Il Network ENCePP EMA

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ENCePP EMA
un po di storia

Analysis of needs

Ability to do pro-active Pharmacovigilance	**Pharmacovigilance**
Ability to do high quality Pharmacoepidemiology studies	**Pharmacoepidemiology**
Increase research capacity and awareness	**Centres**
Ability to do studies in different EU countries	**European**
Ability to do multicentre studies across Europe	**Network**

What is ENCePP ?

An EMEA-led project

bringing together expertise in the fields of PhEpi and PhV scattered across Europe

The Aim

Strengthen further the post-authorisation monitoring of medicinal products in Europe

facilitate post authorisation studies:

- high quality
- Independent
- multi-centre

ENCePP history

2006 Initial contacts with stakeholders (big pharma, existing networks, academics…).

2007 contacted numerous research institutions, held 1st meeting.

Objectives:

- Achieve general agreement on network concept
- Discuss and agree Working Model
- Identify priority actions of the project
- Establish corresponding Working Groups

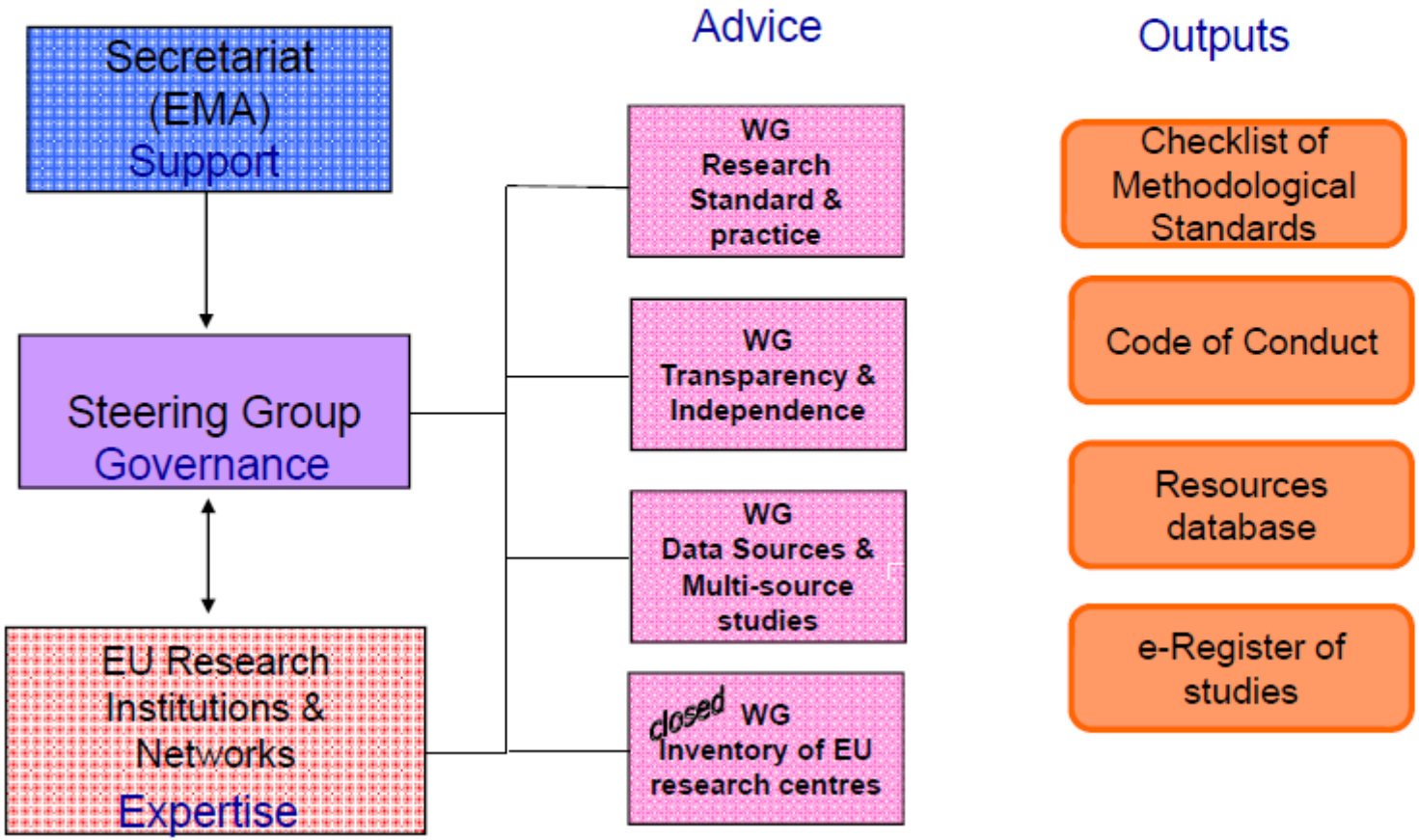
ENCePP History

Main conclusions of meeting

- EMEA to lead and administer ENCePP
- Not overly bureaucratic; no “standing” rigid structure but flexible network,
- Identify existing EU centres and data sources
- Ensure Independence and Transparency (Code of Conduct as opposed to a template contract)
- Define quality standards and develop new Ph’Epi methodologies
- Initially: Self-accreditation + peer-review

2008 Established mandate of ENCePP, ENCIAG, 4 working groups

Structure of ENCePP



ENCePP EMA

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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

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…

European Medicines Agency

London, 13 November 2009
Doc. Ref. EMEA/489873/2008

The ENCePP Code of Conduct

FOR SCIENTIFIC INDEPENDENCE AND TRANSPARENCY IN THE CONDUCT OF PHARMACOEPIDEMIOLOGICAL & PHARMACOVIGILANCE STUDIES

Draft for public Consultation

The ENCePP Code of Conduct was adopted on --/--/---- by the European Medicines Agency (EMEA) and the participants of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The terms of the Code of Conduct will be reviewed periodically after its adoption.

Steps taken

Key elements of the Code of Conduct agreed by the ENCePP Working Group on *Independence and Transparency*	21 November 2008
1st draft Code of Conduct agreed by Drafting Group of the ENCePP Code of Conduct	8 May 2009
2nd draft Code of Conduct agreed by ENCePP Working Group on *Independence and Transparency*	17 June 2009
Final draft Code of Conduct approved by ENCePP Implementation Advisory Group	27 October 2009
Public consultation	*16 November 2009 – 5 January 2010*
Adoption of the Code	--/--/----

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

