EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

EMA/150117/2014 Rev.1
ENCePP Secretariat

ENCePP Work Plan 2015 - 2016

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Adopted by the ENCePP Steering Group on 05/03/2015

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1. Introduction

The European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) is a collaborative scientific network coordinated by the European Medicines Agency. The network was developed in collaboration with European experts to further strengthen the post-authorisation monitoring of medicinal products. ENCePP fosters high quality pharmacoepiemiology and pharmacovigilance research for the benefit of public health by promoting best methodological and governance practices through guidance and standards. ENCePP is globally acknowledged for its expertise and outputs and being part of ENCePP means and being part a unique opportunity to shape observational research in pharmacoepidemiology.

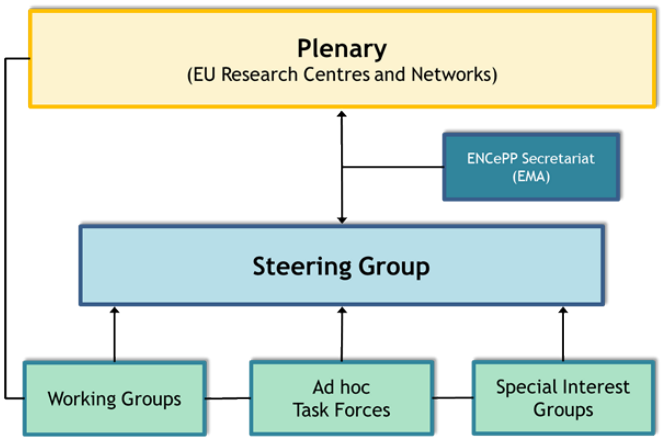
The ENCePP Work Plan organises the activities of the network including those of the Secretariat, the Steering Group and Working Groups, in line with the overall goals of ENCePP and taking account of EMA Work Programmes.

The present ENCePP Work Plan defines the objectives, deliverables and milestones for the years 2015-16 in the context of the continued development of the network in a structured and timely manner.

2. ENCePP Working Model

The working model of the network consists of the following elements:

- **ENCePP Plenary**: The totality of representatives from registered research centres and networks/collaborations; the plenary meets once yearly at the European Medicines Agency (EMA)
- **ENCePP Steering Group**: The Steering Group oversees the network
- **ENCePP Secretariat**: Supports the operational and administrative work of the Steering Group; the Secretariat has been established by the European Medicines Agency
- **Working groups**: To operationalise the relevant expertise within ENCePP, there is a rolling programme of working groups and ad hoc task forces to which ENCePP partners contribute on a voluntary basis
- **Special interest groups**: ENCePP fosters the development of internal networks based around a shared interest in particular topics



3. Background and current status

Consolidation of the network as an important resource in the field of post-authorisation monitoring of medicines was the overarching goal of the ENCePP Work Plan2013 – 2014. The particular aims were on the optimisation of the network, including capacity building and resource efficiency, and on delivering studies that support regulatory decision-making.

3.1. Overview of deliverables and milestones achieved from ENCePP Work Plan 2013-2014

Deliverable	Comment / Milestones achieved
Managing the transition to the new pharmacovigilance legislation and Guideline on good pharmacovigilance practices (GVP), including review of main ENCePP documents and supporting regulatory decision making with best evidence.	• 3rd revision of the ENCePP Guide on Methodological Standards including a new section on vaccines and more detail on efficacy methods. This revision was published as HMTL web pages on ENCePP website (July 2013). • 3rd (editorial) revision of ENCePP Code of Conduct adopted by Steering Group and published on ENCePP website (March 2014). • Revision 2 of Checklist for Study Protocols adopted by ENCePP Steering Group and published on ENCePP website (January 2013). • Ongoing review of ENCePP support to EMA Committees in terms of providing evidence to support regulatory decision-making. • Link placed on ENCePP homepage to signals discussed by PRAC published on EMA website (October 2013). • Information on website relating to ENCePP Study Seal and E-Register/EU PAS Register reviewed and updated (Jan/Feb 2014).
Promotion of the ENCePP Study Seal concept to increase uptake, including by the ENCePP community and the pharmaceutical industry.	• Ongoing maintenance of list of ENCePP centres indicating the number of registered studies and of seal applications per centre, including whether studies sponsored by a MAH. • Survey of ENCePP centres regarding uptake of the ENCePP Seal; results were taken into account in the 3rd (editorial) revision of the Code of Conduct. • ENCePP survey of industry to obtain feedback on industry's perception of ENCePP and the use of its outputs (March/April 2013). Results were presented to industry (May 2013) and the ENCePP Plenary (June 2013). • Meeting with representatives from industry associations; meeting report published (May 2013). • Agreement by SG to proposal of adding additional fields in ENCePP resources database to allow centres to indicate existing accreditations and quality standards; implementation pending (February 2014).

