



European Statistical Meeting on Non-Inferiority

Non-inferiority trials have been around for many years, but are still controversial. Experts from industry, academia and regulatory bodies will present and discuss a range of issues concerning these trials. The meeting is a joint venture between EFSPi, BIAS and SSFA.

Thursday, 20th November 2008

Hotel Leon D'Oro - Verona, Italy

Agenda:

- 09:00-09:30 **Registration**
- 09:30-09:40 **Introduction** - Paolo Morelli, CROS NT, BIAS and EFSPi
- 09:40-10:15 **Non-inferiority trials are unethical** - Vittorio Bertele', Institute for Pharmacological Research, Milan
- 10:15-10:50 **What's inferior about a non-inferiority trial?** – Jorgen Seldrup, Quintiles
- 10:50-11:15 **Coffee break**
- 11:15-11:50 **Non-inferiority trials: A regulator's perspective** - David Brown, MHRA
- 11:50-12:35 **Non-inferiority: Indispensable, inferior or unethical?**
Question time with an expert panel including: Vittorio Bertele, David Brown, Kevin Carroll, Jorgen Seldrup, Simonetta Raimondo (AIFA),
Chair: Kit Roes (Schering Plough)
- 12:35-14:00 **Lunch**
- 14:00-14:30 **Case studies in the design, analysis and interpretation of non-inferiority clinical trials** – Krishan P Singh, GlaxoSmithKline
- 14:30-15:00 **Issues regarding non-inferiority within the anti-infective area** – Jon Armstrong, Astra Zeneca
- 15:00-15:30 **The non-inferiority margin in diabetes trials** - Lars Endahl, Novo Nordisk
- 15:30-16:00 **Coffee break**
- 16:00-16:35 **Sample size re-estimation in non-inferiority trials** - Tim Friede, University of Warwick
- 16:35-17:15 **Non-inferiority: Issues of today and developments for tomorrow** - Kevin Carroll, Astra Zeneca