi Gomberg-Maitland (Washington, USA); Paul Hassoun (Baltimore, USA); Marc Humbert (Paris, FRA); Steve Kawut (Philadelphia, USA); Vallerie McLaughlin (Ann Arbor, USA); Eric Vicaut (Paris, FRA)

THE EVOLVING LANDSCAPE OF PULMONARY ARTERIAL HYPERTENSION PHASE 3 TRIALS

Part 2- REDEFINING CLINICALLY MEANINGFUL ENDPOINTS

Chairpersons: Vallerie McLaughlin (Ann Arbor, USA),
Gérald Simonneau (Paris, FRA)

Theatre
Friday 03 December, 2021
16.30-18.30

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

Proposal of novel endpoints based on multiparametric assessment risk stratification.
Marius Hoyer (Hannover, GER)

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

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

Patient-reported outcomes in PAH
Kelly Chin (Dallas, USA)

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

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

Patients' viewpoint:
Marilena Vrana (Brussels, BEL), Jacqueline Alikhaani (Los Angeles, USA)

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

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

WHAT ENDPOINTS ARE CLINICALLY RELEVANT, REGULATORY APPROVABLE AND ECONOMICALLY VALUABLE?

Chairpersons: Vallerie McLaughlin (Ann Arbor, USA), Gérald Simonneau (Paris, FRA)

Panelists : Jacqueline Alikhaani (Los Angeles, USA); Raymond Benza (Ann Arbor, USA) ; Meindert Boysen (NICE, London, GBR); Kelly Chin (Houston, USA); Marius Hoyer (Hannover, GER); Joerg Koglin (Merck, USA); Vallerie McLaughlin (Ann Arbor, USA); Krishna Prasad (MHRA, GBR); Ionna Preston (Boston, USA); Mitch Psotka (FDA, USA); Gérald Simonneau (Paris, FRA); Thennapan Thennapan (Minneapolis, USA); Marilena Vrana (Brussels, BEL); Roham Zamanian (Stanford, USA)

INCREASING EQUITY AND DIVERSE REPRESENTATION AMONG PARTICIPANTS IN CARDIOVASCULAR CLINICAL TRIALS

Chairpersons: Harriet Washington (New York, USA)

**Ballroom
Friday 03 December, 2021
8.30-10.30**

The historical roots of the diversity and global gap in clinical trials
Harriet Washington (New York, USA)

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

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

Multi-site investigator initiated trials and the role of diversity in clinical trials leadership
Lehana Thabane (Hamilton, CAN)

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

Harnessing the strength of community: participatory research to enhance racial and ethnic diversity in cardiovascular clinical trials.
Michelle Albert (San Francisco, USA)

Role of industry in increasing equity among clinical trial participants and trial investigators.
Natalie Cheung Rotelli (Eli Lilly, USA)

The New NIH Scientific Workforce Diversity UNITE Initiative
Marie Bernard (NIH, USA)

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

Community member viewpoint – Lessons in engagement from the Black Barbershop trial
Eric Muhammad (Inglewood, USA)

Patient Viewpoint
Wanda Moore (Arizona, USA), Penilla Gunther (Stockholm, SWE)

THE CVCT FORUM Multi-Stakeholder Moderated Debate AGENDA FOR BUILDING EQUITY AND DIVERSE REPRESENTATION IN CARDIOVASCULAR CLINICAL TRIALS

Chairpersons: Harriet Washington (New York, USA)

Panelists: Michelle Albert (San Francisco, USA); Antonio Bernabe-Ortiz (Lima, PEN); Marie Bernard (NIH, USA); Penilla Gunther (Stockholm, SWE); Jaime J Miranda (Lima, PEN); Wanda Moore (Arizona, USA); Eric Muhammad (Inglewood, USA); Natalie Cheung Rotelli (Eli Lilly, USA); Harriette Van Spall (Hamilton, CAN); Robert Temple (FDA, USA); Lehana Thabane (Hamilton, CAN); Harriet Washington (New York, USA); Faiez Zannad (Paris, FRA)

VALUATION OF DEVICE CLINICAL EVIDENCE FOR COVERAGE PURPOSES

Chairpersons: Roxana Mehran (New York, USA),

Meindert Boysen (NICE, London, GBR)

Ballroom
Friday 03 December, 2021
11.00-13.00

Assessing health technologies: What evidence is needed to convince payers?

