



ENCePP: Where are we and where are we going?

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Content of this presentation

ENCePP: Where are we?

- What is ENCePP?
- Where are we?
- Guiding principles
- Main deliverables achieved

Where are we going?

- The Work-plan for 2011-2012
- How ENCePP will change the way we work

What is ENCePP?

•An EMA led initiative

 Bringing together the available expertise in the fields of pharmacovigilance & pharmacoepidemiology

•Further strengthening of post-authorisation monitoring of medicinal products in Europe

Facilitating conduct of post-authorisation safety studies





Where are we?

- 89 Centres
- 13 Networks
- 13 Datasources

from 17 different European countries

Data as of 26 May 2011



ENCePP Guiding Principles

Independence

Roles and responsibilities of stakeholders
Freedom to publish results (-ve and +ve)



Code of Conduct

Standards

Stimulate consideration of important methodological principles in design of studies



Checklist & Guide of Methodological Standards

Transparency

Registration of studies

Publication of protocols and results



Resources Database & E-Register of Studies



2010: latest developments

- Code of Conduct
 - ✓ Implementing Rules on access to data
- Checklist of methodological standards
- Public online databases
 - ✓ Inventory of research resources
 - ✓ E-Register of studies



→ ENCePP Studies



The ENCePP Code of Conduct: rationale

Transparency on roles and responsibilities and on the details of the design and the conduct of studies is a cornerstone in building trust and confidence.

There is a need to have clarity of roles and responsibilities in studies.

It is recognised that there are areas in Pharmacoepidemiology and Pharmacovigilance research which would benefit from a higher level of openness, communication and accountability.



The ENCePP Code of Conduct

... provides a set of principles and rules for the conduct of studies to maximise transparency and promote scientific independence throughout the research process...

...is a "charter of rights and obligations" covering essential aspects of the study conduct and outcome...



The ENCePP Checklist of Standards

Purpose is to improve the quality of studies by stimulating consideration of important epidemiological principles for designing a study and writing a protocol

Intention is to promote quality, not uniformity

Innovation and new methods welcomed so some questions may be N/A



The ENCePP Checklist of Standards

Provides for high level information on whether accepted standards and good practice are addressed in the study protocol, in a simplified and condensed way.

Enables easy tracking of the location in the Study Protocol where the MRS are addressed

Promotes the application and implementation of the agreed MRS.

ENCePP Guide on methodological standards

Single overview document and web resource gathering:

- •an overview of internationally acknowledged recommendations,
- key points from other existing English-language guidelines and standards in pharmacoepidemiology, and
- directions for learning on study design and methods.

The intention is not to duplicate the text from existing guidelines and textbooks.

→ Travel guide

ENCePP Database of Resources

Database describing resources in ENCePP and facilitating searches.

available to the general public

offers information on the available sources of expertise and research experience across Europe

for both study sponsors and researchers seeking to identify collaborations for the conduct of specific pharmacoepidemiology and pharmacovigilance studies in Europe

linked to ENCePP e-register of studies

ENCePP e-register of studies

A free, publicly accessible resource for the registration of studies, <u>primarily</u> post authorisation safety studies.

Its aim is to:

- ✓ Increase transparency
- ✓ Reduce publication bias
- ✓ Promote information exchange
- ✓ Facilitate collaborations within the scientific community

ENCePP Studies

To reinforce confidence of:

- ✓ public
- ✓ other researchers
- √ regulators

that research done under the ENCePP "seal" is as far as possible free from biases and commercial, financial and personal influences.

CoRe requirements for ENCePP Studies

Lead investigator from ENCePP Resources Database



The "CoRe requirements" are met:

- ENCePP Code of Conduct
 - √ Signed declaration & checklist





- Methodological standards for ENCePP study protocols
 - ✓ signed checklist



- e-<u>register</u> of studies
 - ✓ prior to study start



ENCePP Seal

If all CoRe requirements are successfully met, the study will be awarded the title of ENCePP study:



a **Seal** will be displayed next to the study in the e-register of studies

The seal places additional obligations on investigators of ENCePP studies:

- Full protocol (original and final) publicly available after the final study report
- Timely (deadline) publication/report of summary of study results
- Subsequent full report/publication of all results

ENCePP Studies

4 Studies found

Status	Official Title	Lead Investigator	Last Updated
Ongoing	International Active Surveillance study - Folate and Oral Contraceptive Utilization Study	Dr Juergen Dinger	03/01/2011
Planned	Impact of risk minimisation in patients treated with rosiglitazone-containing products	Professor Henrik Toft Sørensen	15/02/2011
Planned	International Active Surveillance Study of Women Taking Dienogest for Endometriosis: Visanne Post-approval Observational Study	Dr Juergen Dinger	03/01/2011
Planned	Long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD) - a cohort study based on health information systems in three Italian regions.	Dr Nera Agabiti	27/10/2010

