18 February 2025

ENCePP Seal 2010-2025

Discontinued in February 2025

The Steering Group has agreed to discontinue the ENCePP Seal as of February 2025.

The below information on the Seal is kept on the website for historical and transparency reasons.

Purpose

Upholding high standards throughout the research process of studies in pharmacoepidemiology and pharmacovigilance based on the principles of scientific independence, transparency and robust methodologies is at the core of the ENCePP initiative. The Code of Conduct specifically aims to avoid financial, commercial or institutional interests of the study funder and potential personal interests of researchers that could influence the study results in any particular direction. To recognise studies following these ENCePP core principles, the ENCePP Seal has been introduced.

Studies bearing the ENCePP Seal are performed taking into account the relevant methodological research standards described in the ENCePP Guide on Methodological Standards in Pharmacoepidemiology and conducted in line with the rules and requirements for independent and transparent research laid down in the ENCePP Code of Conduct and in established international guidelines such as the World Medical Association Declaration of Helsinki and the European Code of Conduct for Research Integrity.

The ENCePP Seal publicly identifies studies in the HMA-EMA Catalogue of real-world studies that adhere to the entirety of the Code's provisions. Reference to the Seal is encouraged in publications arising from the study.

Studies conducted in accordance with the following principles may qualify for the ENCePP Seal:

- The study's primary purpose is to generate data of potential scientific or public health importance and not to promote the sale of a medicinal product;
- The design of the research shall aim at minimising any potential bias;
- The highest possible level of transparency regarding the use of methodological standards in the study protocol;
- The contractual arrangements between investigators and the study funder clearly define the research assignment and address critical areas of interaction, remuneration, feasibility assessment, protocol agreement, study registration, data analysis and publication of results;
- Remuneration is only granted as specified in the research contract and independent of a particular study result;
- The study is registered in the HMA-EMA Catalogue of real-world studies prior to its start, thereby making publicly available information on the research process;
- The study results (synopsis or manuscript) are published in the HMA-EMA Catalogue of real-world studies in line with agreed timelines.

Conditions

Note: The documents linked to this section have not been updated and still reference the EU PAS Register. Where reference is made to the EU PAS Register, the HMA-EMA Catalogue of real-world studies references need to be used.

Any pharmacoepidemiological and pharmacovigilance study may qualify for the ENCePP Seal if ALL of the following conditions are met and the respective provisions are implemented:

1. The (primary) lead investigator belongs to an ENCePP partner that is included in the institutions or networks in the HMA-EMA Catalogue of real-world studies.
2. The study is registered in the HMA-EMA Catalogue of real-world studies together with the full protocol prior to study start.
3. The (primary) lead investigator makes the following documentation of commitment to adhere to the provisions of the ENCePP Code of Conduct prior to study start publicly available in the HMA-EMA Catalogue of real-world studies:
    - Signed Checklist of the ENCePP Code of Conduct (Annex 2)
    - Signed Declaration on compliance with the ENCePP Code of Conduct (Annex 3)
    - Signed ENCePP checklist for Study Protocols
    - Signed Declaration of Interests (Annex 5)
4. The (primary) lead investigator publishes the research results in the HMA-EMA Catalogue of real-world studies.

Researchers that follow the provisions of the ENCePP Code of Conduct in its entirety are encouraged to consider applying for the ENCePP Seal if the above conditions are met.

How to apply for the ENCePP Seal

The application process should start at least one month prior to the actual study start date to ensure there is sufficient time for the validation team to check and approve the provided documents before the study commences.

The final version of the full study protocol shall be made publicly available before the study start, as well as the final study report without delay after study completion.

To confirm a commitment to comply with the provisions of the Code, the (primary) lead investigator of the study must **complete** and **sign** the **documents listed under 'Conditions - point 3' of the conditions** above and upload them in the HMA-EMA Catalogue of real-world studies, prior to the study start.

Note: The (primary) lead investigator should inform the ENCePP Secretariat if the study deviates from and/or no longer fulfils the criteria for the ENCePP Seal. Any failure to comply with the entirety of the provisions of the Code may be considered a breach of the declaration (Annex 3) and relevant documentation, and the ENCePP Seal will be removed from the HMA-EMA Catalogue of real-world studies.