



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

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Mandate of ENCePP Special Interest Group (SIG) “Pregnancy”

SIG on Drug Safety in Pregnancy

Chair: Laura Yates

- The work of the group will lead and inform, where applicable, future activities of ENCePP in terms of medicines used in pregnancy and lactation.
- The group will liaise with relevant groups in ENTIS, ISPE and ISOP to support the development of guidance for studies of drug use in pregnant and lactating women.
- Provision of a forum to share experience and insights regarding studies of the safety of drug use in pregnancy.
- Discuss methodological challenges in research on drug safety in pregnancy.
- Respond to specific queries on methodological approaches to pregnancy research from the ENCePP Steering Group and other stakeholders such as the EMA.
- Periodically review the document “[Overview of data sources for drug safety in pregnancy research](#)” and update as necessary.
- Provide input to ENCePP Guide on Methodological Standards in Pharmacoepidemiology and to the development of a GVP module on pregnancy.

