

Cardiovascular Clinical Trialists Workshop

Previous programs from 1999 to 2006



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



Organised in collaboration with American College of Cardiology Foundation



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

CVCT objective

- Producing relevant data from controlled clinical trials that will contribute to better clinical care and to understanding the problems associated with making decisions about what is relevant information, how to do better clinical trials, and, as is commonly the case, how to satisfy regulatory authorities in the end.
- Which hopefully will eventually culminate in an international exchange of ideas – and perhaps innovative thought leadership (not creation of guidelines nor rule making).

CVCT Historical background

- has met yearly since 1998
- organized by the INSERM Clinical Investigation Center, Faculty of Medicine, University Henri Poincaré, Nancy, France
- The 2007 meeting will be the 10th meeting of the group.
- The organization has become shared with
 - the ESC Working Group on Cardiovascular Pharmacology and Drug Therapy,
 - the American College of Cardiology Foundation
 - the Heart, Lung, and Blood Institute of the National Institutes of Health.
- It has been funded by an unrestricted grant from Pfizer.

CVCT participants

- Clinical trial experts principally engaged in cardiovascular clinical trials (hence it's name).
- From various primary job functions in
 - academia
 - the NIH
 - the pharmaceutical industry
 - pharmaceutical regulatory bodies (EMA, FDA)
 - Major journals editors.

CVCT distinct features

- The CVCT meetings are “grass roots” meetings
- Attended by individuals who are eager to communicate with one another
- Attended by people that create and analyze major trials
- Participants are among the group of major international thought leaders
- The CVCT meetings are not like ICH, PMA nor DIA meetings
- CVCT meetings are primarily oriented toward discussion among persons as opposed to lecturing to a broad audience.
- Thought process counts, communication (during the meeting, but more importantly informal discussions outside of the meeting) is the important agenda, as opposed to dictating doctrine
- Personal attendance of each participant is required throughout the full 2 days meeting.

CVCT Format

- The workshop involves a limited number of participants (30-40)
- The CVCT meetings themselves will always remain small, small size is essential to an exchange of ideas and formulating thoughts.
- One speaker covers a topic (a short 10 minutes presentation in order to raise specific issues and set the stage for discussion).
- After each presentation, one or two discussants will complement the speaker's presentation with personal views and additional issues, during a very short 5 minutes presentation.
- Thereafter, and for each topic, a general panel discussion may last for up to 90 minutes, depending on the importance of the topic.
- All presentations and discussions are to be tape-recorded.
- A professional medical writer attends the Workshop and has the task of extracting from the presented material and tape records, manuscripts to be validated by participants.
- Manuscripts are submitted for publication in a major medical journal.



CVCT Workshop December 1st, 2nd 1999
- Monte Carlo -

Chairmen : Bertram Pitt (Ann Arbor), Faiez Zannad (FR)



Program 1999

- ❖ Can we standardize and make simpler the statistics applied to clinical trials?
Speaker : Jacobus LUBSEN (CH)
Discussant : Alain LEIZOROVICZ (FR)
- ❖ In what conditions and how should one adjust sample size during the conduct of a trial ?
Speaker : Janet WITTES (USA)
- ❖ How should results of meta-analyses, subgroup analysis, case-control studies, influence drug approval? How many studies we need in an area?
Speaker : Marc PFEFFER (USA)
Discussants : DAHLÖF Björn (SE), Roberto FERRARI (IT)
- ❖ How should we plan and interpret equivalence trials?
Speaker : Alain LEIZOROVICZ (FR)
- ❖ How negative does a trend have to be before one should recommend discontinuation of a trial?
Speaker : Stuart POCOCK (UK)
Discussant : Bertram PITT (USA)
- ❖ Upon what principles should we generalize from clinical trials to clinical practice?
Speaker : Desmond JULIAN (UK)
Discussant : Eric ABADIE (FR) , Lars WILHELMSEN (SE)



CVCT Workshop December 3rd 2000 - Cannes -

*Chairmen : Desmond JULIAN (UK), Raymond Lipicky
(Rockville), Bertram Pitt (Ann Arbor), Faiez Zannad (FR)*

Faculty

ABADIE Eric
BOISSEL Jea-Pierre
CHIERCHIA Sergio
COHN Jay
EZEKOWITZ Michel
GEORGHIADE Mihai
JULIAN Desmond
JULIUS Stevo
KIRWAN Bridgette-Anne