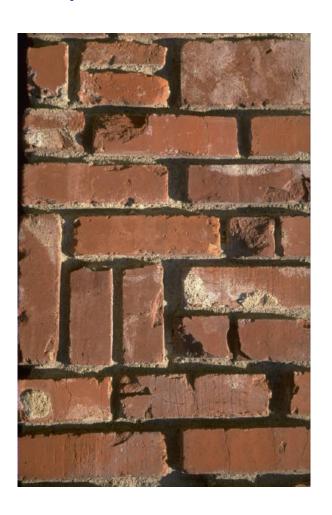
2 other applications under evaluation

Workplan 2011-2012: Main goal and objectives

Building on the initial phase of establishment, the priority will be to consolidate ENCePP as an important and internationally renowned resource in the field of pharmacovigilance and pharmacoepidemiology that delivers for health protection and promotion.

Additionally, during this work plan period, work will be initiated to broaden the scope of the network to further cover health outcome research.

Workplan 2011-2012: Consolidating practice



Review of the Code of Conduct

•After 1 year from its adoption or 15 applications for ENCePP Seal

Review of the Checklist of Methodological Standards for ENCePP Study Protocols

•After 1 year from its adoption or 15 applications for ENCePP Seal

Publication and dissemination of the Guide on Methodological Standards in Pharmacoepidemiology

Adopted and published in May 2011

Workplan 2011-2012: Developing policies

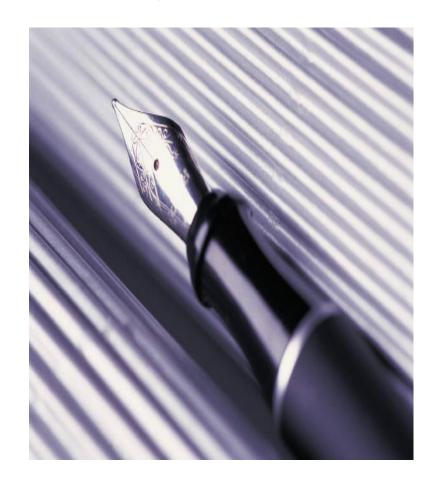
Approaches to facilitate the conduct of multinational studies in light of existing differences in data privacy laws across the EU

•ENCePP Response to Public Consultation on the Commission's comprehensive approach on personal data protection in the European Union

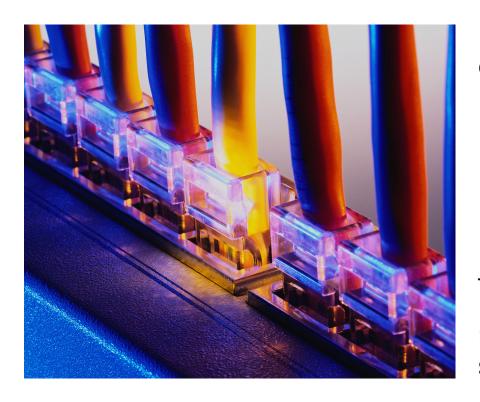
Definition/interpretation of the definition of non interventional trials

- •Within the current legislative framework → position paper developed by a dedicated task force
- •In response to the EC Consultation on the revision of CT Directive 2001/20/EC \rightarrow ENCePP response submitted and published in May 2011

Exploring the merits of developing an accreditation system and its features.



Workplan 2011-2012: Optimising database use



Further development of the ENCePP databases to include:

- oversight of post-authorisation studies
- Consider the needs of HTA bodies
- exploring possible use by EnprEMA

To ensure that the ENCePP e-Register of Studies informs any international discussions on standardisation of data fields.

Workplan 2011-2012:consolidating the network

Devise a strategy to measure the impact of ENCePP on current research practices and on regulatory activities

Ensure visibility of the network through participation in international conferences, symposia

- 2nd ENCePP Infoday to be held at EMA on
- 7 November 2011



Workplan 2011-2012: Resources



ENCePP Secretariat

ENCePP Steering Group

Working groups:

- 1. Research standards & guidance
- 2.Independence & transparency
- 3.Inventory of EU data sources and methodological approaches for multi-source studies

Ad-hoc task forces:

- -Access to data
- -Definition of non-interventional trials

How ENCePP will change the way we work

ENCePP Resources database – builds capacity, helps identify the best resource

ENCePP studies database - a resource for non-interventional studies to be registered:

- Protocols
- Results

ENCePP studies database: a global resource for non-interventional studies



For more information/questions

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