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SCIENCE MEDICINES HEALTH

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ENCePP Secretariat

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Report on ENCePP Activities in 2011

Executive Summary

Milestones

Building on the initial phase of establishment, during 2011 the priority of ENCePP was to further consolidate the network as an important resource in the field of pharmacovigilance and pharmacoepidemiology that delivers for public health.

An major milestone was the adoption of the Guide on Methodological Standards in Pharmacoepidemiology following a public consultation which closed in January 2011. The Guide is an important tool that reviews and gives direct electronic access to methodological guidance for research in pharmacoepidemiology and pharmacovigilance. It provides a framework for thinking and learning on study design and methods through the presentation of internationally agreed recommendations and key points from important guidelines, published articles and textbooks.

In August 2011 the ENCePP Steering Group adopted the first revision of the ENCePP Checklist for Study Protocols**.** The major outcome of the revision of this resource on study methods has been to make the Checklist a 'stand-alone' document to reflect its more general use outside the context of an application for ENCePP study status.

During 2011 ENCePP submitted a number of formal responses to public consultations by the European Commission, notably an ENCePP position paper on personal data protection in the EU, a position on the interpretation on non-interventional trials, and an ENCePP response on the concept paper on the revision of the Clinical Trials Directive 2001/20/EC.

Last, but not least, the ENCePP Code of Conduct for transparent and independent pharmacoepidemiology and pharmacovigilance studies - first released in 2010 – was revised to facilitate the conduct of studies following the Code. The main outcomes of the review include a revision of the guidance for sharing ENCePP Study data, specific provisions for publicly funded studies and the introduction of a declaration of interests form. While maintaining the objectives of independence and transparency, the revisions to the Code should make it easier for investigators to apply for the ENCePP Study seal as a number of perceived barriers to doing so have now been removed.

The new ENCePP Steering Group took up its two-year mandate in November 2011. The group consists of a total of 16 members, six of whom have been elected by and from among ENCePP partners.

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Meetings and Networking

The ENCePP Secretariat organised two ENCePP Plenary meetings in June and November respectively; meetings of all three Working Groups took place in the margins of both plenary meetings. The Steering Group met three times in 2011. Minutes of the Plenary and Steering Group meetings are published on the ENCePP website.

Following on from the success of the first such event in 2010, a second "ENCePP Info Day" was held in November 2011 in collaboration with DIA. The objective of the event was to familiarise the audience – mostly pharmaceutical industry staff - with the key ENCePP principles and associated tools and their applicability throughout the whole research process.

In June 2011 a workshop with medical journal editors took place with the aim of introducing ENCePP and its key principles to journal editors. The feedback from the editors, particularly with regard to study transparency not jeopardising peer-reviewed publication, was very encouraging and it was agreed to organise another workshop in 2012.

The ENCePP website was enhanced by the inclusion of a Q&A-section providing answers to the most frequently asked questions about ENCePP and its key principles. A new process has been put in place to facilitate interaction between ENCePP partners and third parties, including pharmaceutical companies. The new process foresees that third parties can place an announcement (e.g. requests with regards to specific needs to conduct post authorisation studies) on the ENCePP Partners' Forum, which is accessible to ENCePP partners only.

To promote the network further, ENCePP was presented at a number of international fora, most notably at various worldwide DIA events, ICPE (International Conference on Pharmacoepidemiology and Therapeutic Risk Management), ISoP and ISPOR.

Two articles were published in peer reviewed journals:

- *European Medicines Agency review of post-authorisation studies with implications for the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance*; Pharmacoepidemiology and Drug Safety, Volume 20, Issue 10, pages 1021–1029, October 2011.
- *The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance: application to diabetes and vascular disease*; British Journal of Diabetes & Vascular Disease, Volume 11 Issue 6 December 2011 pp. 301–304.

ENCePP Impact Evaluation

One of the deliverables of the ENCePP Work Plan 2011-2012 is a strategy to be used in an ongoing impact analysis aimed at measuring the impact of ENCePP on current research practices and on regulatory activities. In May 2011 the ENCePP Steering Group adopted the 'Concept paper on the proposed strategy for the impact evaluation of ENCePP'. A second milestone was the preparation of summary quantitative outcome measures relating to research capacity building.

The adopted ENCePP strategy for impact evaluation has identified the number of resources (centres, networks & data sources) within the ENCePP database of research resources as a key metric in terms of success in capacity building. Other metrics include various aspects of the resources contained in the database such as the geographical distribution of ENCePP Centres across Europe, the classification of ENCePP Centres in terms of sources of funding, the resources available in ENCePP Centres in terms of personnel/expertise, the therapeutic areas of interest of the centres, the experience of the centres with different types of study design and the data collection resources within centres.

