



European Federation of Statisticians in the Pharmaceutical Industry  
Representing Statistical Associations in Europe



# European Statistical Workshop

## EMA Clinical Trial Data Transparency

Aug 22, 2013 London



# European Statistical Workshop (EFSPI/PSI): EMA Clinical Trial Data Transparency

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*EMA has published its draft policy for comments until September 30th, 2013. EFSPI has issued a position paper on EMA's data transparency initiative and will be submitting comments on this draft policy.*

*This joint EFSPI / PSI workshop will discuss the draft policy and various speakers will highlight key challenges in this area from different angles to stimulate the discussion in the breakout sessions.*

10:00 Welcome & Introduction

10:05 **Draft Policy and Setting the Scene** (*Christoph Gerlinger, EFSPI*)

*Views from Outside Industry*

10:35 **Systematic Review of Tial Data** (*Cartin Tudur-Smith, Liverpool Uni.*)

10:55 **MRC Clinical Trial Unit London** (*Matthew Sydes*)

11:15 Tea & Coffee

11:30 **Start Break-out Discussion Groups**  
(to discuss key challenges and comments on the draft policy)

13:00 Lunch



# Program – Afternoon session



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- 13:45 Continue Break-out Discussion Groups**
  - 14:30 Feedback from each Break-out Discussion Group**
  - 15:30 Tea & Coffee**
  - Specific Company Initiatives***
  - 15:45 GSK (Sara Hughes)**
  - 16:05 Roche (Kathrine Macey)**
  - 16:25 Next Steps**
  - 16:40 Summary**
  - 17:00 Close**

- Would like to thank you!

*in particular the speakers and organisers*

***Hope you've enjoyed it & have a safe trip home!***

In case you need any assistance, please let us know