22 October 2014

ENCePP Working Groups: Report from the Chair[1]

Date of last report: 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 2nd revision of Checklist for Study Protocols.	Q1 2013
	WG2	Establish a link on ENCePP website to safety signals.	**Completed**
	WG1	2nd revision of Guide on Methodological Standards including a section on vaccines and expansion on efficacy methods.	Q2 2013
	WG2	3rd (editorial) revision of the Code of Conduct.	**Completed**
	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 pharmaceutical industry.	**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 revision of the Code of Conduct.	**Completed**
	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

[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
	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:** 18/03/2014 (TC) and 25/06/2014 (TC); 20/10/2014 (f2f)
- **Progress Update:**

  As detailed in table above.

  Additional progress:

  - A draft work plan 2015-2016 for the working group has been agreed (for consideration in overall ENCePP work plan).
  - July 2014: Invitation to PRAC to submit comments and ideas to gather MS feedback on the EU PAS Register functionalities (current and suggested), to complement feedback received from ENCePP partners during survey of centres. Feedback to be discussed at WG meeting in October.

3. Next steps / Milestones:

- Review of survey results along with numbers of ENCePP Seal studies and use of E-Register by ENCePP Centres

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