

18 February 2014

ENCePP Working Groups: Report from the Chair¹

Inaugural report to new ENCePP Steering Group – February 2014

Working Group:	INDEPENDENCE AND TRANSPARENCY
Chairperson:	Laura Yates

1. Key deliverables from current ENCePP Work Plan:

KEY DELIVERABLE	WORKING GROUP	MILESTONES	STATUS
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.	WG1	Publish 2 nd revision of Checklist for Study Protocols.	Q1 2013
	WG2	Establish a link on ENCePP website to safety signals.	Completed
	WG1	2 nd revision of Guide on Methodological Standards including a section on vaccines and expansion on efficacy methods.	Q2 2013
	WG2	3 rd (editorial) revision of the Code of Conduct.	Ongoing Rev3 agreed at WG level; SG endorsement pending; publication scheduled Q1 2014.
	Steering Group	Annual review of ENCePP support to EMA Committees in terms of providing evidence to support regulatory decision-making.	Q4 2013
Promotion of the ENCePP Study Seal concept to increase uptake, including by the ENCePP community and the	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 sponsored by an MAH.	Ongoing
	WG2	Survey of ENCePP centres regarding uptake of the seal. Results to be taken into account for the next	Ongoing

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	WORKING GROUP	MILESTONES	STATUS
pharmaceutical industry.		revision of the Code of Conduct.	
	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	Q4 2013
	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.	Q1 2014
	WG2	Finalise action plan to better monitor/verify compliance of ENCePP studies with the Code.	Ongoing
Encouraging public registration of non-interventional studies.	Steering Group	Discuss and agree the level of involvement of non-EU research centres and networks in ENCePP.	Q2 2013
	WG2	Liaison with medical journal editors including submission of material for publication and possibly a follow-up workshop with journal editors.	Carry over to new work plan

2. Summary of activities:

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

As detailed in table above.

3. Next steps / Milestones:

- Finalise and circulate the Survey of ENCePP centres regarding uptake of the ENCePP Study Seal and entry of studies on the E-Register Q1 2014
- Arrange t/c to:
 - Finalise action plan to better monitor/verify compliance of ENCePP studies with the Code Q1/2 2014
 - Review key deliverables in ENCePP work Plan for 2014/2015 Q1/2 2014
- Review of survey results along with numbers of ENCePP Seal studies and use of E-Register by ENCePP Centres Q2/3 2014