KOBER Lars
KOMAJDA Michel
KRUM Henri
LIPICKY Raymond
LUBSEN Jacobus
LUSCHER Thomas
PITT Bertram
POCOCK Stuart
RUTISHAUSER Wilhelm

SACKNER BERNSTEIN John
SWEDBERG Karl
TORP-PEDERSEN Christian
WAEBER Bernard
WEBER Karl
WEBER Michael
WILHELMSSEN Lars
WILLIAMS Gordon
ZANNAD Faiez



Program 2000

- ❖ Equivalence or non inferiority trials?
Speaker : Stuart POCOCK (UK)
- ❖ The use of the Internet in trials.
Speaker : John SACKNER-BERNSTEIN (USA)
Discussant : Desmond JULIAN (UK)
- ❖ Under what circumstances should the code be broken for regulatory agencies?
Speaker : Eric ABADIE (FR)
- ❖ When enough is enough? (How many trials are needed to establish evidence?)
Speaker : Marc PFEFFER (USA)
Discussants : Jean Pierre BOISSEL (FR),
Raymond LIPICKY (USA)
- ❖ What are the advantages and disadvantages of combining endpoints? E.g. death, myocardial infarction or hospitalization. All cause or cause specific hospitalization.
Speaker : Jacobus LUBSEN (CH)
Discussant : Henry Krum (AU)
- ❖ How should side effects be monitored in trials? Continuous? Open for the DSMB or Chair.
Speaker : M EZEKOWITZ (USA)
Discussant : Lars WILHELMSSEN (SE)
- ❖ Informed consent : for the patient, ethics committee or the lawyer? How to harmonize European and US views.
Speaker : Karl Swedberg (SE)
- ❖ Can large trials be misleading? Sampling problems in trials.
Speaker : Servio JULIUS (USA)
Discussant : Christian TORP-PEDERSEN (DE)



**CVCT Workshop December 5th, 6th 2001
- Monte Carlo -**



Program 2001

- ❖ Should there be consecutive screening of all potential patients for trials, with the keeping of a log? Use of the registries as part of megatrials.
Speaker : John HAMPTON (UK)
Discussants : ALDERSHVILE Jan (DE), Harvey WHITE (NZ)
- ❖ How should be handled drop-outs, permanent drug discontinuation, and lost to follow up patients.
Speaker : Alain LEIZOROVICZ (FR)
Discussant : Jacobus LUBSEN (SW)
- ❖ Surrogate endpoints and their inclusion into combined endpoints.
Speaker : Mihai GHEORGHIADÉ (USA)
Discussants : Raymond LIPICKY (USA), Eric ABADIE (FR)
- ❖ Good and bad ways of presenting survival (or time to event) data in life table plots. How can we improve tables and figures in trial reports.
Speaker : Stuart POCOCK (UK)
Discussant : François GUEYFFIER (FR)
- ❖ How can drug interactions be studied in trials? Can be addressed by factorial design?
Speaker : Jean Pierre BOISSEL (FR)
Discussant : Stuart POCOCK (UK)
- ❖ Role of sponsor in data management, steering committee, DSMB, stopping trials, publication.
Speaker : Desmond JULIAN (UK)
Discussants : Hubert POULEUR (USA), Jim NEATON (USA)
- ❖ Changes in vascular function and structure as an endpoint in atherosclerosis trials. Intermediate for Phase II trials? Surrogate? Acceptable for drug approval?
Speaker : Pierre Jean TOUBOUL (FR)
Discussants : Eric ABADIE (FR), Raymond LIPICKY (USA)



CVCT Workshop December 4th, 5th 2002 - Monte Carlo -

Chairmen : Desmond JULIAN (UK), Raymond Lipicky (Rockville), Bertram Pitt (Ann Arbor), Faiez Zannad (FR)

Panelists

ABADIE Eric
ADAMS Kirkwood
ALDERSHVILE Jan
AMARENCO Pierre
ATAR Dan
BENETOS Athanase
BERNAUD Corine
BORER Jeffrey
BRUCKERT Eric
COLLIER Timothy
DARNE Bernadette
DICKSTEIN Kenneth
FURBERG Kurt B.
GAUDIN Christophe
GHADANFAR Mathieu

