CVCT WORKSHOP 2024
Washington DC, Mayflower Hotel
December 8th, 2024
SCIENTIFIC PROGRAM

8.00-9.30
TREATMENT SWITCHES IN DEVICE TRIALS

Trials of a new device versus standard of care control become challenging when control patients switch to receive device during follow up. It's then hard to reach valid conclusions on the device's true effect. Practice varies widely: some trials (early TAVR, CABANA) have a high crossover rate, while others (COAPT, SPYRAL-HTN-ON-MEDS) permit such switches after a fixed time (2 years, six months, respectively).
How can we improve the timing and design of such device trials to get valid results?

Moderator
Roxana Mehran (New York, NY, USA)

Speaker
Jan Tijssen (Amsterdam, NED)

Discussant
Gregg Stone (New York, NY, USA)
Stuart Pocock (London, UK)
Martin Leon (New York, NY, USA)

9.30-11.00
META-ANALYSES: WHAT TO BELIEVE?

Metanalyses stand at the top of the pyramid of evidence quality, above the single randomized clinical trial, which in turn is above quality, observational studies.

- When can a meta-analysis be granted such a high level of trust?
- Can we define a quality ranking of meta-analyses from best to worst?
- Are standards of meta-analyses improving, given guidelines and greater use of individual patient data?
- Why does NEJM never publish any meta-analyses?

Moderator
Janet Wittes (Wittes LLC, USA)

Speaker
Sanjay Kaul (Los Angeles, CA, USA)

Discussant
Milton Packer (Dallas, TX, USA)
Norman Stockbridge (FDA, USA)
Flavia Geraldes (Lancet, UK)

11.00-11.30
COFFEE BREAK

11.30-12.30
TRAINING OF FUTURE TRIALISTS

CVCT is doing much to help young potential trialist.

- Clinicals need opportunities for formal training in trials methodology (e.g., Master Courses session at the CVCT Forum), exposure to real major trials (as an adjunct member of trial committees) and a career pathway, as practicing clinicians with time to be effective trialists.
- Statisticians need a career development that involves both trial methodology research and collaborative opportunities in design, conduct, analysis and reporting of trials.
- How can both young cardiologists and young statisticians carve out a career as trialists?
- How to help develop adequate training structures and opportunities?
- How can we enhance the desire to become a trialist?
- How can we enhance the trialist career to be an exciting adventure?

Moderator
Faiez Zannad (Paris, FRA)

Introduction
Guiomar Mendieta (Madrid, ESP)

Speaker
Martin Cowie (AstraZeneca, UK)

Discussant
Louise Bowman (Oxford, UK)
Yves Rosenberg (NHLBI, NIH, USA)
Michael Gibson (Boston, MA, USA)

12.30-13.30
LUNCH BREAK

13.30-14.30
JAMA'S NEW GUIDANCE ON NONRANDOMIZED EVIDENCE

A JAMA Special Communication (9th May 2024; 331, 1845-53) proposes that carefully conducted observational studies of interventions can sometimes support causal conclusions. They advocate for new frameworks and statistical methods that yield results with tenable causal interpretations, provided that subject matter knowledge suggests necessary assumptions hold.

Moderator
Rob Califf (FDA, USA)

Speaker
Issa Dahabreh (JAMA, USA)

Discussant
Christopher Granger (Durham, NC, USA)
Janet Wittes (Wittes LLC)
Bram Zuckerman (FDA, USA)

14.-30-16.00
DATA SHARING

This topic has been discussed repeatedly. However, how it works or does not work in practice needs further insight.

Sometimes though there is agreement in principle, long delays occur in getting a trial's data available. This can be frustrating for those planning systematic reviews with 1 key trial missing.