By end December 2011, the number of Centres and Networks in the ENCePP database stood at 99 (*75*) and 13 (*11*), respectively and the number of data sources at 20 (*11*) from 17 different European countries. The figures in brackets and italics are the corresponding numbers as of 15 November 2010. The characteristics of the 99 ENCePP Centres in the database are described in figures 1 – 5.

Figure 1: Classification of centres

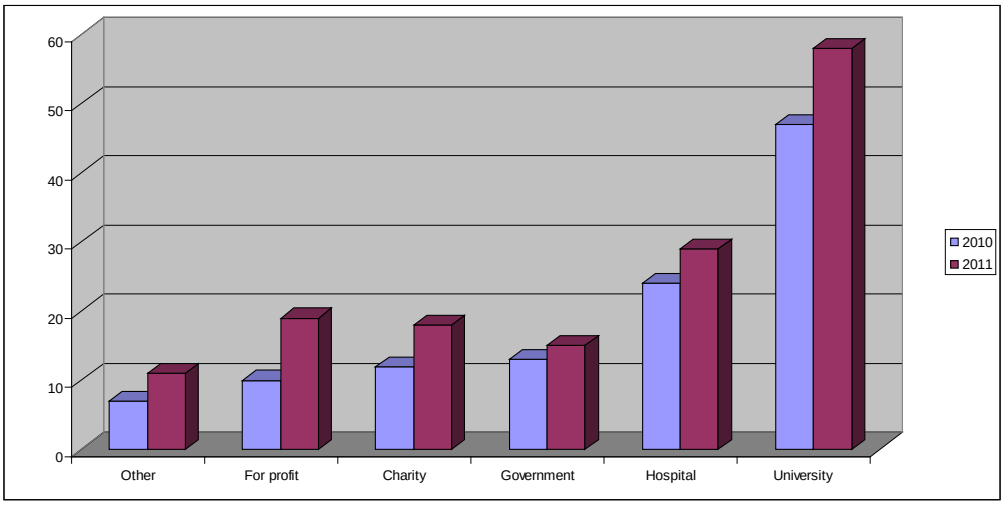


Figure 2: Resources available to centres