GHEORGHIADE Mihai
GIRAL Philippe
GOEHRS Jean-Marie
HAMPTON John Reynold
HODEN Stéphane
JULIAN Desmond
KJEKSHUS John
LECHAT Philippe
LEIZOROVICZ Alain
LIPICKY Raymond
LUBSEN Jacobus
LYFORD Joanna
MAGGIONI Aldo Pietro
MISSOUN Naimi
MITCHEL Yale

NGUYEN Tu
NIEMINEM Markku
NOUGIER Esther
PEDERSEN Terje R.
PERELMAN Michael
PITT Bertram
POCOCK Stuart
POULEUR Hubert
RONIKER Barbara
SHAH Rashmi
STEG Gabriel
STRUTHERS Allan D.
SWEDBERG Karl
WHITE Harvey
ZANNAD Faiez



Program 2002 (1)

- ❖ Techniques to identify responsive subgroups in large clinical trials
Speaker : *Mihai GHEORGHIADÉ (USA)*
Discussants : *Kirkwood ADAMS (USA), Jacobus LUBSEN (SW)*
- ❖ Pharmacogenomics in clinical cardiovascular trials.
Speaker : *Rashmi SHAH (UK)*
Discussants : *Eric ABADIE (FR), Kirkwood ADAMS (USA)*
- ❖ Trials for differentiating drugs within the same class (i.e. statin A vs statin B). Equivalence? Non inferiority? Not useful?
Speaker : *Jacobus LUBSEN (CH)*
Discussants : *Philippe LECHAT (FR), Terje PEDERSEN (NO)*
- ❖ Are there improved methods for presenting treatment effects as a function of baseline covariates. What is the value (if any) of covariate adjustment?
Speaker : *Curt FURBERG (USA)*
Discussants : *Stuart POCOCK (UK), Alain LEIZOROVICZ (FR)*
- ❖ FDA and CPMP rulings on subgroup analysis.
Speaker : *Aldo MAGGIONI (IT)*
Discussants: *Eric ABADIE (FR), Raymond LIPICKY (USA)*
- ❖ Validation process of a "surrogate" outcome.
Speaker : *Alan STRUTHERS (UK)*
Discussants : *Curt FURBERG (USA), Michael PERELMAN (USA)*
- ❖ Is it possible, advisable, to terminate negative trials even earlier ? The triangular test vs. Usual stopping rules.
Speaker : *Philippe LECHAT (FR)*
- ❖ Who should be informed and how, when a trial is stopped prematurely for harm/benefit/futility ?
Who should be informed and how, when a trial is stopped prematurely for harm/benefit/futility ?
Speaker : *Desmond JULIAN (UK)*
Discussants : *Stuart POCOCK (UK)*



Program 2002 (2)

- ❖ What can be done for better implementation of the results of clinical trials ?
Speaker : Mihai GHEORGHIADÉ (USA)
Discussants : Jan Aldershvile (DE), Aldo MAGGIONI (FR)
- ❖ Relevance and design of trials of drugs combining an antihypertensive agent and a lipid lowering agent (dual therapy). Which endpoint (BP, lipids, CV global risk, CV events, or else ?) Which target population ? Dose finding issues.
Speaker : Hubert POULEUR (USA)
Discussants : Raymond LIPICKY (USA), Faiez ZANNAD (FR)
- ❖ Relevance and design of trials of treatments combining two lipid lowering agents (i.e. Drug X + a statin) Which population needs more than a statin's lipid profile a relevant endpoint Alternative and additive endpoints.
Speaker : Terje PEDERSEN (NO)
Discussants : Dan ATAR (NO), Philippe GIRAL (FR)



CVCT Workshop December 4th, 5th 2003 - Versailles -

*Chairmen : Desmond JULIAN (UK), Raymond Lipicky (Rockville),
Eric ABADIE (Paris), Bertram Pitt (Ann Arbor), Faiez Zannad (FR)*

Panelists

Eric ABADIE
Kamran ABBASI
Jean -Pierre BASSAND
René BELDER
Corine BERNAUD
Bertram PITT
Jeffrey S. BORER
Marina CHAUVENET
Björn DAHLÖF
Susan ELLENBERG
Kim FOX
Lawrence FRIEDMAN

Mathieu GHADANFAR
Philip HARRISON
Desmond JULIAN
John KJEKSHUS
Sverre KJELDSEN
Ray LIPICKY
Jacobus LUBSEN
Aldo Pietro MAGGIONI
Harvey MARCOVITCH
Steven NISSEN
Suzanne OPARIL
Michael PERELMAN

Stuart POCOCK
Hubert POULEUR
Marteen L. SIMOONS
Peter SLEIGHT
Gabriel STEG
Kristian THYGESEN
John WARREN
W. Douglas WEAVER
Hans WEDEL
Janet WITTES
Faiez ZANNAD



Program 2003 (1)

- ❖ EU directive on clinical trials.

