

## SPEAKERS

Arnera Valdo	PHT
Bretz Frank	Hannover University & Novartis
Cattaneo Alessandro	Sendo Foundation
Di Giovine Davide	CROS NT
Gregori Dario	University of Padova & SISMEC
Inversioni Barbara	Rottapharm   Madaus
Julious Steven	Sheffield University
Migliori Ivan	OPIS
Rizzi Giada	Helsinn Healthcare
Spagnolo Paolo	University of Modena and Reggio Emilia
Zwingers Thomas	CROS DE

## BIAS STEERING COMMITTEE

Barbetta Beatrice	Rottapharm   Madaus
Comarella Lisa	CROS NT
Costantini Marco	Chiesi Farmaceutici
Lanzarotti Arturo	IBSA
Rizzi Giada	Helsinn Healthcare

## PRESENTATION

The BIAS (Association of the Italian Biostatisticians) National Congress, having reached its second edition, will this year be dedicated to Metanalysis and Multiplicity.

The meeting, held over two days (27<sup>th</sup>-28<sup>th</sup> May 2010), has the pleasure to have amongst its speakers, **Prof. Steven Julious** (Sheffield University) and **Prof. Frank Bretz** (Hannover University and Global Head Statistical Methodology at Novartis) who will be holding 2 separate mini-courses on the main topics.

For the first time this year, a parallel session on Data Management (only open for the Italian speaking attendees) has also been organised, with a specific focus on Efficacy and Safety Data integration taking a closer look at ePRO (electronic Patient Reported Outcome).

Once again, we believe that this meeting will be the ideal occasion for an un-BIASed, open and constructive face-to-face discussion between the various stakeholders (industries, CROs/service providers, the university environment, the independent research and institutions). Together we hope to be able discuss needs and perspectives, coming from the different points of view and environments. The aim being to project and align Italian clinical research with the European outstanding standards.

Consistently with a tradition which started a few years ago with the European Symposium EFSPi/BIAS on non-inferiority studies held in Verona and continued with the 1<sup>st</sup> BIAS National Congress with the tutorial of Prof. Mike Kenward, London School of Hygiene & Tropical Medicine, on missing data, the BIAS Steering Committee, though keeping its national identity, is very keen to promote an international vision on the association.

## LOCATION

CROWNE PLAZA ST. PETERS ROME

Via Aurelia Antica, 415 - 00165 Roma

## ORGANIZING SECRETARY

**LineCongress S.r.l.**

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# II Annual Congress



Rome

May 27<sup>th</sup> and 28<sup>th</sup> 2010



# P R O G R A M M A

Thursday May 27

## General Session: Meta-Analyses

10:00 – 10:15	Welcome and Introduction	Steven Julious
10:15 – 11:15	Introduction to meta analysis	Steven Julious
11:15 – 11:45	Coffee break	
11:45 – 12:45	Investigating heterogeneity in meta analyses	Steven Julious
12:45 – 14:15	Lunch	
14:15 – 15:00	Issues in designing trials based on meta analyses	Steven Julious
15:00 – 15:45	An insight into the respiratory field	Paolo Spagnolo
15:45 – 16:15	Coffee break	
16:15 – 17:00	A meta-analysis used in a regulatory context	Giada Rizzi
17:00 – 17:30	Panel Discussion	

Friday May 28

## Parallel Session: Multiplicity Issues

09:15 - 09.30	Welcome and Introduction	
09:30 - 10.30	Introduction to Multiple Testing	Frank Bretz
10:30 – 11:00	Coffee break	
11:00 – 12:00	Gatekeeping procedures	Frank Bretz
12:00 – 12:45	Multiple testing from a regulatory perspective	Dario Gregori
12:45 – 14:00	Lunch	
14:00 – 15:00	Adaptive designs for confirmatory trials	Frank Bretz
15:00 – 15:30	Pitfalls of Adptive Designs - A pratical view	Thomas Zwingers
15:30 – 16:00	Panel Discussion and Meeting closes	

Friday May 28

## Parallel Session: Efficacy and Safety Data Integration

09:15 - 09.30	Welcome and Introduction	
09:30 - 10.15	e-PRO	Valdo Arnera
10:15 – 10:45	e - PRO Integration with Oracle Remote Data Capture	Davide Di Giovine
10:45 – 11:15	Coffee break	
11:15 – 12:00	SAE reconciliation	Barbara Inversini
12:00 – 12:45	TBD	
12:45 – 14:00	Lunch	
14:00 – 14:45	Collection and management of data from local labs	Alessandro Cattaneo
14:45 – 15:30	IVRS: Vocal technologies for clinical research	Ivan Migliori
15:30 – 16:00	Panel Discussion and Meeting closes	