Deliverable	Comment / Milestones achieved
Development of a stand-alone ENCePP Guide on Data Integration and Pooling of Studies.	• Systematic review of existing guidances completed. • Draft guidance document under development by the WG on data integration with input from WG1. Anticipated for public consultation Q2 2015.
Map current practice for multi-source (two or more) pharmacoepidemiology studies, including methodological approaches.	• Report on current practice based on 2012 survey of EMA/EC funded research published on ENCePP website (Q4 2014).
Develop an impact analysis of national data privacy legislation on the conduct of multi-national (two or more Member States) pharmacoepidemiology studies.	• Results of ENCePP survey of EU Member States on national legal requirements on data protection published on ENCePP website (July 2013).
Continued input to developments in policy, legal and societal change that impact on research, including network responses to public or other consultations.	• Ongoing monitoring of developments and liaising with external organisations including ISPE/ISoP/FDA/Pharmaceutical Industry/EC/IMI. • Submission of response to EC public consultation on post-authorisation efficacy studies (PAES) (February 2013) by the ENCePP HTA WG.
Keeping up to date with the revision of EU data protection rules with expert input to legal rules or guidance considered relevant to the ENCePP mandate.	• Ongoing monitoring of progress of the revision of the EU data protection rules.
Provide a forum of academics and service providers for consultation as appropriate to support the development of guidance by ENCePP, EMA and EUnetHTA, including on post-authorisation efficacy studies, on post-authorisation safety studies and health technology assessment.	• Further consolidation of the ENCePP HTA Working Group established Q4 2012 & revision of mandate • Presentation on ENCePP HTA working group at ISPOR (November 2013) and poster presentations by the WG at ICPE (October 2014) and ISPOR (November 2014)
Capacity building on the conduct of studies that bridge to meet the requirements of medicines regulators and health technology assessment bodies.	• Survey of ENCePP partners on the: 1. experience the members of the WG / ENCePP have in conducting research activities for HTA; 2. resources their centres can provide; 3. specific training needs for HTA (Q2 2014).
Development of virtual ad-hoc special interest groups (e.g. paediatric, the elderly, pregnant women, drug utilisation) based on suggestions from the ENCePP community.	• Establishment of a special interest group (SIG) on drug safety in pregnancy; adoption of SIG mandate by ENCePP SG and publication on ENCePP website (June 2014)
Further investigate potential for cooperation with other sources of healthcare data.	• Significant increase in number of registered data sources in ENCePP database of research resources
On-going impact analysis of ENCePP on current research practices and on regulatory activities.	• Quantitative measures relating to resources in ENCePP and capacity building and qualitative outcome measures using multiple sources have been included in annual activity reports published in December 2012 and December 2013.
Promotion of ENCePP and its principles, including participation in international conferences, symposia.	• Meetings with European Medical Information Framework (EMIF) and European CRO Federation (EUCROF) exploring synergies and possible collaboration.