Speaker : Philip HARRISON (UK)

Discussants : John WARREN (UK), Marina CHAUVENET (FR)

- ❖ Issues with co-primary endpoints.

Speaker : Stuart POCOCK (UK)

- ❖ Combined endpoints : are they misleading?

Speaker : Bertram PITT (USA)

Discussants : Björn DAHLÖF (SE), Stuart POCOCK (UK)

- ❖ Choice of regimen when comparing two active drugs (with special reference to COMET, statin trials, ...)

Speaker : Jeffrey S. BORER (USA)

Discussants : Raymond LIPICKY (USA), John KJESHUS (NO)

- ❖ Registerability of multiple action fixed combination medication.

Speaker : John WARREN (UK)

Discussants : Philip HARRISON (UK), Eric ABADIE (FR)

- ❖ Publication policies : who has the final say as to what is published (or not) when data becomes available ?

Speaker : Maarten L. SIMOONS (NED)

Discussants : Jeffrey BORER (USA), Harvey MARCOVITCH (UK)



Program 2003 (2)

- ❖ Effect of lipid lowering agents : is it entirely dependent upon lipid lowering effect or are there “pleiotropic” actions with specific agents?
Speaker : Peter SLEIGHT (UK)
Discussants : Michael PERELMAN (USA), Hubert POULEUR (USA)
- ❖ How should we handle a) errors in the randomisation process and b) fraud during the conduct of a trial ?
Speaker : Hans WEDEL (SE)
Discussant : Lawrence FRIEDMAN (USA)
- ❖ Detailed case studies of subgroup analysis in specific trials. Subgroup analyses that influenced drug approval and/or clinical practice.
Speaker : Maarten L. SIMOONS (NED)
Discussant : Jeffrey BORER (USA)
- ❖ Effect of antihypertensive drugs : is it entirely dependent upon BP-lowering effect or are there “non-barometric” added value of specific agents?
Speaker : Sverre KJELDSEN (NO)
Discussants : Suzanne OPARIL (USA)
- ❖ Need for a consensus about a single set of events definitions for event adjudication committees.
Speaker : Kristian THYGESEN (DK)
Discussant : Desmond JULIAN (UK)
- ❖ How to improve the implementation of the results of major trials?
Speaker : Faiez ZANNAD (FR)
Discussant : Lawrence FRIEDMAN (USA), Bertram PITT (USA)



CVCT Workshop December 2nd, 3rd 2004 - Versailles -

Chairmen : Desmond JULIAN (UK), Raymond Lipicky (Rockville), Eric ABADIE (Paris), Lawrence FRIEDMAN (USA), Bertram Pitt (Ann Arbor), Faiez Zannad (FR)

Panelists

**ABADIE Eric
BERNAUD Corine
BORER Jeffrey S.
CASTAIGNE Alain
CLOAREC-BLANCHARD Laure
COLLINS Rory
CUTLER Jeffrey
DAGENAIS Gilles
DAHLÖF Björn
DANCHIN Nicolas
FISHER Lloyd
FRIEDMAN Lawrence
GELLER Nancy
GHADANFAR Mathieu
GRINES Cindy**

**HAFFNER Steven
JAMIESON Virginia
JULIAN Desmond
KJELDSSEN Sverre E.
KONSTAM Marvin A
KUPFER Stuart
LIEVRE Michel
LIPICKY Raymond
LUEPKER Russel V
MAILLERE Patricia
NATHWANI Ameet
O'CONNOR Christopher
PITT Bertram
POCOCK Stuart
POOLE WILSON Philip**

**POULEUR Hubert
PRESSLER Milton
RONIKER Barbara
RUILOPE Luis
SENATORE Fortunato
SERRUYS Patrick
SLEIGHT Peter
STEG Philippe Gabriel
STOCKBRIDGE Norman
THYGESEN Kristian
THROCKMORTON Douglas
WEDEL Hans
WITTES Janet
ZANNAD Faiez
ZUCKERMAN Bram**



Program 2004

- ❖ New onset diabetes mellitus as a cardiovascular endpoint

Speaker: Björn DAHLÖF (SWE)

Discussants : Eric ABADIE (FR), Stuart KUPFER (USA)

- ❖ Guidelines on trials in metabolic syndromes. Are any surrogates acceptable?

