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European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Revision 4 of the ENCePP Code of Conduct

Summary of the main changes

1. Background

The ENCePP Code of Conduct was first released in 2010 setting out a framework for good practice, scientific independence and transparency in the conduct of pharmacoepidemiology, pharmacovigilance and post-authorisation studies. While revision 1 focused on the requirements for access to study data, revision 2 provided further clarification on the practical implementation of the Code's requirements on access to study data, declaration of interests and sources of funding. Revision 3 improved the overall readability of the Code and provided clarifications on the key principle of scientific independence, and on the ENCePP Seal. Based on ENCePP partners' 10 years of practical experience in conducting collaborative research and the feed-back from stakeholders including pharmaceutical industry, contract research organisations, learned societies and regulatory authorities, the ENCePP Steering Group adopted on 15 March 2018 revision 4 which has been developed by the ENCePP Working Group on transparency and independence.

2. Summary of the main changes

The fourth revision of the Code aims to facilitate the practical implementation of the Code's key principles of scientific independence and transparency by providing a clear definition of these concepts. The roles of the (primary) lead investigator and the study funder are further clarified to ensure scientific independence throughout the research process, and the need to avoid any influence from commercial, financial or institutional interests that could influence the outcome of a study in any particular direction. The Code also provides for research conducted with authorised medicines in the context of post-approval regulatory requirements for marketing authorisation holders.

In addition, all processes for implementing the ENCePP Seal concept have been removed and summarised in a separate document published on the ENCePP website to improve the Code's overall operability.

These complex changes also required an entirely new structure of the Code and to improve its operability the order of chapters was rearranged to follow the chronological conduct of a study. Furthermore, Annex 4 has been amended accordingly.

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2.1. Scientific independence

The Code now defines scientific independence and provides strategies for its practical implementation that separate the power and influence of study funders from the (primary) lead investigator's responsibility for scientific integrity.

The Code acknowledges personal interests of researchers but distinguishes commercial, financial and institutional interests. A new definition of conflicts of interests in this context was introduced. The Code's core provision is that after protocol finalisation, no person with a commercial, financial or institutional interest in a particular outcome of the study shall take part in any study activity. Moreover, it is now specified that the (primary) lead investigator will always be a person without financial, commercial or institutional interests in a particular outcome of the study, and that all core study team members need to declare personal interests that might impact their impartiality in relation to the study.

However, the Code clarifies that where no other technical expertise for the conduct of the study exists in the study team this may be obtained externally, including from the funding organisation, in a transparent process which ensures that the results are not influenced in a particular direction.

Regarding protocol finalisation the Code now specifies that for studies requested by a competent authority, to meet regulatory requirements for authorised medicines, the final protocol should be agreed between the (primary) lead investigator, the study funder and the competent authority.

2.2. Transparency

The Code clarifies that the responsibility for managing the EU PAS Register® entry is with the (primary) lead investigator (or coordinating study entity). However, the study record may be managed by the marketing authorisation holder in agreement with the (primary) lead investigator to comply with regulatory requirements.

The declarations of conflicts of interests of the (primary) lead investigator, the core study team and the members of the study steering group should all be made public via the EU PAS Register®.

2.3. ENCePP Seal

The ENCePP Seal publicly recognises studies that follow the ENCePP principles of scientific independence, transparency and scientific standards as a quality hallmark. The conditions for a study to qualify for the Seal remain unchanged, however the provisions and processes for obtaining the Seal are now summarised in a separate document published on the ENCePP website.