



## 10<sup>th</sup> CardioVascular Clinical Trialists CVCT- Workshop

The Westin, 3 rue de Castiglione Paris, France

December 6-7<sup>th</sup>, 2007

### - PROGRAM -

#### Chairmen

Faiez ZANNAD (Nancy)  
Desmond JULIAN (London)  
Bertram PITT (Ann Arbor)  
David GORDON (Bethesda)  
Ray LIPICKY (Gaithersburg)



Organised by the Clinical Investigation  
Center (CIC) - INSERM - CHU,  
Faculty of Medicine, University Henri  
Poincaré, Nancy, France

Organised in collaboration  
with the ESC Working Group  
on Cardiovascular  
Pharmacology and Drug  
Therapy

Application for American  
College of Cardiology  
Foundation sponsorship  
under consideration

Organised in collaboration  
with Heart, Lung, and  
Blood Institute (NHLBI) of  
the National Institutes of  
Health (NIH)

## Thursday December 6th

**8:00 Introduction : Faiez Zannad**

**1. 8:30- 10:30.**

**Event driven trials vs. adaptive trials.**

Chair: Faiez Zannad

Speaker: Stuart Pocock

Discussants, Michael Domanski, Janet Wittes, Abraham Karkowsky

**10:30-10:50 Café Break**

**2. 10:50 - 11:40.**

**Are patients better off inside than outside randomised clinical trials?**

Chair: Desmond Julian

Speaker: Jacobus Lubsen

Discussants: David DeMets,

**3. 11:40- 13:00**

**Maximizing scientific knowledge generation from industry trial databases.**

**Accessing trial databases and biobanks.**

Chair: Gabriel Steg

Speaker: Marc Pfeffer

Discussants: Hubert Pouleur, Janet Wittes, Névine Zariffa

**13:00-14:00 Lunch**



## Thursday December 6th

**4. 14:00 – 15:30**

**How to run US NIH trials in Europe? Overcoming the regulatory hurdles for international multicenter clinical trials.**

Chair: David Gordon

Speaker: Faiez Zannad,

Discussants: Jacobus Lubsen, Susan Shurin

**15:30 – 15:50 Café Break**

**15:50 – 17:50**

**5. External validity of randomised clinical trials. Pragmatic trials of intervention strategies.**

Chair: Bertram Pitt

Speaker: Gabriel Steg

Discussants: David Gordon, Stuart Pocock

**18:00 Free time**

**19 :15 Musée des Arts Décoratifs : visit and dinner**



## Friday December 7<sup>th</sup>

**6. 9:00 – 11:00**

**Lessons from IMT and/or IVUS trials. Outcome trials conditional on IMT and/or IVUS surrogate endpoint response?**

Chair: Jeffrey Borer

Speaker: James Revkin

Discussants : Corine Bernaud, Michael Domanski

**11:00 – 11:20 Café Break**

**7. 11:20 – 12:30**

**For how long should drugs be licensed for? Impact of patent duration on trials.**

Chair: Ray Lipicky

Speaker: Bertram Pitt

Discussants: Hubert Pouleur, Bernard Hamelin, Yale Mitchel

**12:30-13:30 Lunch**



**Friday December 7<sup>th</sup>**

**8. 13:30 – 15:30**

**DSMB issues (One half-day session with case studies allowing discussion of main issues. i.e. Two hours break out sessions followed with a 2 hour plenary discussion)**

**Breakout 1**

**1. DSMB conflicts:**

Facilitator: Nancy Geller

Discussant: David DeMets

- Blinding of DSMB's
- "Joint" DSMB: DSMB covering general trials in closely related areas
- Dissent within DSMB

**Breakout 2**

**DSMB communication:**

Facilitator: Jeffrey Borer

Discussant: Bertram Pitt

- Communication of DSMBs with IRBs
- communication between DSMB and PI /sponsor
- Informing participants during the trial

**Breakout 3**

**DSMB responsibilities:**

Facilitator: Janet Wittes

Discussants: David Gordon

- DSMB-legal implications if liability.
- What is DSMB's responsibility for publication?

**Breakout 4**

**Stopping a trial:**

Facilitator: Desmond Julian

Discussants: Stuart Pocock, Yale Mitchel

- How to stop a trial? Procedures by sponsor & DSMB after stopping is recommended (including case studies)
- Stopping for futility, All long term trials should include a futility guideline?

**15:30– 15:50 Café Break**

**9. 15:50 - 17:50**

**DSMB issues. Reporting of breakouts and panel discussion**

**16:20 – 16:50 DSMB conflicts:** Nancy Geller

**16:50 – 17:20 DSMB communication:** Jeffrey Borer

**17:20 – 17:50 DSMB responsibilities:** Janet Wittes

**17:50 – 18:20 Stopping a trial:** Stuart Pocock

**18:10: Opera and dinner**