US perspective
Steven Farmer (CMS, USA)

EU perspective
Meindert Boysen (NICE, London, GBR)

Why and how clinical evidence for payers ("Reasonable and necessary") differs from regulatory approval ("Safe and effective").
Progress in the commitment about aligning payers and regulators.

Andrew Farb (FDA, USA)
Tamara Sysek Jensen (CMS, USA)

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

Investigator viewpoint
William Abraham (Columbus, USA)

Industry viewpoints and case studies

Watchman
Kenneth Stein (Boston Scientific, USA)

Cardiomems
Philip Adamson (Abbott, USA)

Barostim
Nadim Yared (CVRx, USA)

Lawyers viewpoint
Mark DuVal (DuVal & Associates, Minneapolis, USA)

Empowering patients to grow expertise for evidence valuation.
TBD

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

HOW IMPROVING MULTIPLE STAKEHOLDERS UNDERSTANDING, WEIGHTING AND
VALUATION OF CLINICAL EVIDENCE MAY HELP MITIGATE CV DEVICE THERAPY
IMPLEMENTATION HURDLES?

Chairpersons: Roxana Mehran (New York, USA), Meindert Boysen (NICE, London, GBR)

Panelists: William Abraham (Columbus, USA); Philip Adamson (Abbott, USA); Meindert Boysen (NICE, London, GBR); Mark DuVal (DuVal & Associates, Minneapolis, USA); Andrew Farb (FDA, USA); Steven Farmer (CMS, USA) Roxana Mehran (New York, USA); Kenneth Stein (Boston Scientific, USA); Tamara Sysek Jensen (CMS, USA); Nadim Yared (CVRx, USA); Bram Zuckerman (FDA, USA)

PRIMARY PREVENTION. RECENT AND ONGOING TRIALS

Chairpersons: TBD

Ballroom
Friday 03 December, 2021
14.00-16.00

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

Blood pressure lowering therapy.

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

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

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

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

Polypill with or without Aspirin for primary prevention. The TIPS trials.
Salim Yusuf (Hamilton, CAN)

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
PRIMARY PREVENTION. RECENT AND ONGOING TRIALS
Chairpersons: TBD

Panelists: Michel Azizi (Paris, FRA); Bruce Neal (Sydney, AUS); Suzanne Oparil (Birmingham, USA); Kazem Rahimi (Oxford, GBR); Dave Soergel (Novartis, USA); Salim Yusuf (Hamilton, CAN)

PROMOTING THE PRIMARY PREVENTION TRIALS AGENDA

Chairpersons: TBD

Ballroom
Friday 03 December, 2021
16.30-18.30

How to promote primary prevention research

Regulatory solutions.

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

Robert Temple (FDA, USA)
Emmanouil Zouridakis (MHRA, GBR)

Reliance on surrogate endpoints

Jeff Siegel (FDA, USA)

NIH contribution

Lawrence Fine (NHLBI, USA)

The case of food products

TBD

Is primary prevention cost-effective? Who should fund CV primary prevention trials

Rita Redberg (San Francisco, USA)

Addressing CV health disparities

Clyde Yancy (Chicago, USA)

Air pollution and climate change as major rising threats to cardiovascular health. Call for building the evidence.

