

10 October 2014

ENCePP Working Groups: Report from the Chair¹

Date of last report: February 2014

Working Group:	DATA SOURCES AND MULTI-SOURCE STUDIES
Chairperson:	Miriam Sturkenboom

1. Key deliverables from current ENCePP Work Plan:

KEY DELIVERABLE	MILESTONES	STATUS
Map current practice for multi-source (two or more) pharmacoepidemiology studies, including methodological approaches.	Describe current practice based on 2012 survey of EMA/EC funded research.	Completed Manuscript submitted to PeDS July 2014 notice rejection decision received 07 Oct 2014 largely due to small sample size. Alternative options for publication are being considered.
	Develop and maintain a list of current practice via published research conducted by ENCePP partners.	Superseded by initiatives to encourage ENCePP partners to register studies in the E-Register.
Develop an impact analysis of national data privacy legislation	Consolidate information received in response to May 2012 PhVWP and ENCePP surveys on data	Completed

¹ This report is to be completed twice a year in advance of each biannual ENCePP SG face-to-face meeting, and presented to the SG by the relevant working group Chair. Following endorsement of the report, it shall be published on the ENCePP website.

KEY DELIVERABLE	MILESTONES	STATUS
on the conduct of multi-national (two or more Member States) pharmacoepidemiology studies.	privacy.	
	Draft reflection paper relating national data privacy requirements to pharmacoepidemiology research in practice.	Superseded by publication of results of NUI to PhVWP.
	Publication and dissemination of reflection paper on impact of data privacy on conduct of pharmacoepidemiology research in the EU.	Superseded by publication of survey results on data privacy.
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.	Follow the progress of the revision of the EU data protection rules.	Completed New Regulation adopted by Parliament Mar 2014 now awaiting Council
	Once revised rules adopted, analyse implications for ENCePP.	Ongoing – awaiting legislative process.
	If appropriate, contribute to any implementing technical guidelines.	Ongoing – awaiting legislative process.

2. Summary of activities:

- **Number of meetings & dates:** none
- **Progress Update:**

As detailed in table above.

3. Next steps / Milestones:

- There will be no deliverables for this WG in new work plan, but a watch will be kept on implementing guidelines of the data protection regulation and if it is decided at SG level that expert input by the network is appropriate, then a task force approach may be employed.
- Assessment on the need for further work on pooling multi-source studies may be undertaken during the new work plan period in the context of the ENCePP 2015 – 2016 Work Plan.