



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Interface Enpr-EMA and ENCePP

Joint Enpr-EMA/ENCEPP Working Group

7th annual meeting of the Enpr-EMA network



Presented by Kevin Blake 29 May 2015
Pharmacovigilance Department

An agency of the European Union





The European Network of Centres for pharmacovigilance and pharmacoepidemiology www.encepp.eu

An EMA-led initiative since 2006

- Brings together expertise from across Europe to build capacity
- Aimed at strengthening further the post-authorisation monitoring of medicinal products
- Focus is on observational research (pharmacoepidemiology) but centres conducting clinical trials (pharmacovigilance) can be included
- Has developed guiding principles for observational research in terms of robust methodologies, transparency and scientific independence from study funders

Who are the ENCePP partners

- Located in EU with main focus on *pharmacoepidemiology* and *pharmacovigilance*
- No formal accreditation to join but list of publications to assess application
- Universities, hospitals, owners of healthcare databases and/or electronic registries
- Other public/non-profit research centres specialised in pharmacovigilance
- Existing European networks covering certain rare diseases, therapeutic fields and adverse drug events of interest
- For-profit organisations
 - *Same focus but provided they perform studies commissioned by third parties*

Interface with Enpr-EMA

- Shared interest in paediatric drug safety
- Safety data being increasingly used in a complementary manner
- Joint Enpr-EMA/ENCEPP Working Group established as a bridge
 - Contribution to the revision of the paediatric pharmacovigilance guideline
- Participating centres display details in the Resources Database
 - <http://www.encepp.eu/encepp/resourcesDatabase.jsp>
 - *a hub for both researchers and study sponsors to identify organisations for conducting specific pharmacoepidemiology and pharmacovigilance studies in Europe*
- **For consideration:**
 - Enpr-EMA networks wishing to conduct paediatric PASS to join ENCePP
 - ENCePP centres with paediatric interest to share good practice in conducting
 - 3 PASS with interested Enpr-EMA networks



Thank you for your attention

Further information

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