

# 14<sup>th</sup> CardioVascular Clinical Trialists Workshop

December 4 - 5, 2011



*Marshall Center in Hotel Talleyrand*  
Paris

## Chairmen

David GORDON, Bethesda - USA  
Desmond JULIAN, London - GBR  
Christopher O'CONNOR, Durham - USA  
Bertram PITT, Ann Arbor - USA  
Faiez ZANNAD, Nancy - France



**Inserm**  
Institut National de la Santé et de la Recherche Médicale

**Nancy-Université**  
Université Henri Poincaré



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



**National Heart  
Lung and Blood Institute**

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



**Duke Heart Center**  
DUKE UNIVERSITY HEALTH SYSTEM



**EUROPEAN  
SOCIETY OF  
CARDIOLOGY®**

Organised in collaboration with  
A meeting of the European Society of Cardiology  
Working Group of Pharmacology  
and Drug Therapy

Paris, December 4<sup>th</sup>, 2011

**BOARD OF CHAIRMEN**

David GORDON, Bethesda - USA  
Desmond JULIAN, London - GBR  
Christopher O'CONNOR, Durham - USA  
Bertram PITT, Ann Arbor - USA  
Faiez ZANNAD, Nancy - FRA

Dear All,

We are most delighted to welcome you in Paris.

We hope that you have had a safe trip. This is the 14<sup>th</sup> 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 Bertram Pitt  
Pr Christopher O'Connor



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



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



Organised in collaboration with  
A meeting of the European Society  
of Cardiology Working Group  
of Pharmacology and Drug Therapy

## VENUE OF THE CONGRESS

George C. Marshall Center  
In the Hotel Talleyrand  
2, rue Saint-Florentin  
75001 Paris

---

## MEETING ROOM

**“Grand Dining Room” – 1st Floor**

---

## ON SITE CONTACTS

For logistics queries :  
Aurélie Fontenelle: +33 (0) 6 12 78 15 02  
A-Clémence Stadler: +33 (0) 6 77 60 08 55

Scientific Committee:  
Stéphanie Grojean: +33 (0) 6 13 46 77 73

---

## SPEAKERS INFORMATION

To facilitate the progress of the meeting, we would be very grateful if you could give your presentation to the technician in the **“Rothschild Dining Room”**

---

## DINNERS

### **Saturday 3 December 2011**

**19:30** Meet in the lobby Concorde Opéra  
**Dinner** at Brasserie Mollard, located just in front of the hotel, 115 rue Saint-Lazare 75009 Paris

### **Sunday 4 December 2011**

**17:30** Meet in the **“Grand Reception Room”** for an Aperitif and informal presentation on the exhibition with our guides

**19:00** Private transfer by coach to the Grand Palais, Galeries Nationales

**19:15-20:30** Visit of the exhibition **"Matisse, Cézanne, Picasso... The Stein Family: A fabulous history of a family of collectors with one of the most beautiful collections of modern art of the 20th century."**

**20:45** **Aperitif and Dinner** at The Berkeley  
7 avenue Matignon, 75008 Paris

## SUNDAY 4 DECEMBER 2011

---

|                    |   |
|--------------------|---|
| <b>8:20-8:30</b>   | <b>Welcome and Introduction: Faiez Zannad (Nancy, FRA)</b>  |
| <b>8:30-10:00</b>  | Chairperson: Faiez Zannad (Nancy, FRA)<br><input type="checkbox"/> <b>Session 1 - Regulatory approval vs. treatment guidelines and how each influences practice. Why does evidence assessment translate differently in labeling vs. guidelines?</b><br><br>Speaker: John Mc Murray (Glasgow, GBR)<br>Discussant: Jeffrey S. Borer (New York, USA)<br>Discussant: Gonzalo Calvo (Barcelona, ESP) |
| <b>10:00-10:20</b> | Break   |
| <b>10:20-11:30</b> | Chairperson: Jeffrey S. Borer (New York, USA)<br><input type="checkbox"/> <b>Session 2 - Why do regulatory agencies differ in their verdicts? Is alignment among agencies desirable?</b><br><br>Speaker: Angeles Alonso (Madrid, ESP)<br>Discussant: Norman Stockbridge (Rockville, USA)<br>Discussant: Mathieu Ghadanfar (Novartis,CHE)  |
| <b>11:30-13:00</b> | Chairperson: Nancy Geller (Bethesda, USA)<br><input type="checkbox"/> <b>Session 3 - Dose selection for phase III trials</b><br><br>Speaker: Janet Wittes (Washington, USA)<br>Discussant: Susan Shurin (Bethesda, USA)   |
| <b>13:00-14:00</b> | Lunch and visit at leisure of Hotel Talleyrand and Marshall Center  |
| <b>14:00-15:40</b> | Chairperson: Bertram Pitt (Ann Arbor, USA)<br><input type="checkbox"/> <b>Session 4 - Difference between device trials and drug trials. Are they inevitable and how to improve device trials?</b><br><br>Speaker: Roxana Mehran (New York, USA)<br>Discussant: Stuart Pocock (London, GBR)<br>Discussant: Ileana L. Pina (New York, USA)<br>Discussant: Joerg Koglin (Merck, USA)               |
| <b>15:40-16:00</b> | Break   |
| <b>16:00-17:30</b> | Chairperson: Mihai Gheorghide (Chicago, USA)<br><input type="checkbox"/> <b>Session 5 - Regional differences in CV disease and international differences in randomized clinical trials. Are they real? Should we care?</b><br><br>Speaker: Yves Rosenberg (Bethesda, USA)<br>Discussant: Christopher O'Connor (Durham, USA)<br>Discussant: Salim Yusuf (Hamilton, CAN)                          |

