17 February 2014

ENCePP Working Groups: Report from the Chair[1]

Inaugural report to the new ENCePP Steering Group – February 2014

Working Group:	**RESEARCH STANDARDS AND GUIDANCES**
Chairperson:	Alejandro Arana

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.	**Completed**
	WG2	Establishing a link on ENCePP website to safety signals.	Q1 2013
	WG1	2nd revision of Guide on Methodological Standards including a section on vaccines and expansion on efficacy methods.	**Completed**
	WG2	3rd 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
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.	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	**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	WORKING GROUP	MILESTONES	STATUS
		methodologies	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.	Initial deadline: Q1 2014
	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:** One TC on Monday, 3 February after our F2F WG meeting
- **Progress Update:**

  As detailed in table above.

  Some training needs for the implementation of the ENCePP standards have been already identified.

  - Members of ENCePP will be encouraged to include and reference the Standards in their teaching activities.
  - We will encourage the Eu2P training partnership to include the ENCePP Standards in their program.
  - Symposiums have been submitted to the 30Th ICPE that will describe the ENCePP standards
  - We are exploring the possibility of promoting Webminars on the topic.

3. Next steps / Milestones:

3rd revision of 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. Q4 2014

Annex:

List of additional data fields relating to self-accreditation (as proposed by WG1)

ANNEX

Proposal for fields for a new tab on the ENCePP Centre database: "Accreditation and quality control".

	Yes	No	Not applicable
1. Has your Centre received an accreditation or award for excellence (e.g. ISO 9001, national accreditation)? If Yes: which one(s):	☐	☐	☐
2. Does your Centre have Standard Operating Procedures or other document on processes for quality control and assurance? If No or Not applicable, use the Additional Comments field below to provide additional information if appropriate If Yes, indicate which ones:	☐	☐	☐
• Project management (e.g. contract management, study set-up/follow-up)	☐	☐	☐
• Document management/safe storage of records	☐	☐	☐
• Database management (e.g. set-up, validation, hosting, maintenance, security systems, back up)	☐	☐	☐
• Data management (e.g. data entry, query management, cleaning, data validation, data transformation)	☐	☐	☐
• Data analysis programming	☐	☐	☐
• Scientific writing and/or review of study materials, reports and manuscripts	☐	☐	☐
• Quality control	☐	☐	☐
• Curriculum vitae of researchers/employees	☐	☐	☐
• Training plans and training records	☐	☐	☐
• Business continuity plan/Disaster recovery plan	☐	☐	☐
• Others (please specify in the Additional Comments field below)	☐	☐	☐
3. How many times has your Centre been audited over the last 5 years: • By a sponsor: • By a regulatory agency:			
4. If your Centre maintains a webpage providing the references to all its scientific publications, please provide the link here:			
5. Additional comments:			