Speaker: Steven HAFFNER (USA)

Discussant: Luis RUILOPE (ESP)

- ❖ Registerability of multiple action fixed combination medication

Speaker: Peter SLEIGHT (UK)

Discussants : Ray LIPICKY (USA) , Hubert POULEUR (USA)

Via teleconference: Norman STOCKBRIDGE (USA)

- ❖ Subsequent uses of major trial databases: eg prognostic models, individual patient data meta-analyses

Speaker: Stuart POCOCK (UK)

Discussant: Gabriel STEG (FR)

Via teleconference: Norman STOCKBRIDGE (USA)

- ❖ Adverse event definition and reporting

Speaker: Larry FRIEDMAN (USA)

Discussant: Janet WITTES (USA)

- ❖ Need for a consensus about Acute Coronary Syndromes and Heart Failure definitions for event adjudication committees

Speaker: Kristian THYGESEN

Discussant 1: Aldo MAGGIONI (IT)

Discussant 2: Russel LUEPKER (USA)

- ❖ Randomization methods, minimization, stratification: Advantages and limitations

Speaker: Rory COLLINS (UK)

Discussant 1: Lloyd FISHER (USA), Stuart POCOCK (UK)

- ❖ Combination of surrogates and biomarkers vs outcome trials

Speaker: Bertram PITT (USA)

Discussant 1: Patrick SERRUYS (NED)

Discussant 2: Fortunato SENATORE

Via teleconference: Doug THROCKMORTON (USA)

- ❖ Positive control trials and what are they for?

Speaker: Lloyd FISHER (USA)

Discussants: Alain CASTAIGNE (FR), Sverre

KJELDTSEN (NOR)



CVCT Workshop December 1st-2nd, 2005 - Versailles -

*Chairmen : Desmond JULIAN (UK), Raymond Lipicky (Rockville), Eric
ABADIE (Paris), David GORDON (USA), Bertram Pitt (Ann Arbor), Faiez
Zannad (FR)*

Panelists

**ABADIE Eric
ADAMS Kirkwood
BERNAUD Corine
BORER Jeffrey
CLELAND John
COLLINS Rory
DANCHIN Nicolas
DE METS David
FOLLATH Ferenc
GATTIS Wendy
GELLER Nancy
GHADANFAR Mathieu**

**GORDON David
HELD Peter
HUNG James
JULIAN Desmond
KIRWAN Bridget-Anne
LEIZOROVICZ Alain
LEWIS Richard
LIPICKY Ray
MASCETTE Alice
PFEFFER Marc
PITT Bertram
POCOCK Stuart**

**POOLE-WILSON Philip
POULEUR Hubert
ROLAND Edmond
SIMONS-MORTON Denise
SOLOMON Scott
STOCKBRIDGE Norman
TORP PEDERSEN Christian
WITTES Janet
ZANNAD Faiez**



Program 2005

- ❖ Assessment of CV safety of drugs not intended for CV use. What needs to be done?
Speaker: Jeffrey BORER (USA)
Discussants : Eric ABADIE (FR), Hubert POULEUR (USA)
- ❖ Heart failure events in heart failure and non-heart failure trials
peaker: Faiez ZANNAD (FR)
Discussant: Bertram PITT (USA), Ferenc FOLLATH (SWI)
- ❖ Stopping trials for futility
Speaker: David De METS (USA)
Discussants : Denise SIMONS-MORTON (USA) , Janet WITTES (USA)
- ❖ Changing endpoints during the trial.
Speaker: Janet WITTES (USA)
Discussant: David GORDON (USA), David De METS (USA)
Via teleconference: Norman STOCKBRIDGE and James HUNG (USA)
- ❖ Co-variate analysis, why and how to do it?
Speaker: Nancy GELLER (USA)
Discussant: David De METS (USA), Stuart POCOOCK (UK)
Via teleconference: Norman STOCKBRIDGE and James HUNG (USA)
- ❖ What does a positive trial in 45000 Chinese mean to a Western clinician?
Speaker: Sidney GOLDSTEIN (USA)
Discussant 1: Denise SIMONS-MORTON (USA), Rory COLLINS (UK)
- ❖ Biological and cell therapy trials. How different from drug trials?
Speaker: Richard LEWIS (USA)
Discussant 1: David GORDON (USA)
- ❖ Need for mechanistic sub studies, Public (NIH)-Industry interaction; Under funding of clinical trials.
Speaker: Marc PFEFFER (USA)
Discussant 1: Bertram PITT (USA), Alice MASCETTE (USA)
- ❖ Improving patient recruitment in US/western Europe
Speaker: Christien TORP PEDERSEN (DN)
Discussants: Sidney GOLDSTEIN (USA), Faiez ZANNAD (FR)



