13th CardioVascular Clinical Trialists (CVCT) WORKSHOP
Paris, December 5th and 6th, 2010

Objective: CVCT Workshops is a series of workshops dedicated to discussion among experts with the aim of improving future CV treatment discovery and development and more specifically trials designs leading optimally to new therapy approval and therapeutic progress.

Attendees (On invitation only): The workshop is attended by clinical trial experts and major international thought leaders principally engaged in cardiovascular clinical trials. These individuals come from various primary job functions in academia, the NIH, the pharmaceutical industry, and pharmaceutical regulatory bodies (EMEA and FDA). Small size is essential to an exchange of ideas and formulating thoughts. Attendance is on invitation only and is limited to 35-40 participants

Format: 2 full day workshop. The Workshop is primarily oriented toward discussion among persons as opposed to lecturing to a broad audience, not all participants are speakers/discussants. Interacting and participating to the discussion as panelists is most important. **Participation to the full 2 days meeting is required**
For each topic, one speaker gives a short 10 minutes presentation in order to raise specific issues related to the assigned topic and set the stage for discussion, capitalising on the expertise of the group and assuming the high level of knowledge of the attendees. Subsequently, discussants are supposed to complement the speaker's presentation with personal views and additional issues during a very short 5 minutes presentation each. Thereafter, and for each topic, a general panel discussion may last for up to 60-90 minutes, depending on the importance of the topic.

Publication: All discussions are tape recorded. Faculty members may volunteer to take the lead in producing manuscripts, possibly assisted by a professional medical writer, tentatively capturing any relevant new thoughts which could emerge from the discussion. Other faculty members will be invited to review, comment and eventually co-author manuscripts produced by respective lead authors. After approval from participants, manuscripts are submitted to major medical journals. It is agreed (and stated so in the manuscripts) that views expressed in the CVCT published manuscripts are individual views not binding to any faculty member institution or organisation. Publications will comply with the EMEA and FDA procedures and rules.

Organisation: Since 1997, CVCT Workshops are organised by the Centre d'Investigation Clinique (CIC-Inserm, University and Centre Hospitalier Universitaire) of Nancy, occasionally in collaboration with the European Society of Cardiology Working Group on CV pharmacology and Drug Therapy and/or the American College of Cardiology Foundation. Starting in 2005, CVCT Workshops have been also organised in collaboration with the NHLBI (NIH).

Support: CVCT Workshops have been supported by educational grants from the pharmaceutical industry to the Centre d'Investigation Clinique of Nancy. The unrestricted grant mechanism has guaranteed that CVCT organisation remained totally independent.

SCIENTIFIC PROGRAMME

Day 1 Sunday December 5th

8-8.15 Welcome and introduction

8.15-10: Session 1: Dose finding adaptive design from a practical perspective, real experiences

Speaker: Stuart Pocock
Discussant: Nancy Geller
Discussant Regulatory: Armin Koch

10-10.30 Break

10.30-11.30. Session 2: Trial design for antiarrhythmic agents. Need for outcome studies. EMEA new notes of guidance

Speaker Regulatory: Gonzalo Calvo
Discussant Regulatory: Norman Stockbridge
Discussant 2: Stefan Hohnloser

11.30- 1 pm. Session 3: Timing of events in composite endpoints. Repeated measures for continuous data. Making the most of repeated events outcomes.

Speaker: Janet Wittes
Discussant: Hans Wedel
Discussant Regulatory: Aldo Maggioni

1 pm – 2 pm Lunch Break

2 pm – 3.30 pm. Session 4. Non scientific influence on trial conduct: Politicians/ Litigations / analysts /media/ activists.

Speaker: John Jarcho
Discussant 1: Maarten Simoons
Discussant 2: Marc Pfeffer

3-3.30 Break

3.30-5 pm Session 5. Comparative effectiveness, Comparative cost effectiveness (AHRQ)

Speaker: Sir Michael Rawlins
Discussant 1: John Spertus
Discussant 2: David Gordon

Day 2. Monday December 6th

8.30-10 am, Session 6: Device and interventional cardiology trials: Are there specific design, endpoint and interpretation issues?