- What is the right time span from trial completion to starting data sharing?
- Is there a consistent way how people apply to obtain data access?
- How does Vivli and other data access platforms work in practice?
- How common is it for sponsors to deny data sharing?
- What are the current guidelines on data sharing? From Journal editors, from health authorities, and from trialists

Moderator
Jeff Popma (Cardiovascular Research Foundation, USA)

Speaker
Harlan Krumholz (JACC, USA)

Discussant
Joao Ferreira (Porto, POR)
Kenneth Stein (Boston Scientific, USA)
Frank Rockhold (Durham, NC, USA)
Jane Leopold (NEJM, Boston, USA)

16.00-16.30
COFFEE BREAK

16.30-18.00
SECONDARY PUBLICATIONS OF MAJOR TRIALS: IS THE PLETHORA OUT OF CONTROL?

Moderator
Stuart Pocock (London, UK)

Speaker
Javed Butler (Dallas, TX, USA)

Discussant
Biykem Bozkurt (Houston, USA)
Alexandre Mebazaa (Paris, FRA)
David Cohen (New York, NY, USA)
Jyothis George (Amgen, USA)

18.00 ADJOURN AND OFF-SITE DINNER

TENTATIVE FACULTY

ACADEMY

1. Louise Bowman (Oxford, UK)
2. Javed Butler (Dallas, TX, USA)
3. David Cohen (New York, NY, USA)
4. Michael Gibson (Boston, MA, USA)
5. Christopher Granger (Durham, NC, USA)
6. Sanjay Kaul (Los Angeles, CA, USA)
7. Carolyn Lam (Singapore, SIN)
8. Martin Leon (New York, NY, USA)
9. Alexandre Mebazaa (Paris, FRA)
10. Roxana Mehran (New York, NY, USA)
11. Milton Packer (Dallas, TX, USA)
12. Bertram Pitt (Ann Arbor, MI, USA)
13. Stuart Pocock (London, UK)

14. Jeff Popma (Cardiovascular Research Foundation, USA)
15. Frank Rockhold (Durham, NC, USA)
16. Gregg Stone (New York, NY, USA)
17. Jan Tijssen (Amsterdam, NED)
18. Bryan Williams (London, UK)
19. Faiez Zannad (Paris, FRA)

JOURNAL/MEDIA

20. Michael Basson (Nature Medicine, USA)
21. Biykem Bozkurt (Houston, USA)
22. Issa Dahabreh (JAMA, USA)
23. Flavia Geraldes (Lancet, UK)
24. Harlan Krumholz (JACC, USA)
25. Jane Leopold (NEJM, Boston, USA)

INDUSTRY

26. Arnaud Bastien (BMS, USA)
27. Maria Borentain (Bayer, GER)
28. Kristine Buchholtz (NovoNordisk, DEN)
29. Martin Cowie (AstraZeneca, UK)
30. Jyothis George (Amgen, USA)
31. Nadim Geloo (Abbott, USA)
32. Anastasia Lesogor (Novartis, USA)
33. Masahiro Murakami (Eli Lilly, USA)
34. Kenneth Stein (Boston Scientific, USA)
35. Janet Wittes (Wittes LLC,USA)

REGULATORY

36. Rob Califf (FDA, USA)
37. Jennifer Clark (FDA, USA)
38. Charu Gandotra (FDA, USA)
39. Ileana Piña (FDA, USA)
40. John Sharretts (FDA, USA)
41. Norman Stockbridge (FDA, USA)
42. Aliza Thompson (FDA, USA)
43. Changfu Wu (FDA, USA)
44. Bram Zuckerman (FDA, USA)

NIH / PUBLIC HEALTH INSTITUTIONS

45. Yves Rosenberg (NHLBI, NIH, USA)

CVCT FUTURE TRIALISTS

46. Joao Ferreira (Porto, POR)
47. Masatake Kobayashi (Tokyo, JPN)
48. Ahmed Kolkailah (Dallas, TX, USA)
49. Matthew Lee (Glasgow, UK)
50. Guiomar Mendieta (Madrid, ESP)
51. Elke Platz (Boston, MA, USA)

PATIENTS/PATIENTS' REPRESENTATIVES

52. Penilla Gunther (Stockholm, SWE)
53. Nick Hartshorne-Evans (Pumping Marvellous Foundation, UK)