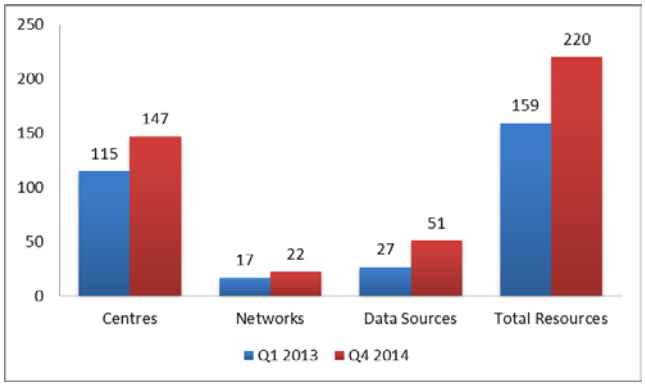
Deliverable	Comment / Milestones achieved
	ENCePP presentations at: • DIA EuroMeeting, Amsterdam (March 2013) • ICPE, Montreal (August 2013) [POSTER] • EACPT Conference, Geneva (August 2013) • ISPOR, Dublin (November 2013) [HTA Working Group – poster & workshop] • Conference of the South-Asia Chapter of American College of Clinical Pharmacology, Mumbai (April 2014) • ICPE, Taiwan (October 2014) [HTA Working Group – poster] • ISPOR, Amsterdam (November 2014) [HTA Working Group – poster] ENCePP participation in: • US DIA, Boston (June 2013) [EMA booth]

3.2. Other Achievements 2013-2014

- Organisation of three Plenary meetings:
  - 18 June 2013
  - 12 November 2013
  - 25 November 2014.
- Calls for information and experts from ENCePP partners (support to referrals at the Pharmacovigilance Risk Assessment Committee).
- Establishment of Enpr-EMA - ENCePP Working Group on paediatric pharmacovigilance (September 2013).
- Liaison with Enpr-EMA regarding definition of AE severity in paediatric clinical trials.
- Election of a new ENCePP Steering Group for the 2014-2016 term.

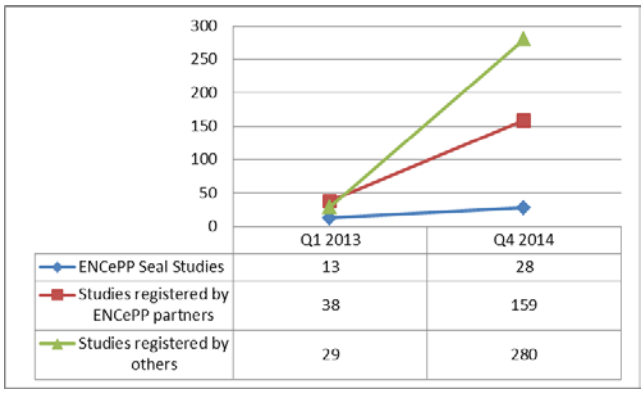
3.3. Number of research resources in ENCePP database (2013-2014)

Figure 1: Number of research resources in ENCePP database - *as of 23/12/2014*



3.4. Number of studies in E-Register of Studies / EU PAS Register (2013-2014)

Figure 2: Number of studies registered in E-Register (EU PAS Register) – *as of 23/12/2014*



	Q1 2013	Q4 2014
ENCePP Seal Studies	13	28
Studies registered by ENCePP partners	38	159
Studies registered by others	29	280

Figure 3: ENCePP Seal Studies
(as of 23/12/2014)

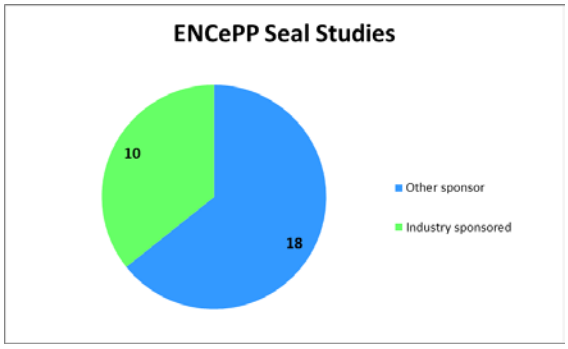
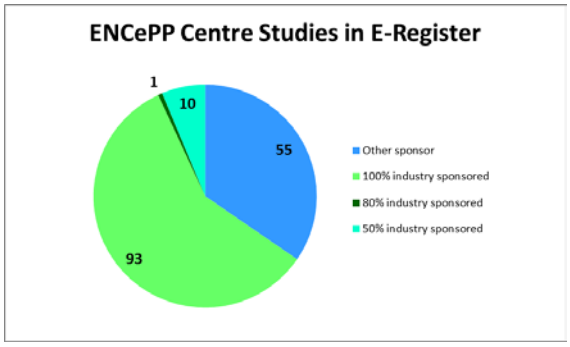