Speaker: Roxana Mehran
Discussant Industry: Rita Peeters
Discussant Regulatory: Bram Zuckerman

10-10.30 Break

10.30-11.30. Session 7: Criteria for trial validation of telemedicine devices for heart failure patients?

Speaker: John Cleland
Discussant Regulatory: Bram Zuckerman
Discussant Industry: Katrin Leadley

11.30-12.30. Session 8: Design of trials of personalized medicine. Use of genetics/biomarkers for guiding/individualizing CV therapy.

Speaker: Jan Staessen
Discussant-: James Januzzi
Discussant: Yves Rosenberg
Discussant Industry: Christian Zaugg

12.30– 1.30 pm. Lunch Break

1.30-3.00 pm. Why are clinical trials so complicated and expensive? How can they be made less so?

Speaker: Christian Torp Pedersen
Discussant: Alice Mascette

3-3.30 pm. Break.

4.00- 5.00 pm. How can we learn to back winners? Why are so many trials neutral/ negative? Case-studies of "failures"

Speaker: Jeffrey Borer
Discussant 1: John Mac Murray
Discussant 2: David Gordon

5.00 pm. Adjourn

Faculty
(All provisional)

Academy

1. Borer Jeffrey S. (New York, USA)
2. Cleland John (Hull, GBR)
3. Eikelboom John (Perth, AUS)
4. Gheorghiade Mihai (Chicago, USA)
5. Hohnloser Stefan (Frankfurt, GER)
6. Januzzi James (Boston, USA)
7. Jarcho John (Boston, USA)
8. Julian Desmond (London, GBR)
9. Kober Lars (Copenhagen, DEN)
10. Mac Murray John (Glasgow, GBR)
11. Mancia Giuseppe (Monza, ITA)
12. Mehran Roxana (New York, USA)
13. Pfeffer Marc (Boston, USA)
14. Pitt Bertram (Ann Arbor, USA)
15. Pocock Stuart (London, GBR)
16. Rawlins Michael (Newcastle, GBR)
17. Serebruany Victor (Towson, USA)
18. Simoons Maarten (Rotterdam, NLD)
19. Spertus John (Kansas City, USA)
20. Staessen Jan (Leuven, BEL)
21. Tavazzi Luigi (Cotignola, ITA)
22. Torp Pedersen Christian (Copenhagen, DEN)
23. Wedel Hans (Gothenburg, SWE)
24. Wittes Janet (Washington, USA)
25. Zannad Faiez (Nancy, FRA)

NIH (NHLBI)

26. Geller Nancy (Bethesda, USA)
27. Gordon David (Bethesda, USA)
28. Mascette Alice (Bethesda, USA)
29. Rosenberg Yves (Bethesda, USA)
30. Fine Lawrence (Bethesda, USA)

Regulatory

31. Alonso Angeles (Madrid, ESP)
32. Calvo Gonzalo (Barcelona, ESP)
33. Koch Armin (Hannover, GER)
34. Laslop Andrea (Innsbruck, AUT)
35. Maggioni Aldo (Florence, ITA)
36. Stockbridge Norman (Rockville, USA)
37. Zuckerman Bram (Rockville, USA)

Industry

38. Bernaud Corine (AstraZeneca, Zaventem, BEL)
39. Boudjadja Azzedine (Bayer, Loos, FRA)
40. Cody Robert (Merck, Rahway, USA)
41. Lerebours Guy (Servier, Paris, FRA)
42. Pouleur Hubert (Pfizer, New York, USA)
43. Leadley Katrin (Boston Scientific, New York, USA)
44. Friedman Jeffrey (Boehringer Ingelheim)
45. Hans-Juergen Woerle (Boehringer Ingelheim)
46. Rita Peeters (Medtronic, USA)
47. Christian Zauggg (Roche Diagnostics, Rostkreutz, SWI)
48. Tsouderos Yannis (Servier, Paris, FRA
49. TBD (Takeda, Chicago, USA)
50. Gunnar Olsson (AstraZeneca, Gothenburg SWE)