



European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Working Group 1
"Research Standards and Guidances"



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Guide on methods of PV

- ENCePP SG discussion:
 - NM (Nicholas Moore) informed the Steering Group that he was in the process of consulting ISoP, requesting feedback on the need for additional pharmacovigilance guidance.
 - It was agreed to await feedback from ISoP relating to gaps in the existing guidance. If gaps are identified, they will be included in the current guide. The need for additional expertise will be addressed if and when it arises.

Accreditation system

- WG agreed to test a self assessment accreditation questionnaire to provide information on the ENCePP center database
- New tab “Accreditation and quality assurance systems” for the Center Database”

Guide on Methodological Standards in Pharmacoepidemiology

- Compendium of knowledge applicable to practical pharmacoepidemiology
- Second revision approved June 2013
- Website improved, high Quality hyperlinks.
- THANKS to the IT and web-design tem

Guide on Methodological Standards in Pharmacoepidemiology

- New topics for Revision 3
 - - use of genetic data in PE studies
 - Nada Bozina / Olaf Klungel
 - - paediatric PE studies
 - Jan Bonhoeffer / Xavier Fournie / Xavier Kurz
 - support from Enpr-EMA
- Chapter to be revised
 - Drug exposure/outcome/covariate definition and validation
 - Gillian Hall / Rachel Boggon / Alejandro Arana
- Proposed new chapter
 - Drug Utilization Studies
 - Jesper Hallas

Guide on Methodological Standards in Pharmacoepidemiology

- Initiate Standard Methods for Revision 3
 - Open for public comments (ENCePP members should receive a reminder)
 - Chapter review by authors
 - Expert review of selected chapters
 - Text adapted to new presentation

Guide on Methodological Standards in Pharmacoepidemiology

- Improve communication of information
 - Pilot summary box in selected chapters
 - Pilot diagrams to help accessing the guide

Guide on Methodological Standards in Pharmacoepidemiology

- Interaction with other initiatives
 - ENCePP guideline on data integration
 - EMA scientific guideline on post-authorization efficacy studies (PAES)
 - Methods for vaccine safety/effectiveness/B-R studies (ADVANCE)
 - Question from Pregnancy/Mother-child epidemiology

Questions

- Thanks