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ENCePP

(European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)

Mandate of ENCePP Working Group 3

Scope	<i>Inventoy of EU data sources and methodological approaches for multi-source studies</i>
Chair: Rapporteur(s): ENCIAG:	Miriam Sturkenboom Jim Slattery (EMEA), Stefanie Prilla (EMEA) Francisco de Abajo Iglesias, Tjeerd Van Staa
Mandate	<p><u><i>EU inventory of data sources.</i></u></p> <ul style="list-style-type: none">▪ Define the elements that the EU inventory of data sources should have, according to different categories (e.g. databases, disease registries, exposed registries, case-control surveillance, etc.)▪ Identify existing data sources useful for PE and PV research▪ Identify relevant areas of PE and PV not covered by the existing data sources in the EU▪ Explore ways to stimulate and support initiatives to create new data sources in EU Member States <p><u><i>Approaches & processes for interoperability and sharing of European epidemiology data sources.</i></u></p> <ul style="list-style-type: none">▪ Discuss operational approaches for organising, initiating and performing of observational safety studies through ENCePP, as well as large simple randomised clinical trials▪ Explore ways of performing multi-source studies (e.g. combining data, using common protocols)▪ Develop training programs <p><u><i>Data privacy restrictions for PE/PV research.</i></u></p> <ul style="list-style-type: none">▪ Develop approaches to overcome differences in national legislation on data privacy in order to facilitate multi-national database studies, taking into account legal advice▪ Develop common rules to protect patients' and providers' rights with respect to data confidentiality. <p><u><i>Input to the design of the ENCePP web page.</i></u></p>