



How can ENCePP contribute to research? Experience from a non-EU academics

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Potential Conflict of Interest disclosure

- None for this presentation
- I am a faculty of a public university
- I conduct public domain research sponsored by medical product companies



- I represent International Society for Pharmacoepidemiology to participate in the ENCePP Steering Group
 - I have experience in US and East Asia
 - Academia and industry





pharmacoepi.org

ABOUT ISPE

Overview

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The International Society for Pharmacoepidemiology (ISPE) is an international organization dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information and for the development of policy, education, and advocacy for the field of pharmacoepidemiology, including such areas as pharmacovigilance, drug utilization research, comparative effectiveness review, and therapeutic risk management.

- Real World Studies with public health, scientific and regulatory impact



Three main points

- Code of Conduct
 - Scientific independence
 - Transparency
- Methods
- Data development model



Frequently
updated



The screenshot shows the ENCePP website interface. At the top is the ENCePP logo and the text "European Network of Centres for Pharmacoepidemiology and Pharmacovigilance". Below this is a navigation bar with links: Home, Sitemap, Q & A, Notice Board, Links, and Contact Us. A breadcrumb trail indicates the current location: Home > Standards & Guidances > Methodological Guide. On the left is a sidebar menu with categories: News, About Us, ENCePP Documents, Training in PhEpi and PV, Code of Conduct, Standards & Guidances (with sub-items: Checklist for Protocols, Methodological Guide), ENCePP Study Seal, Public Consultation, Glossary of terms, Resources Database, Partners forum, and EU PAS Register. The main content area is titled "ENCEPP Guide on Methodological Standards in Pharmacoepidemiology". The text describes the guide as a single web resource for methodological English language guidance in pharmacoepidemiology, mentioning that it includes direct electronic access to internationally agreed recommendations, published articles, and textbooks. It notes that the current version is revision 8, dated July 2020, and that the 8th revision includes revisions, amendments, and new references. A foreword highlights the importance of the guide for pharmacoepidemiological studies in the context of the COVID-19 pandemic. The guide is updated annually by structured review. A list of relevant documents is provided, including the Foreword to Encepp Guide Revision 8 (marked as new), the Guide on Methodological Standards in Pharmacoepidemiology (Revision 8), a List of references, and Authors & acknowledgements.

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Home > Standards & Guidances > **Methodological Guide**

ENCEPP Guide on Methodological Standards in Pharmacoepidemiology

The Guide on Methodological Standards in Pharmacoepidemiology offers a **single web resource for methodological English language guidance in pharmacoepidemiology**. For each topic covered, direct electronic access is given to internationally agreed recommendations, and key points from important guidelines, published articles and textbooks are highlighted. Where relevant, gaps in existing guidance are addressed with what ENCePP considers good practice.

The current version of the Guide is **revision 8**, dated July 2020.

The 8th revision of the Guide on Methodological Standards in Pharmacoepidemiology includes revisions, amendments and new references in most of the chapters. Revisions were performed by the authors in collaboration with the editorial group. External comments received were also considered.

For this 8th revision, a foreword highlights the importance of the Guide for pharmacoepidemiological studies carried-out in the context of the COVID-19 pandemic in order to provide valid results useful for clinicians and regulators. The foreword guides the reader to the chapters that may be particularly relevant for such studies.

The Guide is updated annually by structured review to maintain its dynamic nature. It may also be amended as necessary in response to comments received. For this purpose, any comment and additional relevant guidance document may be forwarded to ENCEPP_Secretariat@ema.europa.eu.

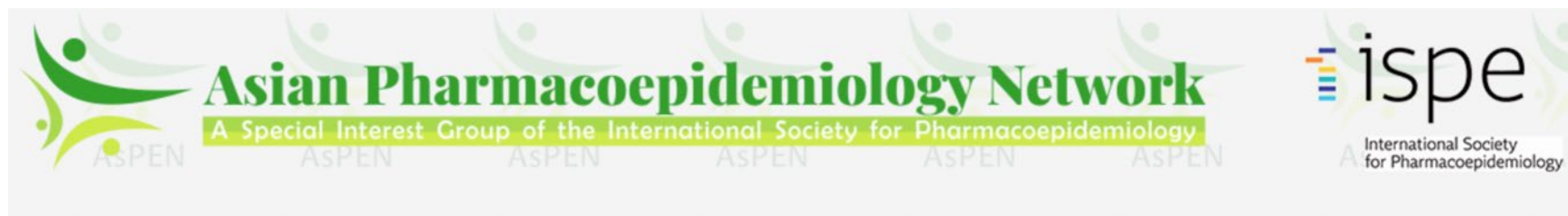
Relevant documents:

-  **Foreword to Encepp Guide Revision 8** NEW
-  **Guide on Methodological Standards in Pharmacoepidemiology (Revision 8)**
-  **List of references**
-  **Authors & acknowledgements**



Data development across multiple data sources

- <https://www.aspensig.asia>



ABOUT US NATIONAL GROUPS AND CONTACT PERSONS ACTIVITIES PUBLICATIONS HISTORY ▼ RELATED LINKS

- Similar issues as with ENCePP, US FDA Sentinel, and CNODES



Preparation for COVID-19 vaccines

- Background rates of adverse events of special interest (AESI)
- Spontaneous reports of adverse events
- Signal detection and refinement
- Formal epidemiology evaluations, if needed

