European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Working Group 1
"Research Standards and Guidances"

Guide on Methodological Standards in Pharmacoepidemiology

- Compendium of knowledge applicable to practical pharmacoepidemiology
- First revision approved June 2012
- How to improve dissemination
  - Website
  - workshop

Guide on Methodological Standards in Pharmacoepidemiology

- (Revision 2)
    - Open for public comments (ENCePP members should receive a reminder)
    - Chapter review by authors
    - Expert review of selected chapters

Guide on Methodological Standards in Pharmacoepidemiology

- Develop new sections
  - Vaccines – Xavier Kurz
  - Pharmacogenetics -
  - Comparative effectiveness research -
- Further development of methods section
  - Treating missing data – Alejandro Arana
  - Effect modification – Olaf Klungel
- Other sections/developments based on ENCePP members'survey
- Call for Volunteers and encourage membership

Guide on Methodological Standards in Pharmacoepidemiology (2)

Survey on use of the guidance to be organised

- Ask investigators about use/usefulness of the Guidance, most useful sections, areas for improvements, etc…
  - Survey investigators, regulators, ENCePP members, manufacturers associations
- ENCePP questionnaire automatically sent to survey the usefulness of the guidance

Development of an ENCePP Guide on data integration and pooling of pharmacoepidemiological studies

- WG1 supports the initiative and proposed drafting group
- WG1 has the experience. Studies in Nordic countries. Encourage participants in study to collaborate with initiative
- WG1 members are willing to participate as individual reviewers.
- Role of WG1 as a whole unclear at this stage

ENCePP checklist

- First priority for ENCePP WG1

- Modify the ENCePP checklist according to new template of PASS protocol submission (some differences in the two documents)

Acreditation system

- Look at other countries accreditation systems

- Look at EMA acreditation for specific projects (finantial)

- Is there a need for acreditation? Is there a way of doing so? Is a more formal proccess needed apart from current level of information provided in ENCePP registry database?

Training needs

- Encourage members of ENCePP (Eu2P) to reference ENCePP guidelines and codes and deliverables in their training.

As an Example. University of Utrecht evaluates protocols in training programs using the ENCePP checklist