

## **CVCT Workshop 2023**

Embassy of France, Reservoir Road, Washington DC

Sunday Dec 3<sup>rd</sup> 2023

8.00 – 17.30

**On invitation ONLY**

**Attendance during the full day is kindly required**

**Scientific program.**

**8.00-9.20**

**EXTENSION STUDIES: DO WE NEED TO DEFINE BETTER STRATEGIES FOR SEQUENCES OF  
EXTENSION STUDIES? ANY MERIT FOR NON-RANDOMIZED EXTENSION PHASE OF RCT?  
RANDOMIZED WITHDRAWAL AT THE TERMINATION OF THE TRIAL**

Chairperson: Faiez Zannad (Paris, FRA)

Speaker : Frank Rockhold (Durham, NC, USA)

Discussants :

Milton Packer (Dallas, TX, USA)

Mahesh Patel (Merck, USA)

Janet Wittes (Washington, DC, USA)

**9.20-10.40**

**WIN RATIO, UPDATE.**

Chairperson: Harriette Van Spall (Hamilton, CAN)

Speaker: Stuart Pocock (London, UK)

Discussants:

Jim Januzzi (Boston, MA, USA)

Janet Wittes (Washington, DC, USA)

Benjamin Saville (Berry Consultants, USA)

Mark Rothmann (FDA, USA)

**10.40- 11.00**  
**Coffee break**

**11.00-12.20**  
**IS "REPEAT EVENTS" OF VALUE COMPARED TO CONVENTIONAL TIME-TO-FIRST  
EVENT-ANALYSIS?**

Chaiperson: Roxana Mehran (New York, NY, USA)

Speaker: Robert Mentz (Durham, NC, USA)

Discussants:

Don Cutlip (Boston, MA, USA)

Stuart Pocock (London, UK)

Benjamin Saville (Berry Consultants, USA)

Mark Rothmann (FDA, USA)

**12.20- 13.20**  
**Lunch break**

**13.20-14.40**  
**WHEN A POSITIVE OVERALL RESULT MAY NOT APPLY TO ALL PATIENTS?  
WHEN A TREATMENT SUCCESS IS CONVINCING OVERALL THERE MAY BE SEVERAL  
REASONS WHY ITS USE SHOULD NOT APPLY TO EVERYONE.**

Chaiperson: Brendon Neuen (Sydney, AUS)

Speaker: Anthony Rodgers (Sydney, AUS)

Discussants:

Ellis Unger (Heyman Phelps, USA)

Benjamin Saville (Berry Consultants, USA)

Kenneth Stein (Boston Scientific, USA)

Norman Stockbridge (FDA, USA)

**14.40-15.50**  
**SHOULD WE BE WORRIED ABOUT MULTIPLICITY?  
HIERARCHICAL PROTECTION, BAYESIAN APPROACH, GRAPHICAL APPROACH.**

Chairperson: Micheal Gibson (Boston, MA, USA)

Speaker: Janet Wittes (Washington, DC, USA)

Discussants:

Brendon Neuen (Sydney, AUS)

Benjamin Saville (Berry Consultants, USA)

Ellis Unger (Heyman Phelps, USA)

**15.50- 16.10**  
**Coffee break**

**16.10-17.30**

**DO TRIALISTS NEED TO UNDERSTAND CELLULAR BIOLOGY? DOES MECHANISM MATTER?**

Chairperson: Carolyn Lam (Singapore, SIN)

Speaker: Jane Leopold (NEJM, USA)

Discussants :

Milton Packer (Dallas, TX, USA)

Jim Januzzi (Boston, MA, USA)

Janet Wittes (Washington, DC, USA)

**17.30**

**Adjourn**

**TENTATIVE FACULTY**  
**(Provisional, please keep confidential)**

**ACADEMY**

1. Stefan Anker (Berlin, GER)
2. Javed Butler (Dallas, TX, USA)
3. Don Cutlip (Boston, MA, USA),
4. David DeMets (Madison, WI, USA)
5. Bernard Gersh (Rochester, MN, USA)
6. Michael Gibson (Boston, MA, USA)
- ~~7. Nicolas Girerd (Nancy, FRA)~~
- ~~8. Chris Granger (Durham, NC, USA)~~
9. Joseph Hill (Circulation Editor, USA)
10. Jim Januzzi (Boston, MA, USA)
11. Peter Juni (Oxford, UK)
12. Paulus Kirchhof (Hamburg, GER)
13. Jane Leopold (NEJM, USA)
14. Carolyn Lam (Singapore, SIN)
15. Hiddo Lambers Heerspink (Groningen, NED)
16. Alexandre Mebazaa (Paris, FRA)
17. Roxana Mehran (New York, NY, USA)
18. Robert Mentz (Durham, NC, USA)
19. Brendon Neuen (Sydney, AUS)
20. Milton Packer (Dallas, TX, USA)
21. Mark Petrie (Glasgow, UK)
22. Bertram Pitt (Anna Arbor, MI, USA)
23. Stuart Pocock (London, UK)
24. Frank Rockhold (Durham, NC, USA)
25. Anthony Rodgers (Newtown, AUS)
26. Robert Rosenson (New York, NY, USA)
27. Jennifer Sargent (Nature, USA)
- 28.** Scott Solomon (Boston, MA, USA)
29. Stuart Spencer (The Lancet, UK)
30. Jan Tijssen (JACC, NED)
31. Harriette Van Spall (Hamilton, CAN)
32. Janet Wittes (Washington, DC, USA)
33. Faiez Zannad (Paris, FRA)

**INDUSTRY**

34. Arnaud Bastien (BMS, USA)
35. Maria Borentain (Bayer, GER)
36. Frank Bretz (Novartis, USA)
37. Kristine Buchholtz (Novonordisk, DEN)
38. Martin Cowie (AstraZeneca, UK)
39. Jyothis George (Amgen, USA)
40. Makesh Patel (Merck, USA)
41. Benjamin Saville (Berry Consultants, USA)
42. Charles Simonton (Abiomed, USA)
43. Kenneth Stein (Boston Scientific, USA)
44. Pierluigi Tricoci (CSL Behring, USA)
45. Ellis Unger (Heyman Phelps, USA)
46. Cordula Zeller (Boehringer, GER)

**NHLBI**

47. David Goff (NHLBI, USA)
48. Yves Rosenberg (NHLBI, USA)
- 49.** James Troendle (NHLBI, USA)

**REGULATORY**

50. Gregory Alexander (FDA, USA)
51. Andrew Farb (FDA, USA)
52. Alar Irs (EMA, EST)
53. Mark Rothmann (FDA, USA)
54. Norman Stockbridge (FDA, USA)
55. Bram Zuckerman (FDA, USA)
56. TBD (Stat from CEDER)