Sanjay Rajagopalan (Cleveland, USA)

Patient Perspective

Sadegh Alikhaani (Los Angeles, USA)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

PROMOTING THE PRIMARY PREVENTION TRIALS AGENDA

Chairpersons: TBD

Panelists: Sadegh Alikhaani (Los Angeles, USA); Lawrence Fine (NHLBI, USA); Sanjay Rajagopalan (Cleveland, USA); Rita Redberg (San Francisco, USA); Jeff Siegel (FDA, USA); Robert Temple (FDA, USA); Clyde Yancy (Chicago, USA); Faiez Zannad (Paris, FRA); Emmanouil Zouridakis (MHRA, GBR)

DEVELOPMENTS IN ATHEROSCLEROSIS FAMILIAL HYPERCHOLESTEROLEMIA TRIALS

Chairpersons: TBD

Tocqueville
Friday 03 December, 2021
8.30-10.30

Atherosclerosis Drug Discovery
TBD

Genetics of familial hypercholesterolemia: What is an extreme heterozygous FH phenotype?
Marina Cuchel (Philadelphia, USA)

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

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

What is orphan indication? Regulatory viewpoint
TBD (FDA)
TBD (EMA)

Industry viewpoint
Shazia Ali (Regeneron, USA), Antonio Lopez (Amgen, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate DEVELOPMENTS IN FAMILIAL HYPERCHOLESTEROLEMIA TRIALS Chairpersons: TBD

Panelists : Shazia Ali (Regeneron, USA); Marina Cuchel (Philadelphia, USA); Antonio Lopez (Amgen, USA); Robert S. Rosenson (New York, USA); Leslie Shaw (New York, USA)

DEVELOPMENTS IN HYPERTRIGLYCERIDEMIA TRIALS

Chairpersons:TBD

Tocqueville
Friday 03 December, 2021
11.00-13.00

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

Early development in therapies that lower triglyceride-rich lipoproteins

Apo C-III inhibitors
TBD

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

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

Industry viewpoint
Manish Ponda (Regeneron, USA); Giacomo Ruotolo (Eli Lilly, USA), Javier San Martin (Arrowhead, USA), Sotirios Tsimikas (Akcea, USA)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

DEVELOPMENTS IN HYPERTRIGLYCERIDEMIA TRIALS

Chairpersons: TBD

Panelists : Borge Nordestgaard (Copenhagen, DEN); Manish Ponda (Regeneron, USA); Robert S. Rosenson (New York, USA); Giacomo Ruotolo (Eli Lilly, USA); Javier San Martin (Arrowhead, USA); Erik Stroes (Amsterdam, NED); Sotirios Tsimikas (Akcea, USA)

LIPOPROTEIN (a) INHIBITORS LOWERING DRUGS TRIALS

Chairpersons: TBD

**Tocqueville
Friday 03 December, 2021
14.00-16.00**

**Atherothrombosis of lipoprotein (a): new concepts in immunothrombosis
Sascha Goonewardena (Ann Arbor, USA)**

**PCSK9 inhibitors
Lale Tokgözoğlu (Ankara, TUR)**

**siRNA inhibitors
Florian Kronenberg (Innsbruck, AUS)**

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

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

THE CVCT FORUM Multi-Stakeholder Moderated Debate LIPOPROTEIN (a) INHIBITORS LOWERING DRUGS TRIALS Chairpersons: TBD

Panelists: Sascha Goonewardena (Ann Arbor, USA); Brian Ference (Oxford, GBR) Helina Kassahun (Amgen, USA); Florian Kronenberg (Innsbruck, AUS); Santica Marcovina (MedPace, USA); Giacomo Ruotolo (Eli Lilly, USA); Sotirios Tsimikas (Akcea,USA); Lale Tokgözoğlu (Ankara, TUR)

TARGETING HDL AND INFLAMMATION TRIALS

Chairpersons: TBD

Tocqueville
Friday 03 December, 2021
16.30-18.30

1. HDL

Dal-Gene
Jean Claude Tardif (Montreal, CAN)

Industry viewpoint
Fouzia Laghrissi (Dalcore, CH), Giacomo Ruotolo (Eli Lilly, USA), Samuel Wright (CSL Behring, USA)

