

# CardioVascular Clinical Trialists CVCT Workshop 4th December 2022

Embassy of France  
Reservoir Road, Washington DC

## FACULTY (All confirmed)

### ACADEMY

1. Stefan Anker (Berlin, GER)
2. Brian Clagget (Boston, MA, USA)
3. Scott Evans (Washington DC, USA)
4. Joao Ferreira (Porto, POR)
5. Bernard Gersh (Rochester, MN, USA)
6. Nicolas Girerd (Nancy, FRA)
7. Hiddo Heerspink (Groningen, NED)
8. Adrian Hernandez (Durham, NC, USA)
9. Darren K McGuire (Dallas, TX, USA)
10. Roxana Mehran (New York, NY, USA)
11. Milton Packer (Dallas, TX, USA)
12. Marc Pfeffer (Boston, MA, USA)
13. Bertram Pitt (Ann Arbor, MI, USA)
14. Stuart Pocock (London, UK)
15. Robert Rosenson (New York, NY, USA)
16. Naveed Sattar (Glasgow, UK)
17. Scott Solomon (Boston, MA, USA)
18. Jan Tijssen (Narnden, NED)
19. Harriette Van Spall (Hamilton, CAN)
20. Faiez Zannad (Paris, FRA)

### JOURNAL/MEDIA

21. Filippo Crea (EHJ, Rome, ITA)
22. Joe Hill (Circulation, USA)
23. Jane Leopold (NEJM, USA)
24. Chana Sacks (NEJM Evidence, USA)
25. Jennifer Sargent (Nature Medicine, USA)
26. Stuart Spencer (The Lancet, UK)

### INDUSTRY

27. Philip Adamson (Abbott, USA)
28. Tomas Andersson (AstraZeneca, SWE)
29. Gabriel Brooks (Pfizer, USA)
30. Jennifer Conte (Medtronic, USA)
31. Mahesh Patel (Merck, USA)
32. Amy Sehnert (BMS, USA)
33. Martin Unverdorben (Daiichi Sankyo, USA)
34. Janet Wittes (Wittes LLC, USA)
35. Antoine Yver (Centessa, USA)
36. Cordula Zeller, (Boehringer, GER)

### REGULATORY

37. Angeles Alonso (MHRA, UK)
38. Andrew Farb (FDA, USA)
39. Mitch Psootka (FDA, USA)
40. Norman Stockbridge (FDA, USA)

41. Aliza Thompson (FDA, USA)
42. George Van Hare (FDA, USA)
43. Bram Zuckerman (FDA, USA)

- NIH**
44. Lawrence Fine (NHLBI, USA)
  45. Yves Rosenberg (NIH, USA)

### Program

8.00-9.30

**The obsession with  $P < .05$  continues unabated:  
is it time for trialists, journals and regulators to get smarter?**

Chairperson : Faiez Zannad (Paris, FRA)

Speaker: Stuart Pocock (London, UK)

Discussants: Scott Evans (Washington DC, USA), Mahesh Patel (Merck, USA)

9.30-11.00

**The concept of “totality of evidence” how does it work? And when is it useful?**

Chairperson ; Yves Rosenberg (NHLBI, USA)

Speaker: Milton Packer (Dallas, TX, USA)

Discussants: Norman Stockbridge (FDA, USA), Janet Wittes (Wittes LLC, USA)

11.00-11.30 Coffee Break

11.30-13.00

**Planning future heart failure trials: is the reduced/preserved EF dichotomy out-of-date?**

Chairperson ; Scott Solomon (Boston, MA, USA)

Speaker: Harriette Van Spall (Hamilton, CAN)

Discussants: Tomas Andersson (AstraZeneca, SWE), Joe Hill (Circulation, USA), Mitch Psocka (FDA, USA)

13.00-14.00 Lunch

14.00-15.30

**How can we integrate real world evidence alongside randomized trials?**

Chairperson ; Filippo Crea (EHJ, Rome, IT)

Speaker: Bernard Gersh (Rochester, MN, USA)

Discussants: Jennifer Conte (Medtronic, USA), Joao Ferreira (Porto, POR), Yves Rosenberg (NHLBI, USA), George Van Hare (FDA, USA)

15.30-15.50 Coffee break

15.50- 17.20

**Should all trial data become open access at least 1 year after the main publication?**

Chairperson ; Stuart Spencer (The Lancet, UK)

Speaker: Milton Packer (Dallas, TX, USA)

Discussants: Filippo Crea (EHJ, Rome, ITA), Jane Leopold (NEJM, USA)

17.20 Adjourn