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ENCePP
 (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)

**Mandate of
 ENCePP Working Group 2**

Scope	<i>Independence and Transparency</i>
Chair: Rapporteur(s): ENCIAG:	Helen Dolk Henry Fitt, Hans-Georg Eichler Ingemar Persson, Deborah Ashby
Mandate	<ul style="list-style-type: none"> ▪ To develop a code of conduct governing the responsibilities and interaction of stakeholders (industry, research centres, regulators, etc) in the conduct of PhV studies in order to ensure scientific independence and transparency, including: <ul style="list-style-type: none"> - Data ownership: raw data, analysed data - Centres' right/commitment to submit for publication - Centres' and MAHs' obligation to follow transparency rules - Authorships - Funders' or sponsors' rights: observer/presence in steering groups, information and comments on reports and manuscripts, time limits for comments, etc. - Regulatory requirements for reporting; interventional and non-interventional studies - Rules for financial interactions - Liability issues - Mandatory elements for standard contracts and legal issues (e.g. legislation under which study is carried out, copyright) - Introduce Annex with sample/template contract protocol agreement, reporting of results, etc. - Define milestones when information details of a PhEpi study in progress shall be made available, or public, to stakeholders - Elaborate approaches/ways to ensure transparency, e.g. web-publication of the research protocol and/or the study results, etc. - Ensure transparency translates into effective public communication (e.g. on future EMEA Safety Portal) - Develop training programs ▪ Register of non-interventional PhEpi safety studies: develop a draft paper addressing the appropriateness, feasibility, scope and framework. Start with ENCePP studies. <ul style="list-style-type: none"> - Elaborate approaches for establishment of a register of initiated and conducted studies through ENCePP - Define rules for the access of third parties to research data in the register - Develop a proposal for standard forms for website publication and entries in the register.