2. Inflammation

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

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

Anti-cytokine Agents
Paul Ridker (Boston, USA)

Industry viewpoint
Gerard Kornelis Hovingh (Novonordisk, DEN), David Soergel (Novartis, USA), Hafrun Fridriksdottir (Teva, USA)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

TARGETING HDL AND INFLAMMATION TRIALS

THE VALUE OF BIOPROFILE-GUIDED THERAPY TRIALS

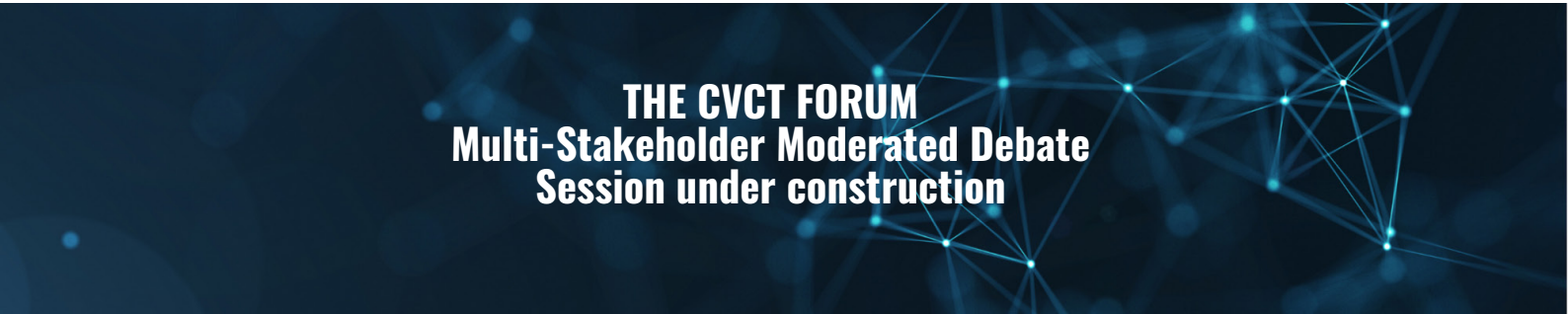
Chairpersons: TBD

Panelists: Nadia Bouabdallaoui (Montreal, CAN); Hafrun Fridriksdottir (Teva, USA); Gerard Kornelis Hovingh (Novonordisk, DEN); Wolfgang Koenig (Münich, GER); Fouzia Laghrissi (Dalcore, CH); Paul Ridker (Boston, USA); Giacomo Ruotolo (Eli Lilly, USA); David Soergel (Novartis, USA); Jean Claude Tardif (Montreal, CAN); Samuel Wright (CSL Behring, USA)

INTERVENTIONAL CARDIOLOGY TRIALS (ICVCT) 5
Chairpersons: Michael Gibson (Boston, USA), Roxana Mehran New York, USA)
Program under construction.

Library
Friday 03 December, 2021
08.30-10.30

Session under construction



THE CVCT FORUM
Multi-Stakeholder Moderated Debate
Session under construction

Session under construction

INTERVENTIONAL CARDIOLOGY TRIALS (ICVCT) 6

Program under construction.

Library
Friday 03 December, 2021
11.00-13.00

Session under construction

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
Session under construction

Session under construction

MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE APPLIED TO TRIALS.

Chairpersons: TBD

**Library
Friday 03 December, 2021
16.30-18.30**

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

Using unbiased machine learning algorithms to boost power for randomized clinical trials
Devan Mehrotra (Merck, USA)

Surveillance science. Issues with FDA safety datasets
Alan Cheng (Medtronic, USA)

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

Undiagnosed Atrial fibrillation.