Figure 4: Studies registered by ENCePP partners *(as of 23/12/2014)*



4. Main goal and objectives of the 2015 – 2016 Work Plan

Continuing to consolidate the network as an important resource in the field of post-authorisation research on medicinal products, the focus during 2015 and 2016 will be on extending the scope of the network to support regulatory decision-making across the product life cycle.

This will take ENCePP to the next level as a key provider for data and information for regulatory and health-care decision-making and patients.

4.1. Key objectives

- Develop a more systematic approach to the interface between EMA/Committees and ENCePP.
- ENCePP as a forum for consultation on development of methods and guidance.
- Explore additional models to support the Code of Conduct.
- Promote the ENCePP guiding principles of scientific independence and transparency.
- Development of business pre-requisites to upgrade ENCePP databases in line with legislative developments and stakeholder requirements.

- Monitor impact of public funding on pharmacoepidemiology in the EU.
- Finalise guidance on data integration.
- On-going review of existing ENCePP methodological guidances.
- Implement ENCePP Communications Plan.

5. Resources and possible constraints

The delivery of this ENCePP work plan is dependent on the EMA ENCePP budget for each of the years 2015 and 2016. This budget will cover, *inter-alia*, ENCePP Plenary, Steering Group and Working Group meetings.

The achievement of the key deliverables described above requires continued voluntary collaboration within ENCePP, including the exchange of information and knowledge. The Agency shall continue to coordinate the network through the provision of a Secretariat and maintaining ENCePP databases.

The ENCePP Secretariat will ensure timely flow of information and organise the activities of the network, including meetings.

The current ENCePP Working Groups will work according to their agreed mandates and prioritised activities. The ENCePP Secretariat, Senior Agency staff and SG Sponsors will support the Working Groups and will, together with the respective Working Group Chairs, ensure adequate progress. The Working Groups will meet regularly by teleconference or the Agency's interactive meeting tool AdobeConnect®. Subject to the availability of necessary funds, at least one annual face to face meeting per working group will be organised.

A list of current working groups and their mandates may be consulted on the ENCePP website.

The ENCePP SG will meet face to face or virtually on a regular basis (at least quarterly) to oversee the delivery of the outcomes of the various groups.

6. Action plan

See attached table of deliverables.

Deliverables – ENCePP Work Plan 2015-2016

Objective	Deliverable	Working Group	EMA lead SG sponsor	Milestones	Initial deadline
Develop a more systematic approach to the interface between EMA/Committees and ENCePP.	Agency position on researcher's (not limited to ENCePP) sharing data prior to publication.	SG	Kevin Blake n/a	• SG orientation on Agency position document	Q3 2015
	Agency position on ENCePP researchers declaring any interests if (a) data and information submitted to EMA in the context of ongoing procedures, and (b) providing input directly to EMA on methodologies on substance-specific (single drug or class) post-authorisation studies to support regulatory decision-making.	SG	Xavier Kurz Yola Moride	• Develop draft concept paper • Presentation of draft concept paper to SG • Finalise and publish Agency position	Q2 2015 Q3 2015 Q1 2016
	Review of available ENCePP resources in database (filter by speciality).	SG	Thomas Goedecke Morten Andersen	• Report from ENCePP Secretariat including sub-list of ENCePP data sources • Process for gathering additional information to evaluate the access and availability of data sources for regulatory needs	Q2 2015 Q2 2016
	Define an ENCePP mandate considering extension of scope beyond post-authorisation.	SG	Peter Arlett	• Concept paper EMA/SG	Q4 2016
ENCePP as a forum for consultation on development of methods and guidance	Approach to validating impact of results from methodology research projects using PROTECT as an example.	SG	Xavier Kurz Marieke de Bruin	• Draft report to SG	Q3 2015
	Input to EMA strategy on registries (on standard protocols, data fields, governance).	WG1	Xavier Kurz Susana Perez-Gutthann	• Draft EMA strategy on registries	Q4 2015
	Input to EMA guidance on special populations,	Enpr-EMA	Xavier Kurz	• Revision of the paediatric	Ongoing