CVCT Workshop December 7-8, 2006 - Paris -

Chairmen : Desmond JULIAN (UK), Raymond LIPICKY (USA), Eric ABADIE (FR), David GORDON (USA), Bertram PITT (USA), Faiez ZANNAD (FR)

Panelists

ABADIE Eric
ADAMOPOULOS Chris
ADAMS Kirkwood
AHMED Ali
ALLA François
ALTMAN Douglas
BERNAUD Corine
BORER Jeffrey
CLELAND John
COHN Jay
DESAI Mehul
EVANS Stephen
FAY Renaud
GATTIS STOUGH Wendy
GELLER Nancy

GHADANFAR Mathieu
GORDON David
GUEZ David
HUNG James
HUELLE Etienne
JULIAN Desmond
LEMAIRE François
LIPICKY Ray
LONGROIS Dan
LUBSEN Koos
MADSEN Steinmar
MAILLERE Patricia
MOUNDEJI-BOUDIAF Lamia
PERELMAN Michael
PITT Bertram

PITT Bertram
POCOCK Stuart
POULEUR Hubert
ROLAND Edmond
ROSSIGNOL Patrick
SACKETT David
SHURIN Susan
SLEIGHT Peter
SOPKO George
STEG Philippe Gabriel
SUGARMAN Jeremy
WARREN John
WEDEL Hans
WITTES Janet
ZANNAD Faiez



Program 2006

- ❖ *Why are we fixated with the number 5 in morbidity mortality trials? ($p < 0.05$, $NNT > 5/1000$, 5 years Follow up....)*
Speaker: Stuart POCOCK (UK)
Discussants : Koos LUBSEN (SUI), David SACKETT (CAN)
- ❖ *Unconventional end points (e.g., days alive and out of hospital) pros and cons*
Speaker: Koos LUBSEN (SUI)
Discussants: Jay COHN (USA), Janet WITTES (USA)
- ❖ *Adaptive designs in CV trials*
Speaker: Janet WITTES (USA)
Discussants : Ray LIPICKY (USA), Hans WEDEL (SWE)
- ❖ *Positive control trials and what is non-inferiority.*
Speaker: David SACKETT (CAN)
Discussants: Stuart POCOCK (UK), John WARREN (UK)
Via teleconference: James HUNG (USA) and Mehul DESAI (USA)
- ❖ *Picking the right dose for clinical trials*
Speaker: Ray LIPICKY (USA)
Discussants: Edmond ROLAND (FR), Hubert POULEUR (USA)
- ❖ *Under what circumstances the DSMB may share interim trial data with investigators/ government sponsors?*
Speaker: Jeffrey BORER (USA)
Discussants :David GORDON (USA), Nancy GELLER (USA)
- ❖ *Under what conditions is it ethical to do a trial without informed consent?*
Speaker: Jeremy SUGARMAN (USA)
Discussant :François LEMAIRE (FR)
- ❖ *Should we be moving from morbidity mortality endpoints toward end organ protection endpoints in CV prevention trials*
Speaker: Jay COHN (USA)
Discussants : Philippe Gabriel STEG (FR), John CLELAND (UK), Michael PERELMAN (USA)
- ❖ *Usefulness of non randomised data for drug safety: Post marketing surveillance, provisional approval and epidemiology registries*
Speaker: Stephen EVANS (UK)
Discussants: Steinmar MADSEN (NOR), Douglas ALTMAN (UK)