Verily
Rob Califf (Verily Life Sciences and Google Health, USA)

ALIVECORE
Bernard Gersh (Cleveland, USA)

PULsEAI
John Camm (London, GBR)

Risk of developing heartfailure. CardAIc.
Dipak Kotecha (Birmingham, GBR)

AI applied to trial data. Owkin
Thomas Clozel (Owkin, Paris, FRA)

AI applied to echocardiography. Eko AI
James Hare (eko-ai, Singapore, SG)

AI for patients screening TriNetx
Jennifer Stacey (TriNetx, USA)

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
WHERE BEST TO USE MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE
APPLIED TO TRIALS.
Chairpersons: TBD

Panelists: Rob Califf (Verily Life Sciences and Google Health, USA); John Camm (London, GBR); Thomas Clozel (Owkin, Paris, FRA); Bernard Gersh (Cleveland, USA); Alan Cheng (Medtronic, USA); James Hare (eko-ai, Singapore, SG); Dipak Kotecha (Birmingham, GBR); Devan Mehrotra (Merck, USA); Jennifer Stacey (TriNetx, USA); Lehana Thabane (Hamilton, CAN); Harriette Van Spall (Hamilton, CAN)



INTERVENTIONAL CARDIOLOGY TRIALS (ICVCT) 1

Program under construction.

Theatre
Saturday 04 December, 2021
08.30-10.30

Session under construction



THE CVCT FORUM
Multi-Stakeholder Moderated Debate
Session under construction

Session under construction

INTERVENTIONAL CARDIOLOGY TRIALS (ICVCT) 2

Program under construction.

Theatre
Saturday 04 December, 2021
11.00-13.00

Session under construction

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
Session under construction

Session under construction

INTERVENTIONAL CARDIOLOGY TRIALS (ICVCT) 3

Program under construction.

Theatre
Saturday 04 December, 2021
14.00-16.00

Session under construction

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
Session under construction

Session under construction

INTERVENTIONAL CARDIOLOGY TRIALS (ICVCT) 4

Program under construction.

Theatre
Saturday 04 December, 2021
16.30-18.30

Session under construction

THE CVCT FORUM
Multi-Stakeholder Moderated Debate
Session under construction

Session under construction

PATIENT VOICE IN CLINICAL TRIAL - GETTING BEYOND LIP SERVICE

**Chairpersons: Cynthia Chauhan (Wichita, USA),
Penilla Gunther (Stockholm, SWE)**

**Ballroom
Saturday 04 December, 2021
8.30-10.30**

Welcome and objectives of the session.

Cynthia Chauhan (Wichita, USA)

Why and how bring the patient voice to the research table. What works and what doesn't work.

Steven Macari (Poitiers, FRA)

Inclusiveness among trial patients participants

Inclusion/exclusion of patients with comorbidities in trials

Patrick Gee (Chesterfield, USA)

Diversity among trial patients participants

Wanda F Moore (Arizona, USA)

How do we reach out to diverse patients? Cultural competency, Unserved minorities, Transgender

Sadegh Alikhaani (Los Angeles, USA)

Making trial language intelligible to all patients

Interpretation of Statistical Data Meaning and value of risk reduction, and How can patients be taught to understand the data?

TBD

Lay Language publications in Trial Literature when and why do they matter?

Robin Martinez (Denver, USA)

European Heart Network

Marilena Vrana (Brussels, BEL)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

PATIENT VOICE IN CLINICAL TRIAL - GETTING BEYOND LIP SERVICE

Chairpersons: Cynthia Chauhan (Wichita, USA), Penilla Gunther (Stockholm, SWE)

Panelists: Bill Adams (Erhard, USA); Jacqueline Alikhaani (Los Angeles, USA) ; Sadegh Alikhaani (Los Angeles, USA); Marc Bains (Vancouver, CAN); Cynthia Chauhan (Wichita, USA); Jillianne Code (Vancouver, CAN); Patrick Gee (Chesterfield, USA); Penilla Gunther (Stockholm, SWE); Nick Harshorne-Evans (London, GBR); Steven Macari (Poitiers, FRA); Robin Martinez (Denver, USA); Rob Mentz (JCF, Durham, USA); Greg Merritt (Brighton, USA); Wanda F Moore (Arizona, USA); Marilena Vrana (Brussels, BEL)