Objective	Deliverable	Working Group	EMA lead SG sponsor	Milestones	Initial deadline
	including paediatrics and pregnancy.	/ENCePP WG SIG Pregnancy	Corinne de Vries	pharmacovigilance guidance • Update of overview of data sources for drug safety in pregnancy research	Q3 2015
	Methodological input to PRAC strategy on measuring impact of PhV activities	SIG Impact	Thomas Goedecke Marieke de Bruin	• Set up ENCePP Special Interest Group (SIG) 'Impact' • Report on data sources and methods to measure impact and health outcomes of PhV activities	Q1 2016 Q4 2016
Explore additional models to support the Code of Conduct.	Assessment of the need to supplement the Code with additional tools to support good governance e.g. joint PASS, joint registries, other partnerships, such as Enpr-EMA, on the basis of research funding models.	WG2	Thomas Goedecke Morten Andersen Tom MacDonald	• Draft paper based on existing WG2 concept paper on research funding route for industry with focus on pregnancy (e.g. pregnancy as pilot) • Draft paper on central mechanism for voluntary industry funded studies • Paper on potential governance models taking account of the survey of ENCePP centres, funding models and of other developments (e.g. ADVANCE)	Q1 2016 Q4 2016 Q4 2016
Promote the ENCePP guiding principles of scientific independence and transparency.	Revision of Q&A clarifying the issues identified in the 2014 ENCePP survey.	WG2	Thomas Goedecke Morten Andersen	• Publication of updated Q&A	Q3 2015
Development of	Business case for upgrade of functionality of	WG2	Thomas Goedecke	• Standing item on SG agendas to	Q3 2015

Objective	Deliverable	Working Group	EMA lead SG sponsor	Milestones	Initial deadline
business pre-requisites to upgrade ENCePP databases in line with legislative developments and stakeholder requirements.	E-Register/EU PAS Register.		Pierre Engel	update on progress	
	Establish a business case for upgrade of functionality of ENCePP Resources Database.	WG2	Thomas Goedecke Nicholas Moore	• Define and agree business requirements by SG • Draft business case	Q4 2015 Q1 2016
Monitor impact of public funding on pharmacoepidemiology in the EU.	Draft business case for EU public funding for benefit-risk studies post Horizon 2020.	SG	Peter Arlett	• Draft paper for SG consideration	Q4 2016
Finalise guidance on data integration.	Stand-alone guidance on data integration from completed observational studies of safety of medicines.	WG DI	Jim Slattery Nawab Qizilbash	• Public consultation launched • Publication of guidance document	Q2 2015 Q1 2016
On-going review of existing ENCePP methodological guidances.	Gap analysis of existing guidance documents in relation to efficacy and effectiveness, in particular taking account of new guidance on PAES.	WG1	Xavier Kurz Marieke de Bruin	• Gap analysis completed & report to SG	Q2 2016
	Revision of ENCePP Guide on Methodological Standards in Pharmacoepidemiology including possible new chapters on special populations/topics.	WG1	Xavier Kurz Teresa Herdeiro	• Publication of revision 4	Q3 2015
Implement ENCePP Communications Plan.	Define a Communication Plan in line with the agreed 2014 communication priorities.	SG	Thomas Goedecke David Haerry	• Publication of Communication Plan and milestones in line with the communication priorities	Q3 2015