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SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

1 5 November 2010
2 EMA/95098/2010
3 Patient Health Protection

4 ENCePP Guide on Methodological Standards in 5 Pharmacoepidemiology

6

Step	Date
Agreed by ENCePP Working Group 1	4th October 2010
Peer Review	4th – 15th October 2010
Adoption by ENCePP Steering Group for release for consultation	21st October 2010
End of consultation (deadline for comments)	3rd January 2011

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il registro studi osservazionali

ENCePP … PAS

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ENCePP E-Register ➲ EU PAS Register

- GVP Module VIII B.4: EU electronic register of post-authorisation studies (EU PAS Register) maintained by the Agency accessible via European medicines web-portal
- Building on the development of the ENCePP E-Register by Working Group 2, and the subsequent experience of EMA in maintaining the E-Register, the proposal now is that the E-Register also serves as the EU PAS Register to meet regulatory requirements in relation to non-interventional post-authorisation studies.
- E-Register fields to be updated (mostly new ones added re. tracking etc) - requirements of legislation and WHO TRDS for ICTRP status but guiding principles remain transparency and independence
- ENCePP E-/EU PAS Register as *THE* register for observational studies

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situazione attuale e sviluppi

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ENCePP networks within the network

- ENCePP now 108 centres, 14 networks, 24 data sources
- All 6 EMA contracted studies and 9 out of 10 EC FP7 funded consortia coordinated by investigators from ENCePP
- Unclear to what extent being in ENCePP has contributed
- **Problem:** *how ENCePP might be optimised to further translate into strategic sub-networks for collaborative research?*

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for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 11 October 2012

Presented by: Stella Blackburn

In this presentation

- Key deliverables – ENCePP Work Plan 2013-2014
- ENCePP HTA task force
- ENCePP guidance on data integration of pooling of studies
- Revision to plenary mandate to promote ENCePP
- ENCePP contribution to the scientific research agenda of any future public private partnership that follows IMI
- ENCePP plenary dates 2013

ENCePP Work Plan 2013-2014
Key deliverables: Evolution

- Managing the transition to the new PhV legislation and GVP, including review of relevant ENCePP documents.
- Promoting pharmaceutical industry understanding of the ENCePP study concept to increase the uptake of the ENCePP study seal.
- Promoting public registration of non-interventional studies, including from outside Europe.
- Exploring inclusion of non-EU research centres and networks in ENCePP.