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

Ballroom
Saturday 04 December, 2021
11.00-13.00

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

His Bundle/Left Bundle Pacing vs. Biventricular pacing
Pugazhendhi Vijayaraman (Wilkes-Barre, USA)

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

SCD risk prediction model across the EF spectrum and the case for risk guided ICD trials
Sarah Zaman (Melbourne, AUS)

Which patients are eligible for implantable HF Cardiac Monitors? The trial evidence so far and real world data.
TBD

How to overcome the hurdles of implementing guideline-directed HF device therapy
Ulrika Birgersdotter-Green (San Diego, USA)

Regulatory viewpoints
Andrew Farb (FDA, USA)

Payers viewpoints
TBD

Patients viewpoints
Trudie Lobban (London, GBR)
Marc Bains (Vancouver, CAN)

Industry viewpoints
Robert Kowal (Medtronic, USA)

HRS-EHRA-CVCT joint session
THE CVCT FORUM
Multi-Stakeholder Moderated Debate
ELECTROPHYSIOLOGY & HEART FAILURE & NEUROLOGY SIBLINGS:
CAN WE BRIDGE THE GAP OR DOES SIBLING RIVALRY KILL US?
Chairpersons: Biykem Bozkurt (Houston, USA), Thomas Deering (Atlanta, USA)

Panelists : William Abraham (Columbus, USA); Marc Bains (Vancouver, CAN); Biykem Bozkurt (Houston, USA); Ulrika Birgersdotter-Green (San Diego, USA); Nikolaos Dagres (Leipzig, GER); Thomas Deering (Atlanta, USA); Andrew Farb (FDA, USA); Robert Kowal (Medtronic, USA); Trudie Lobban (London, GBR); Pugazhendhi Vijayaraman (Wilkes-Barre, USA); Sarah Zaman (Melbourne, AUS)

HRS-EHRA-CVCT joint session
ATRIAL FIBRILLATION
PREVENTION OF PROGRESSION AND MORTALITY & MORBIDITY RISK REDUCTION
TRIALS

Chairpersons: Gerhard Hindricks (Leipzig, GER), Elaine Hylek (Boston, USA)

Ballroom
Saturday 04 December, 2021
14.00-16.00

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

AF Ablation trials in target patient populations. (Early, persistent, asymptomatic, Heart Failure).
Atul Verma (Toronto, CA)

Trials with new technologies, Electroporation
Pierre Jais (Bordeaux, FRA)

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

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

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

Investigator viewpoints
Douglas Packer (Rochester, USA)

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

Payers viewpoints
Piotr Szymański (Warsaw, POL)

Patients viewpoints
Mellanie True Hills (Stop AFib, Greenwood, USA)

Industry viewpoints
Kenneth Stein (Boston Scientific, USA)

HRS-EHRA-CVCT joint session
THE CVCT FORUM
Multi-Stakeholder Moderated Debate
ATRIAL FIBRILLATION. PREVENTION OF PROGRESSION AND MORTALITY & MORBIDITY
RISK REDUCTION.
WHAT NEEDS SHOULD BE MET IN FUTURE TRIALS?
Chairpersons: Gerhard Hindricks (Leipzig, GER), Elaine Hylek (Boston, USA)

Panelists: Gerhard Hindricks (Leipzig, GER); Elaine Hylek (Boston, USA); Pierre Jais (Bordeaux, FRA); Paulus Kirchhof (Hamburg, GER); Gregory Lip (Liverpool, GBR); Douglas Packer (Rochester, USA); Richard Page (Burlington, USA); Krishna Prasad (MHRA, GBR); Kimberly Selzman (Salt Lake City, USA); Mellanie True Hills (Stop AFib, Greenwood, USA); George Van Hare (FDA, USA); Atul Verma (Toronto, CA); Kenneth Stein (Boston Scientific, USA)

