

8 October 2014

## ENCePP Working Groups: Report from the Chair<sup>1</sup>

Date of last report: February 2014

<b>Working Group:</b>	<b>RESEARCH STANDARDS AND GUIDANCES</b>
<b>Chairperson:</b>	Alejandro Arana

### 1. Key deliverables from current ENCePP Work Plan:

KEY DELIVERABLE	WORKING GROUP	MILESTONES	STATUS
<b>Managing the transition to the new pharmacovigilance legislation and Guideline on good pharmacovigilance practices (GVP), including review of CoRe ENCePP documents and supporting regulatory decision making with best evidence.</b>	WG1	Publish 2 <sup>nd</sup> revision of Checklist for Study Protocols.	<b>Completed</b>
	WG2	Establishing a link on ENCePP website to safety signals.	Q1 2013
	WG1	2 <sup>nd</sup> revision of Guide on Methodological Standards including a section on vaccines and expansion on efficacy methods.	<b>Completed</b>
	WG1	3 <sup>rd</sup> revision Guide on Methodological Standards including a section on use of genetic data in pharmacoepidemiologic studies, and expansion on methods on drug exposure/outcome/covariate definition and validation and drug utilization.	<b>Completed</b>
	WG2	3 <sup>rd</sup> revision of the Code of Conduct.	Q3 2014
	Steering Group	Annual review of ENCePP support to EMA Committees in terms of providing evidence to support regulatory decision-making.	Q4 2013
<b>Promotion of the ENCePP Study Seal concept to increase</b>	WG2	Maintain a list(s) of ENCePP centres indicating the number of ENCePP registered studies and of seal applications per centre and the numbers of each	Ongoing

<sup>1</sup> 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	WORKING GROUP	MILESTONES	STATUS
uptake, including by the ENCePP community and the pharmaceutical industry.		sponsored by an MAH.	
	WG2	Survey of ENCePP centres regarding uptake of the seal. Results to be taken into account for the next revision of the Code of Conduct.	Q2 2013
	Steering Group	Meeting with representatives of industry associations.	Q2 2013
	WG1	Report on exploration of the merits of developing an accreditation system and its methodologies	<b>Completed:</b> List of additional data fields for ENCePP Resources database identified, agreed and transmitted to ENCePP Secretariat for implementation.
	n/a	Organisation of ENCePP Information Day taking account of suggestions from industry associations.	Q4 2013
	WG1	Identify training needs for the implementation of the ENCePP standards.	Ongoing
	WG2	Finalising action plan to better monitor/verify compliance of ENCePP studies with the Code.	Q4 2014

## 2. Summary of activities:

- **Number of meetings & dates:** f2f meeting scheduled for 6 November 2014
- **Progress Update:**  
As detailed in table above.

## 3. Next steps / Milestones: