



**TEDDY contribution to ENCePP- European
Network of Centres for Pharmacoepidemiology
and Pharmacovigilance**

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EMC

ENCePP: European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

- Network coordinated by the **European Medicines Agency (EMA)**
- **ENCePP partners:**
 - public institutions (like academia)
 - contract and research organisations (CRO)
- **Research interests:**
 - safety of medicines
 - benefits and risks of medicines
 - disease epidemiology
 - drug utilisation

ENCePP aims

- To strengthen the monitoring of the benefit-risk balance of medicinal products in Europe by:
 - Facilitating the **conduct of high quality**, multi-centre, independent post-authorisation studies (PAS) with a focus on observational research
 - **Bringing together expertise and resources** in pharmacoepidemiology and pharmacovigilance across Europe and providing a platform for collaborations
 - Developing and maintaining **methodological standards** and governance principles for research in pharmacovigilance and pharmacoepidemiology.

ENCePP key outputs

- ENCePP Database of Research Resources
- ENCePP Code of Conduct
- ENCePP Checklist for Study Protocols
- ENCePP Guide on Methodological Standards in Pharmacoepidemiology

ENCePP – Meeting Londen

22 November 2016

- **Report from WGs:**
SIG - “Drug research in pregnancy”
- 50 years of pharmacovigilance: unfinished job
- Identifying **opportunities for 'Big Data'** in medicines development and regulatory science
- **Meta-analysis of safety** - thoughts from CIOMS X
- **EURO-SALT** - a study of drug exposed acute liver injury in European transplant centres
- **Pragmatic Trials** - The Salford Lung Study
- Scientific guidance on post-authorisation efficacy studies
- The General **Data Protection Regulation** and use of health data: challenges for pharmaceutical regulation
- **ENCePP Seal studies and imposed PASS:** new compliance and disclosure measures

ENCePP and pediatric research (1)

- **TEDDY studies:**
 - According to ENCePP code of conduct
 - Use checklist for study protocol
 - Register studies on EU PAS register
→ ENCePP seal

ENCePP and pediatric research (2)

- SIG – pregnancy:
 - The work of the group will lead **future activities** of ENCePP of medicines used in pregnancy and lactation
 - The group will **liaise with relevant groups** in ENTIS, ISPE and ISOP
 - Provision of a forum to share experience/insights regarding studies of the safety of drug use in pregnancy
 - Discuss **methodological challenges**
 - Respond to specific **queries** on methodological approaches to pregnancy research
 - 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.
- → Established June 2015 – Laura Yates (Chair)
AP: Check whether TEDDY can join SIG

ENCePP and pediatric research (3)

- EMA tender studies
- Example: “Methods and datasources for determining long term effects of drug exposure during pregnancy, with application to antiepileptic medicines” → March 2016
- EMA website:
To obtain the latest information on tenders in this range of values, please send the following information to contracts@ema.europa.eu:
 - the name and address of your company
 - the business area you are involved in
 - the nature of the tenders that you are interested in.

ENCePP and pediatric research (4)

- EMA tender studies
- How many of the TEDDY members are already registered as organisation interested to participate in EMA tender studies?

ENCePP and pediatric research (5)

- 24 November 2016: call for information: Impact of valproate exposure in utero on neurodevelopmental development
- *“Dear ENCePP partners,
We are emailing you to ask for the most recent data, as yet unpublished, that you could share with the European Medicines Agency regarding the impact of valproate exposure in utero on neurodevelopmental development.”*

TEDDY and ENCePP

- Action Points:

- Register TEDDY studies on ENCePP PAS
- Become member of SIG – pregnancy
- Register to become informed on EMA tenders

- Other ideas????