ENCePP Work Plan 2013-2014
Key deliverables: Development

- Optimising ENCePP's contribution to monitoring of drug safety in special populations (e.g. paediatrics, elderly, pregnancy).
- Development of ad-hoc special interest groups, including on drug utilisation, based on suggestions from the ENCePP community.
- Further investigate potential for cooperation with other sources of healthcare data.
- Progressing the scope of ENCePP in terms of delivering data and information for health technology assessment.

ENCePP Work Plan 2013-2014
Key deliverables: Guidelines and Standards

- Development of a stand-alone *ENCePP Guide on Data Integration and Pooling of Studies*.
- Development of guidance for multi-source pharmacoepidemiology research in light of data privacy legislation.
- Development of ENCePP methodological guidance on efficacy research in every-day clinical practice.

ENCePP Work Plan 2013-2014
Key deliverables: Advocacy

- Continued representation of ENCePP non-interventional researchers when developments in policy, legal and societal change.
- Keeping up to date with the revision of EU data protection rules and provide expert input to legal rules or guidance relevant to ENCePP mandate.

ENCePP HTA Task Force

- ENCePP HTA Survey (May 2012)
  - Very good response rate reflecting experience in HTA
  - A number of partners interested in joining in a **leading role**

- Next steps:
  - **Inaugural meeting** (in margins of plenary meeting 11/10/2012)
    - Election of Chair
    - Drafting of mandate

ENCePP guide on data integration & pooling of studies

- Agreement for stand-alone guidance
- Drafting Group to be formed
  - Nawab Qizilbash has agreed to Chair the group
  - Susana Perez-Gutthann and Miriam Sturkenboom are SG Sponsors

Volunteers with relevant expertise will be sought shortly

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The way ahead …

ENCePP EMA dove siamo?

- Un Network di Centri Europei?
- Buona l’idea di costruire una Directory per dare visibilità ai Centri e dare rilevanza al field pharmacoepidemiology
- Utile il prossimo registro degli studi PAS/(ENCePP)
- Molto limitato il networking e il lavorare su studi di valutazione di rischi emergenti
- Nullo ancora il lavoro svolto a supporto degli organismi decisionali e la committenza ricevuta

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il committment … gli impegni

The Statement

"We are an ENCePP Centre, part of the ENCePP collaborative scientific network coordinated by the European Medicines Agency.

We are dedicated to following the ENCePP Code of Conduct to promote scientific independence and transparency and to adhere to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology.

We publish in the ENCePP E-Register of Studies, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies."

The ENCePP Logo

- The ENCePP logo will be provided for download in different formats (jpg, tif, eps, png) to accompany the website statement.
- The logo may also be used in presentations.
- A disclaimer is added:

  The ENCePP logo has been created by and is the exclusive property of the European Medicines Agency (EMA). ENCePP partners are permitted to use the ENCePP logo on their website in connection with the statement or in presentations. Its use by third parties is prohibited without the prior written permission of the ENCePP Secretariat (on behalf of EMA).

The statements in comparison

"We are an ENCePP Centre, part of the ENCePP collaborative scientific network coordinated by the European Medicines Agency.

We are dedicated to following the ENCePP Code of Conduct to promote scientific independence and transparency and to adhere to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology.

We publish in the ENCePP E-Register of Studies, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies."

"We are a partner centre of the ENCePP collaborative scientific network which is coordinated by the European Medicines Agency.

We are dedicated in the research we undertake to following the ENCePP Code of Conduct and obtaining the ENCePP Study seal that indicates scientific independence and transparency.

We register studies in the ENCePP E-Register of Studies, a publicly accessible resource for the registration of pharmacoepidemiological and pharmacovigilance studies."

Commitment of one study/year

The use of the statement & the ENCePP logo will be reflected in a commitment to **register at least one study per year in the ENCePP Register** in line with the proposed statement and the spirit of ENCePP as reflected in the amended Plenary mandate.