

19 February 2014

ENCePP Working Groups: Report from the Chair¹

Inaugural report to new ENCePP Steering Group - 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.	Manuscript being finalised for submission to peer-reviewed journal
	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	Superseded by initiatives to encourage ENCePP partners to register studies in the E-Register.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 on the conduct of multi-national (two or more Member States) pharmacoepidemiology studies.	Consolidate information received in response to May 2012 PhVWP and ENCePP surveys on data privacy.	Completed
	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	Superseded by publication of results of NUI to PhVWP.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	Superseded by publication of survey results on data

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
		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.	Ongoing – delay in legislative process
	Once revised rules adopted, analyse implications for ENCePP.	Ongoing – delay in legislative process
	If appropriate, contribute to any implementing technical guidelines.	Ongoing – delay in legislative process

2. Summary of activities:

- **Number of meetings & dates:** N/A
- **Progress Update:**

As detailed in table above.

3. Next steps / Milestones:

- Major deliverable for now is the submission for publication of the findings of the survey of publicly funded researchers that is being used to map current practice in pooling multi-database studies. A mature draft was circulated 18 February 2014 for final comment by the WG prior to sending to the researchers surveyed for their input. Taking account of EMA internal review the aim is to submit for publication (BMJ Commentary) end March 2014.
- Regarding the General Data Protection Regulation, a summary of the 22/11/2013 Committee report has been tabled for plenary, 1st reading/single reading and is available at <http://www.europarl.europa.eu/oeil/popups/summary.do?id=1324830&t=d&l=en>. From the European Parliament website [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0011\(COD\)#tab-0](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2012/0011(COD)#tab-0) the indicative date for plenary, 1st reading/single reading is **11/03/2014**.
- The number of data sources registered in the ENCePP Resources Database continues to slowly increase and as of 18 February 2014 stood at 49. Of note, there are now several non-EU based resources.