



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Infoday London – 26 November 2010

Presentation by Henry Fitt
ENCePP Steering Group Meeting, 07 May 2010





Meeting Format

(total: 360 mins presentations)

08:45 – 09:00 Welcome and Introduction

09:00 – 10:30 Session (90 minutes)

10:30 – 11:00 Coffee break (30 minutes)

11:00 – 12:30 Session (90 minutes)

12:30 – 13:30 Lunch break (60 minutes)

13:30 – 15:00 Session (90 minutes)

15:00 – 15:30 Coffee break (30 minutes)

15:30 – 17:00 Session (90 minutes)

17:00 End of Information Day

Chaired by: Noël Wathion,
European Medicines Agency

Chaired by: Jytte Lyngvig,
Danish Medicines Agency



Session 1: Introducing ENCePP

- * Importance of post-authorisation studies
 - Valerie Simmons, European Federation of Pharmaceutical Industries and Associations (EFPIA)

- * The EMA and Drug safety studies: Overview & History of ENCePP
 - Henry Fitt, European Medicines

- * Research Centres, Networks & Data Sources
 - Camilla Smeraldi, European Medicines Agency



Session 2: Pillars of ENCePP

* Common issues with pharmacoepidemiology studies (standards, transparency)

- Bert Leufkens, Medicines Evaluation Board (MEB), Holland

* Checklist of Methodological Standards for ENCePP Study Protocols

- Xavier Kurz, European Medicines Agency

* ENCePP Code of Conduct

-Stefanie Prilla, European Medicines Agency



Session 3: Registration and ENCePP Studies

- * The need to register studies before they start
 - Ingemar Persson, Karolinska Institute, Sweden

- * The ENCePP electronic registry of studies
 - Rocio Fernandez, European Medicines Agency

- * Concept of “ENCePP study” / How will ENCePP change the way we work?
 - Peter Arlett, European Medicines Agency



Session 4: Brave New World

* Post-authorisation studies: new legislation

- Els Geeraerts, Belgian Federal Agency for Medicines and Health Products

* ENCePP: Future developments

- June Raine, Chair of PhVWP, Medicines and Healthcare products Regulatory Agency, United Kingdom

* Other EMA activities in the field of pharmaco-epidemiology

- Henry Fitt, European Medicines Agency