## MONDAY 5 DECEMBER 2011

9:00-10:40 Chairperson: Marc Pfeffer (Boston, USA)

---

**Session 6 - New designs and new paradigm for large simple trials**

Speaker: Michael S. Lauer (Bethesda, USA)  
Speaker: Salim Yusuf (Hamilton, CAN)  
Discussant: Michael Domanski (New York, USA)  
Discussant: Efthymios Deliargyris (The Medicines Company, GER)

10:40-11:00 Break

---

11:00-13:00 Chairperson: John Mc Murray (Glasgow, GBR)

---

**Session 7 - Safety scares arising from trial evidence. Can we handle them better?**

- **Issues with meta-analysis**  
Speaker: Stuart Pocock (London, GBR)  
Speaker: John Jarcho (Boston, USA)  
Discussant: David Gordon (Bethesda, USA)  
Discussant: Salim Yusuf (Hamilton, CAN)
- **The role of communication/media**  
Speaker: Marc Pfeffer (Boston, USA)  
Discussant: Alfonso Perez (Takeda, USA)  
Discussant: Alice Mascette (Bethesda, USA)

13:00-14:00 Lunch at Brasserie Les Flottes, 2 rue Cambon, 75001 Paris

---

14:00- 15:30 Chairperson: Roxana Mehran (New York, USA)

---

**Session 8 - Can we agree on definitions of endpoints in thrombosis clinical trials?**

- **Bleeding endpoints**  
Speaker: Roxana Mehran (New York, USA)  
Discussant: Micheal Ezekowitz (Wynnewood, USA)  
Discussant: Armin Koch (Hannover, GER)

15:30-15:50 Break

---

15:50-17:20 Chairperson: Christopher O'Connor (Durham, USA)

---

**Session 9 - Can we agree on definitions of endpoints in thrombosis clinical trials?**

**Endpoints in atrial fibrillation prevention/treatment trials**

Speaker: Lars Wallentin (Uppsala, SWE)  
Discussant: Hubert Pouleur (Pfizer, USA)  
Discussant: Eric Abadie (Paris, FRA)

## Faculty

---

### Academy

Borer Jeffrey S; (New York, USA)  
Domanski Michael (New York, USA)  
Ezekowitz Micheal (Wynnewood, USA)  
Fiuzat Mona (Durham, USA)  
Gheorghide Mihai (Chicago, USA)  
Jarcho John (Boston, USA)  
Julian Desmond (London, GBR)  
Mc Murray John (Glasgow, GBR)  
Mebazaa Alexandre (Paris, FRA)  
Mehran Roxana (New York, USA)  
O'Connor Chris (Durham, USA)  
Pfeffer Marc (Boston, USA)  
Pina Ileana L. (New York, USA)  
Pitt Bertram (Ann Arbor, USA)  
Pocock Stuart (London, GBR)  
Rossignol Patrick (Nancy, FRA)  
Verheugt Freek W.A (Amsterdam, NDL)  
Wallentin Lars (Uppsala, SWE)  
Wittes Janet (Washington, USA)  
Yusuf Salim (Hamilton, CAN)  
Zannad Faiez (Nancy, FRA)

### Industry

Berkowitz Scott (Bayer, USA)  
Bernaud Corine (AstraZeneca, BEL)  
Deliargyris Efthymios (The Medicines Company, GER)  
Friedman Jeffrey (Boehringer, GER)  
Ghadanfar Mathieu (Novartis, SWI)  
Koglin Joerg (Merck, USA)  
Kupfer Stuart (Takeda, USA)  
Lerebours Guy (Servier, FRA)  
Perez Alfonso (Takeda, USA)  
Pouleur Hubert (Pfizer, USA)  
Zalewski Andrew (Novartis, USA)  
Zariffa Nevine (AstraZeneca, USA)

### Regulatory (EMEA – FDA)

Abadie Eric (Paris, FRA)  
Alonso Angeles (Madrid, ESP)  
Calvo Gonzalo (Barcelona, ESP)  
Koch Armin (Hannover; GER)  
Parks Mary (Rockville, USA)  
Stockbridge Norman (Rockville, USA)  
Unger Ellis (Rockville, USA)

### NHLBI

Geller Nancy (Bethesda, USA)  
Gordon David (Bethesda, USA)  
Lauer Michael S (Bethesda, USA)  
Mascette Alice (Bethesda, USA)  
Rosenberg Yves (Bethesda, USA)  
Shurin Susan (Bethesda, USA)