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Considerations on ENCePP and best pharmacoepidemiology methods for PASS

The emergence of major issues concerning drug safety and more recently the need for comparative effectiveness studies for regulators and HTA bodies has led to the development of risk management plans and the definition of post-authorisation safety and effectiveness studies (PASS and PAES). Because these were very different from the studies most commonly done by industry mostly clinical trials, and beyond traditional spontaneous reporting based pharmacovigilance, the EMA sought to develop a network of centres that would be available to provide advice, perform studies on its behalf and assist industry. The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) emerged from this need, with a three-fold main objective: establish a database of centres, resources and studies; develop methodological recommendations that would ensure study quality; and develop a framework of collaboration between centres and sponsors, the ENCEPP code of conduct and seal, that could ensure transparency and independence. At this time Centres have been identified in most European countries, as well as data resources. A methods guide has been produced and is now in its 5th revision as well as the relevant checklist. They are regularly enriched, and any suggestions for further improvement are welcome. ENCEPP has also provided advice on GVP (especially modules V, VI, VIII) and is regularly consulted on topics of interest, such as the interactions between PASS, PAES and HTA.

To date, 895 studies have been registered in the EU PAS registry, 41 with the ENCEPP Seal. Registration is mandatory for PASS and PAES requested by the authorities, but there are also many non-PASS studies registered. The Register now provide a unique registration number, and auditable traceability

Registering a study is open to all studies and all sponsors. However the seal imposes independence of the study centre from the sponsor, and only non-industry ENCePP centres may apply for the Seal. At this time, only centres within Europe may become members of ENCePP and apply for a study Seal, but studies are also open to non-European centres. ENCePP can serve as a template for private-public collaboration in the field of pharmacoepidemiology, preserving each partner's interests, and ensuring the highest possible quality studies, adapted to the issues at hand.