

10th Cardiovascular Clinical Trialists Workshop

December 6-7, 2007

Westin
Paris, France



Chairmen

Faiez ZANNAD, Nancy
Desmond JULIAN, London
Bertram PITT, Ann Arbor
David GORDON, Bethesda
Raymond LIPICKY, Gaithersburg



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



EUROPEAN
SOCIETY OF
CARDIOLOGY

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



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



**10th CardioVascular Clinical
Trialists Workshop**

Paris, December 6th, 2007

Board of Chairmen :

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

Dear All,

We are most delighted to welcome you in Paris.

We hope that you have had a safe trip. This is the 10th time that the Workshop on cardiovascular clinical trials is organised. There will be several participants familiar with the workshop and many new faces.

Thanks to your personal input and feedback from participants to the previous workshops we believe we have achieved an exciting program. We hope that you will enjoy the interactive format of the workshop, the variety of respective background of each participant, the science and also, hopefully, the camaraderie to which we all look very much forward. Should you need any assistance or have any query, please contact my assistant Stéphanie GROJEAN. She will attend the whole workshop.

We wish you a very successful meeting and a pleasant stay in Paris.

With our best regards,

Pr Faiez Zannad

and Co-Chairmen :

Pr Desmond JULIAN
Pr Bertram PITT
Pr David GORDON
Pr Ray LIPICKY



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



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Institutes of Health (NIH)

General Information

VENUE OF THE CONGRESS

The Westin
3, rue de Castiglione - 75001 Paris
Ph: +33 (0)1 44 77 11 11
Fax: +33 (0)1 44 77 14 60

MEETING ROOM

Napoleon Room

ON SITE CONTACTS

Anne-Sophie Montariol: +33 (0)6 76 87 56 61
Martha Linhares: +33 (0)6 89 90 51 68

TECHNICAL INFORMATION

To facilitate the progress of the meeting, we would be very grateful if you could give your presentation to the hostess at the welcome desk or to the technician in the Napoleon room.

DINNERS

December 5th, 2007:
Dinner at the Westin Hotel
3, rue de Castiglione - 75001 Paris
Restaurant “Le First”
Meeting in the restaurant at 08:00 pm

December 6th, 2007:
Dinner in Paris - Musée des Arts Décoratifs
Visit of the museum (on demand)
Restaurant “Le Saut du Loup”
(departure by foot)
Meeting in the lobby at 07:15 pm

December 7th, 2007:
Opéra Bastille - Ballet Casse-Noisette
Meeting in the lobby at 06.10 pm for Opera at 7:30 pm
Dinner will take place at the restaurant
“Les Grandes Marches” after the Opera

Scientific Program

Thursday, December 6th, 2007

8:00 INTRODUCTION: Faiez ZANNAD

8:30 - 10:30 CHAIRMAN: Faiez ZANNAD

Event driven trials vs. adaptive trials

Speaker: Stuart POCOCK

Discussants: Michael DOMANSKI, Janet WITTES, Abraham KARKOWSKY

10:30 - 10:50 COFFEE BREAK

10:50 - 11:40 CHAIRMAN: Desmond JULIAN

Are patients better off inside than outside randomised clinical trials?

Speaker: Jacobus LUBSEN

Discussant: David DEMETS

11:40 - 13:00 CHAIRMAN: Gabriel STEG

Maximizing scientific knowledge generation from industry trial databases. Accessing trial databases and biobanks

Speaker: Marc PFEFFER

Discussants: Hubert POULEUR, Janet WITTES, Névine ZARIFFA

13:00 - 14:00 LUNCH

14:00 - 15:30 CHAIRMAN: David GORDON

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

Speaker: Faiez ZANNAD

Discussants: Jacobus LUBSEN, Susan SHURIN

15:30 - 15:50 COFFEE BREAK

15:50 - 17:50 CHAIRMAN: Bertram PITT

External validity of randomised clinical trials Pragmatic trials of intervention strategies

Speaker: Gabriel STEG

Discussants: David GORDON, Stuart POCOCK

20:00 DINNER IN RESTAURANT "LE SAUTDU LOUP"

Friday, December 7th, 2007

9:00 - 11:00 CHAIRMAN: Jeffrey BORER

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

Speaker: James REVKIN
Discussants: Corine BERNAUD, Michael DOMANSKI

11:00 - 11:20 COFFEE BREAK

11:20 - 12:30 CHAIRMAN: TBD

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

Speaker: Bertram PITT
Discussants: Hubert POULEUR, Bernard HAMELIN, Yale MITCHEL

12:30 - 13:30 LUNCH

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

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

Discussant: 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 COFFEE BREAK

15:50 - 17:50

DSMB issues
Reporting of breakouts and panel discussion

DSMB conflicts: Nancy GELLER
DSMB communication: Jeffrey BORER
DSMB responsibilities: Janet WITTES
Stopping a trial: Stuart POCOCK

18:10 OPERABASTILLE - BALLETCASSE-NOISETTE

20:00 DINNER IN RESTAURANT "LES GRANDES MARCHES"
