



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

ENCePP Working Group 1: Standards and Guidances

ENCePP Steering Group meeting
1 December 2023

Alejandro Arana

An agency of the European Union





Mandate and members of WG1

Overall mandate:

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

WG1 members:

Xavier Kurz, Catherine Cohet, Susana Perez-Gutthann, Tania Schink, Massoud Toussi, Marina Davoli, Xavier Fournie, Jesper Hallas, Olaf Klungel, Yola Moride, Gillian Hall, Helga Gardarsdottir, Daniel Prieto Alhambra, Arnold Chan, Xabier Garcia de Albeniz, Liesbet Peeters, Katja Hakkarainen, Vera Ehrenstein and Alejandro Arana.

Carla Torre in progress



11th Revision of the ENCePP Guide; Released July 13, 2023

- The structure of the Guide has been revisited to better illustrate the evidence generation flow and to increase the emphasis on important methodology
- The use of the causal inference target trial emulation approach and the estimand framework, and the use of the HARPER protocol template is recommended to foster transparency and high quality of non-interventional studies, and to facilitate their assessment
- Foreword highlighting the continued involvement of ENCePP in sound pharmacoepidemiological research including COVID-19 topics

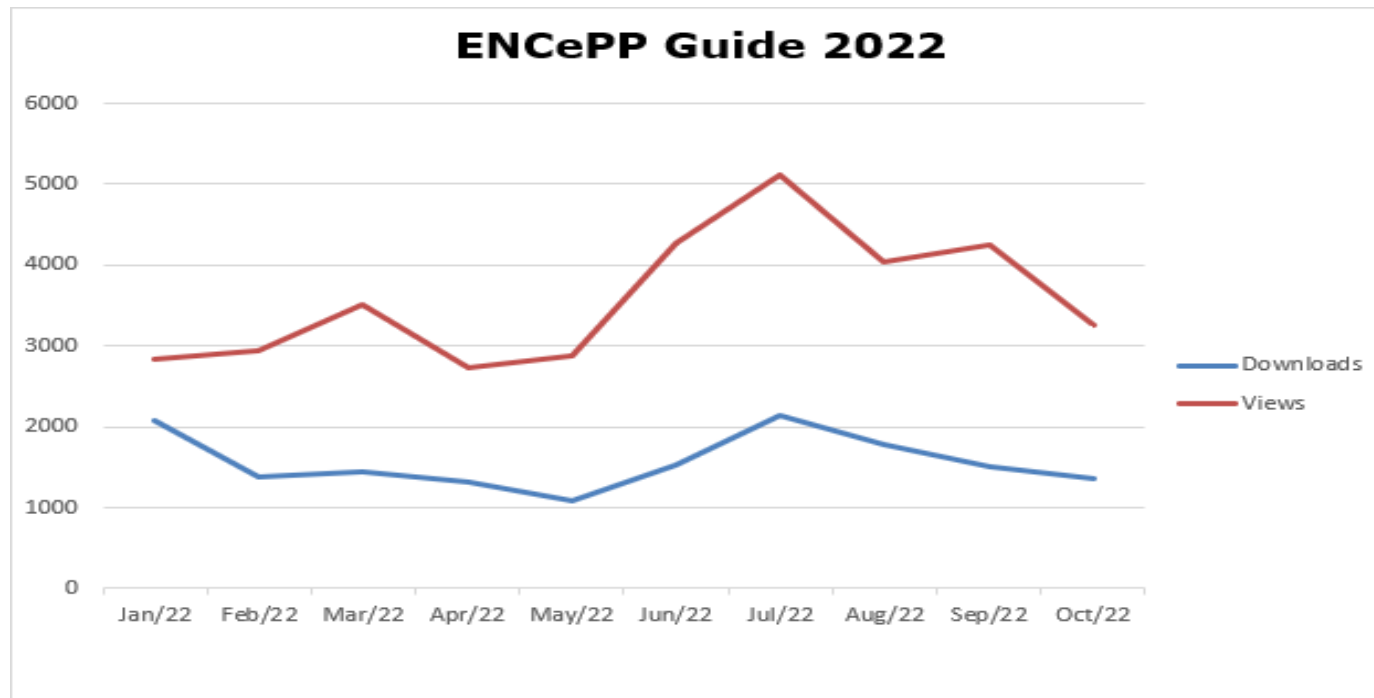


11th Revision of the ENCePP Guide; Released July 13,2023

- Update of each chapter by the corresponding authors
 - Chapter 9 on Research networks for multi-database studies addresses the expansion and use of DARWIN EU®
 - Chapter 16.1 on Comparative effectiveness research has been extensively revised
 - Chapter 16.5 on Artificial intelligence has been extensively revised
 - Chapter 16.6 on RWE and pharmacoepidemiology has been extensively revised
- https://www.encepp.eu/standards_and_guidances/index.shtml



ENCePP Guide





Next steps

- WG1 meeting held November 21
- 12th Revision of the ENCePP Guide expected 2025 (exploring moving to bi-annual updates)
 - WG1 will study and explore the publication in peer reviewed Journals
 - Additional/increased visualization and dissemination (Catherine & OHDSI community call journal session)
- RE-evaluate the need to adapt the Protocol check-list to HARPER initiative or target trial emulation approach until new GVP Guidelines are published



Thank you for your attention!

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