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

Chairpersons: Stephan James (Uppsala, USA), TBD

**Ballroom
Saturday 04 December, 2021
16.30-18.30**

**What exactly is a pragmatic Trial?
Colin Baigent (Oxford, GBR)**

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

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

**Ethical considerations in consent: benefits and challenges of waived and integrated consent in pragmatic trials
Shona Kalkman (Utrecht, NED)**

**Are regulators serious about overlooking 'weaknesses' of pragmatic trials?
Ellis Unger (FDA, USA)
Krishna Prasad (MHRA, GBR)**

Lessons from Covid pragmatic trials. The role of International trialists consortia

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

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

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

**Patient viewpoint
Greg Merritt (Brighton, USA)**

**THE CVCT FORUM
Multi-Stakeholder Moderated Debate
PRE-APPROVAL VS. POST-APPROVAL TRIALS. WHERE BEST STREAMLINED TRIALS MAY
APPLY?
Chairpersons: TBD**

Panelists: Colin Baigent (Oxford, GBR); David DeMets (Madison, USA); Adrian Hernandez (Durham, USA); Stephan James (Uppsala, USA); Shona Kalkman (Utrecht, NED) Martin Landray (Oxford, GBR); Renato Lopez (Duke, USA); Greg Merritt (Brighton, USA); Krishna Prasad (MHRA, GBR); Yves Rosenberg (NIH/NHLBI, USA); Ellis Unger (FDA, USA); Wendy Weber (NIH, NCCIH, USA)

WEARABLE, IMPLANTABLE AND DIGITAL HEALTH TRIALS

**Chairpersons : Martin Cowie (London, GBR),
Carolyn Lam (Singapore, SIN)**

**Tocqueville
Saturday 04 December, 2021
8.30-10.30**

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

Wearable devices for ambulatory cardiac monitoring
Furrukh Sana (Boston, USA)

Implantable Loop Recorder to Detect Atrial Fibrillation and Prevent Stroke
Jesper Hastrup Svendsen (Copenhagen, DEN)

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

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

Industry viewpoint
Philip Adamson (Abbott, USA); Rob Kowal (Medtronic, USA); Kenneth Stein (Boston Scientific, USA)

Editors viewpoint
Rupa Sarkar (The Lancet Digital Health, GBR)
Rita Redberg (JAMA internal medicine, USA)

NIH viewpoint
Erin Iturriaga (NIH, NHLBI, USA)

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

Patient viewpoint.
Mellanie True Hills (Stop AFib, Greenwood, USA)

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

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

Panelists : Philip Adamson (Abbott, USA); Martin Cowie (London, GBR); Alan Fraser (Cardiff, GBR) ; Christopher Granger (Durham, USA); Jesper Hastrup Svendsen (Copenhagen, DEN); Adrian Hernandez (Durham, USA); Mellanie True Hills (Stop AFib, Greenwood, USA); Erin Iturriaga (NIH, NHLBI, USA); Rob Kowal (Medtronic, USA); Carolyn Lam (Singapore, SIN); Bakul Patel (FDA, USA); Rita Redberg (JAMA internal medicine, USA); Furrukh Sana (Boston, USA); Rupa Sarkar (The Lancet Digital Health, GBR); Kenneth Stein (Boston Scientific, USA); Mintu Turakhia (Stanford, USA); Harriette Van Spall (Hamilton, Canada)

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

Chairpersons: TBD

Tocqueville
Saturday 04 December, 2021
11.00-13.00

Biologic plausibility of machine-learning selected proteins – is it adequate?

