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Press Office

Press release

European Medicines Agency and European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) launch electronic Register of Studies (E-Register)

E-Register increases transparency of pharmacovigilance research and helps to improve patient safety

The European Medicines Agency and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) have launched the ENCePP E-Register of Studies. This electronic register is a publicly accessible resource for the consultation of pharmaco-epidemiological and pharmacovigilance studies conducted by academic centres and other research organisations.

The purpose of the E-Register is to increase the availability of information on the utilisation, safety and effectiveness of medicines used in clinical practice through a readily accessible database resource.

It will also contribute to reducing publication bias by handling both positive and negative study results in the same manner and promote exchange of information, thereby facilitating collaboration within the scientific community and preventing unnecessary duplication of research.

Registration of studies in the register is voluntary, except for those studies wishing to apply for the status of 'ENCePP Studies', a seal awarded to wholly or partially EU-based, benefit/risk studies that are carried out in compliance with the ENCePP Code of Conduct for independence and transparency and the ENCePP Checklist of Methodological Research Standards. Studies that potentially qualify for this seal must be entered into the E-Register before they commence.

The E-Register of studies can be accessed through the ENCePP website: http://www.encepp.eu/encepp/studiesDatabase.jsp.

For all studies included in the E-Register, investigators are required to regularly update the information that is available in the register.

The launch of the E-Register of Studies is the latest milestone achieved by ENCePP, following the adoption of the ENCePP Code of Conduct, the launch for public consultation of the Guide on

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Methodological Standards for pharmacoepidemiological studies and the launch of an inventory of resources. The ENCePP project, which is led by the European Medicines Agency, is intended to enhance the way medicines are monitored once they have been approved for use in the European Union by facilitating the conduct of high quality, multi-centre, independent, post-authorisation studies.

An ENCePP information day, introducing the ENCePP Network of Excellence to a wider audience, including pharmaceutical industry professionals, as well as other interested parties including academics, regulatory, editors of medical journals and other professionals specialising in the field of observational research will be held on Friday, 26 November 2010.

Notes

1. This press release, together with all related documents, is available on the European Medicines Agency's website.
2. More information about ENCePP is available here: www.encepp.eu
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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