12th CardioVascular Clinical Trialists (CVCT) WORKSHOP
Luxembourg, December 6th and 7th, 2009

SCIENTIFIC PROGRAMME

DAY ONE - Sunday December 6th, 2009

8.00 Welcome and Introduction : Faiez Zannad

8.20 - 12.50
Topic 1
Development of new agents for the treatment of heart failure.
Chairmen: Robert Temple, Faiez Zannad

8.20 - 9.30 Unmet needs in heart failure

Speaker: Mihai Gheorghiade
Discussant: Faiez Zannad

9.30 - 10.20 Are trials with "add on therapy design" the only way to go?
Speaker: Bruno Flamion
Discussant: Robert Cody

10.20 - 10.40 Coffee Break

10.40 - 11.40 The use of biomarkers in heart failure trials (for patient selection and/or surrogates)
Speaker: Norman Stockbridge,
Discussant 1 : Robert Morrow,
Discussant 2 : Nancy Geller

11.40 - 13.00 Endpoint related issues: Unconventional and patient related outcomes vs survival.
Speaker: Bertram Pitt
Discussant 1: Armin Koch,
Discussant 2: Stuart Pocock

13.00 – 14.00 Lunch

14.00 – 18.30
Topic 2:
Risk-benefit decisions for anti-thrombotic therapies: Clinical and Regulatory challenges.
Chairmen: Marteen Simoons, Norman Stockbridge

14.00 – 15.00 Selecting the appropriate study design: Positive control vs. non inferiority comparative trials. Which way to go?
Speaker: Robert Temple
Discussant: Stuart Pocock

15.00 – 16.10 Risk benefit issues in progressing to Phase III. .Do surrogates and/or adaptive design help?
Speaker: Norman Stockbridge
Discussant 1: Sidney Goldstein
Discussant 2: Hubert Pouleur

16.10 – 16.30 Tea Time

16.30 – 17.30 Bleeding outcomes: Definition and adjudication issues.
Speaker: Marteen Simoons
Discussant : Armin Koch

17.30 – 18.30 Combining efficacy and safety in Composite endpoints.
Speaker: Lennart Forslund
Discussant : Janet Wittes

20.00 Off Site Dinner

DAY TWO - Monday December 7th, 2009

8.30 – 11.50 Topic 3:
Need for outcome studies in the development of anti-diabetic medicinal products.
Chairman: Jeffrey Borer

8.30 – 9.30 Cardiovascular efficacy outcomes in diabetes trials
Speaker: Christian Torp Pedersen
Discussant : Hans-Juergen.Woerle

9.30 – 10.30 Cardiovascular safety outcomes in diabetes trials.
Speaker: Stuart Pocock,
Discussant : Janet Wittes

10.30 – 10.50 Coffee break

10.50 – 11.50 Macro and Microvascular endpoint definition
Speaker: Gilles Dagenais
Discussant : Guy Lerebours

12.00 – 13.00
Topic 4: Current limitations of registration data package
Chairman: Pieter de Graeff

Speaker: Gonzalo Calvo
Discussant: Robert Temple

13.00 – 14.00 Lunch

14.00 - 15.00 Topic 6: Comparative effectiveness. Pragmatic trials of alternative intervention strategies. (eg. SYNTAX, RITA 3, COURAGE…)
Chairman: Stuart Pocock

Speaker: Michael Lauer
Discussant : Jeffrey Borer

15.00 – 17.10
Topic 7: Alternatives to Randomized Clinical Trials ?
Chairman : Bertram Pitt

15.00 – 15.40 Registries vs. trials
Speaker: Aldo Maggioni
Discussant: Stuart Pocock

15.40 – 16.00 Tea Time

16.00 – 16.40 Bias vs. Real world representation
Speaker: Christian Torp Pedersen
Discussant: James Hung

16.40 Wrap up and adjourn: Faiez Zannad