David Lanfear (Detroit, USA)

Why surrogate endpoints are important to “Critical Path Innovation”

TBD

What is the FDA’s framework for evidentiary standards for surrogate endpoints as drug development tools

Jeff Siegel (FDA, USA)

Industry viewpoint – what are the benefits and risks of using surrogate endpoints in drug development

Agim Beshiri (Abbott Diagnostics, USA) ; Serge Masson (Roche, CH) ; John Wagner (Cygnal Therapeutics, USA) : TBD
(Olink, SWE) : TBD (CRO)

Statistician viewpoint: fulfilling the “Universality” requirement to drug and disease mechanism (Prognostic performance, “proportionality” requirement, Sensitivity to change...)

Stuart Pocock (London, GBR)

Practitioner view – how do surrogates help medical practice

Peter Ganz (San Francisco, USA)

Proteomic surrogate program design, results to date

Steve Williams (Somalogic, USA)

How to secure robustness of surrogates to geographic and ethnic variation

Joe Coresh (Baltimore, USA)

THE CVCT FORUM Multi-Stakeholder Moderated Debate ROADMAP TOWARDS ACTIONABLE “UNIVERSAL” SURROGATE ENDPOINT FOR CARDIOVASCULAR TRIALS Chairpersons: TBD

Panelists : Agim Beshiri (Abbott Diagnostics, USA) ; Joe Coresh (Baltimore, USA);
Peter Ganz (San Francisco, USA); David Lanfear (Detroit, USA); Serge Masson (Roche, CH) ; Stuart Pocock (London,
GBR); Jeff Siegel (FDA, USA); John Wagner (Cygnal Therapeutics, USA) ; Steve Williams (Somalogic, USA)

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY

Part 1 : ONGOING TRIALS

Chairpersons: TBD

Tocqueville
Saturday 04 December, 2021
14.00-16.00

Device guided therapy trials in heart failure.

Cardiomems GUIDE-IT
Joann Lindenfield (Nashville, USA)

MANAGE HF
Adrian Hernandez (Durham, USA)
ALLEVIATE-HF
Javed Butler (Jackson, USA)

Biomarker triggered optimization of therapy

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

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

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

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

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

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY

Part 1 : ONGOING TRIALS

Chairpersons: TBD

Panelists: Javed Butler (Jackson, USA); Adrian Hernandez (Durham, USA); Ziad Hijazi (Uppsala, SWE); Carolyn Lam (Singapore, SIN); Joann Lindenfield (Nashville, USA); Alexandre Mebazaa (Paris, FRA); Carolyn Lam (Singapore, SIN); Arshed Quyyumi (Atlanta, USA); Paul Ridker (Boston, USA)

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY

Part 2 : METHODOLOGICAL ISSUES

Chairpersons: TBD

**Tocqueville
Saturday 04 December, 2021
16.30-18.30**

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

**Registry based risk assessment and longitudinal follow up
Gillian Murtagh (Abbott Dx, USA)**

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

**Statistician viewpoint. When and why adaptive, baskets and platforms trials are needed
Lisa Lavange (Chapel Hill, USA)**

**Industry viewpoint:
Frank Kramer (Bayer, GER), André Ziegler (Roche, GER), Agim Beshiri (Abbott Dx, USA), Steve Williams (Somalogic, USA),
TBD (Olink, SWE)**

**Regulatory Viewpoint:
Kristina Dunder (EMA, SWE)
Fred Senatore (FDA, USA)**

THE CVCT FORUM

Multi-Stakeholder Moderated Debate

MONITOR AND BIOMARKER TRIGGERED OPTIMIZATION OF THERAPY LESSONS LEARNT AND FUTURE DIRECTIONS

Chairpersons: TBD

Panelists: Agim Beshiri (Abbott Dx, USA), Joe Coresh (Baltimore, USA); Kristina Dunder (EMA, SWE); Jim Januzzi (Boston, USA); Frank Kramer (Bayer, GER); Lisa Lavange (Chapel Hill, USA); Gillian Murtagh (Abbott Dx, USA); Fred Senatore (FDA, USA); Steve Williams (Somalogic, USA); André Ziegler (Roche, GER)