

ENCePP Guide on Methodological Standards in Pharmacoepidemiology

TRENDING TOPICS

The Guide on Methodological Standards in Pharmacoepidemiology (PE) continues to be a useful resource for researchers, regulators, and marketing authorization holders and applicants. The current version of the Guide is [Revision 11](#), dated July 2023.

In this revision, new recommendations include the use of the:

- causal inference target trial emulation approach to improve internal validity and increase transparency on study designs, unless an alternative strategy is justified;
- estimand framework – in accordance with ICH Addendum E9 (R1), 2019 - to inform study design and analysis choices; and
- **HARPER** protocol template to foster transparency, reproducibility and harmonization of non-interventional study protocols and facilitate their assessment. HARPER is compatible with the legal format and content of GVP Module VIII and can be used in PASS protocols (or the protocol of any PE study) without change of structure.

Nearly all chapters have been updated and include new references, and some chapters have been revised to reflect the fast changing environment in the field of PE and real-world evidence (RWE):

- **[Chapter 9](#)** on Research networks for multi-database studies addresses the expansion and use of DARWIN EU®, and chapters
- **[16.1](#)** on Comparative Effectiveness Research (CER) and in particular CER based on:
 - a. randomized clinical trials (RCTs),
 - b. evidence synthesis of published RCTs (meta-analysis of results),
 - c. observational data, and
 - d. cross-design synthesis
- **[16.5](#)** on Artificial intelligence in PE (refer to the [draft EMA reflection paper](#), section 2.2.7, outlining the current thinking on the use of AI to support applications within pharmacovigilance in general), and
- **[16.6](#)** on RWE and PE have been extensively revised.

Keywords: Pharmacoepidemiology, ENCePP, Guide, HARPER, AI, casual inference, estimand, RWE

