

ENCePP Work Group 1

ENCePP research standards and guidances: report on activities



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance



Mandate

To address methodological aspects of the generation of evidence-based information supporting the needs of regulatory and HTA decision-making.

Identify areas in which research standards and guidances relevant for ENCePP activities are needed and identify or develop such guidance.

- Periodically review the ENCePP Checklist for Study Protocols.
- Periodically review the Guide on Methodological Standards in Pharmacoepidemiology.
- Monitor the development of accreditation systems and their methodologies.
 - Support training relevant to the ENCePP standards.
- Support the implementation of new and existing standards



Participants

- **WG Members:** Alfonso Carvajal, Xavier Fournie, Helga Gardarsdottir, Victor Kiri, Ursula Kirchmayer, Olaf Klungel, Gillian Hall, Susana Perez-Gutthann, Yvonne Lis, Federica-Edith Pisa, Annie Fourier-Reglat, Massoud Toussi, Rachael Williams, Vera Ehrenstein, Alfonso Carvajal, Alejandro Arana, Thomas Goedecke, Marina Davoli, Jesper Hallas, Nadia Bozina, Yola Moride, Marieke deBruine
- **SG sponsor:**
- Maria Teresa Herdeiro
EMA:
- Xavier Kurz, Alexandra Pacurariou



Review of the ENCePP Checklist for Study Protocols

ENCEPP WG1 finalised Revision 4 of the ENCePP Checklist for Study Protocols. Revision 4 was posted on the ENCePP



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Doc.Ref. EMA/540136/2009



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

ENCEPP Checklist for Study Protocols (Revision 4)

Adopted by the ENCePP Steering Group on 15/10/2018

The [European Network of Centres for Pharmacoepidemiology and Pharmacovigilance \(ENCEPP\)](#) welcomes innovative designs and new methods of research. This Checklist has been developed by ENCePP to stimulate consideration of important principles when designing and writing a



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance



Review of the Guide on Methodological Standards in Pharmacoepidemiology

The 7th Revision of the Guide on Methodological Standards in Pharmacoepidemiology was published in July 2018. It includes revisions, amendments and new references in all the chapters. Revisions were performed by the authors (34 authors) in collaboration with the editorial group. External comments received were also considered.



EMA/95098/2010 Rev.7

The European Network of Centres for
Pharmacoepidemiology and Pharmacovigilance (ENCePP)
Guide on Methodological Standards in
Pharmacoepidemiology
(Revision 7)

More significant Review

4.3. Patient registries

4.5. Social media and electronic devices

4.6. Research networks

5.1. Definition and validation of drug exposure, outcomes and covariates

5.3. Methods to address bias

5.9 Methods for pharmacovigilance impact research

Chapter 5.9 is complemented by Annex 2 which provides more detailed guidance on methods for pharmacovigilance impact research developed by an ENCePP Special Interest Group.



4 July 2018
EMA/458754/2018
ENCePP Secretariat



Annex 2 to the Guide on Methodological Standards in
Pharmacoepidemiology

Methods for pharmacovigilance impact research

Revision 8. New chapters proposed

- ENCePP SG proposed to include a new section/chapter/annex on methods for benefit/risk assessment to be written by Hans Hillege's team at Groningen University.
- Plans to modify sections of Chapter 4 on surveys and social media.



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance



Other activities

- Monitor the development of accreditation systems and their methodologies
- Expand ENCePP to Eastern European countries
- Increase visibility of ENCePP
 - The Guide on Methodological Standards in Pharmacoepidemiology (Rev.6) has registered 4300 views and 890 downloads on average per month
 - Members of WG1 actively participated in the workshop held in Prague during the ICPE 2018 to commemorate the 10th anniversary of ENCePP and discuss its future direction.
- Support training relevant to the ENCePP standards
- Revision of fields of the ENCePP Resource database



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