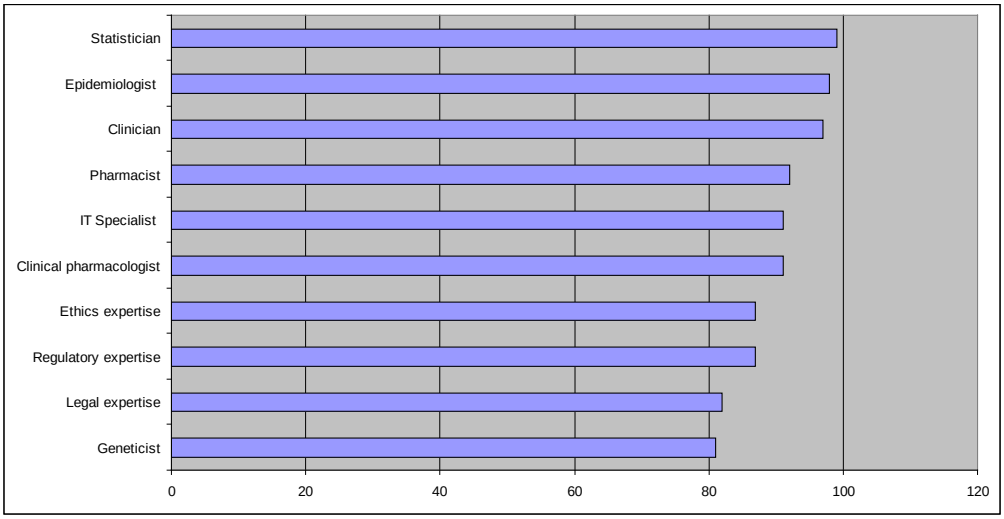


Figure 3: Experience with study designs

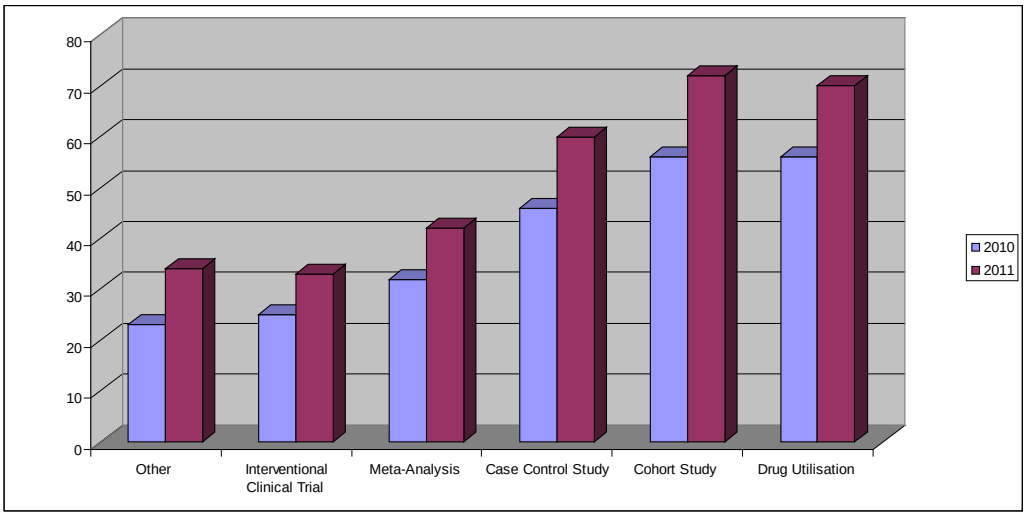


Figure 4: Experience in research collaboration

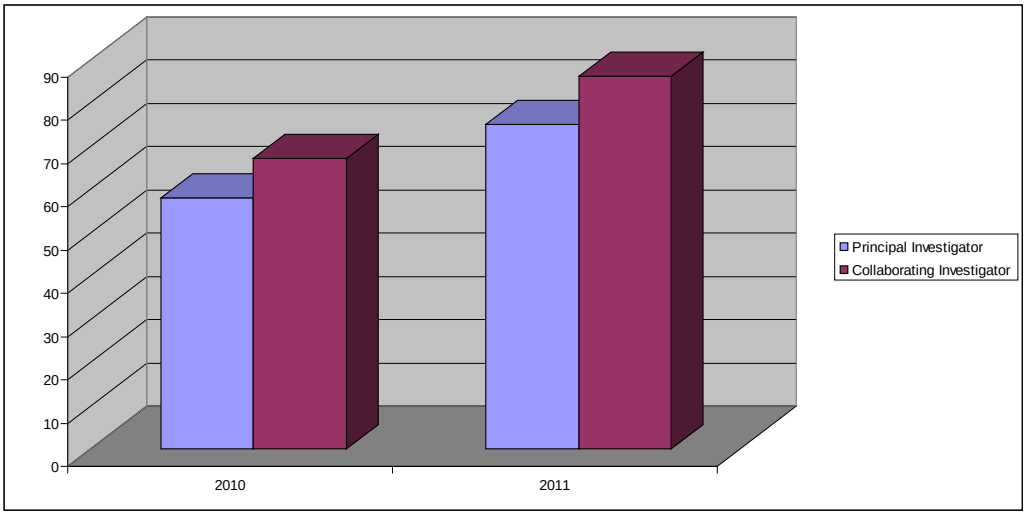
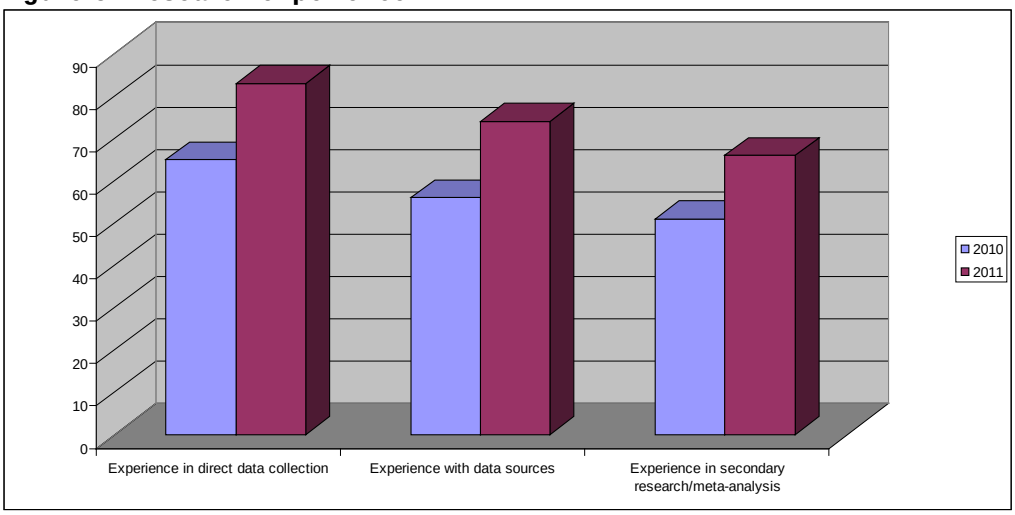


Figure 5: Research experience



Finally, the number of registrations in the ENCePP E-Register of Studies has risen from 9 to 20 between January and December 2011, whereby 6 of these studies have been awarded the ENCePP study seal.