

19 February 2014

ENCePP Working Groups: Report from the Chair¹

Inaugural report to the new ENCePP Steering Group – February 2014

Working Group:	GUIDANCE FOR DATA INTEGRATION
Chairperson:	Nawab Qizilbash

1. Key deliverables from current ENCePP Work Plan:

KEY DELIVERABLE	MILESTONES	STATUS
Development of a stand-alone ENCePP Guide on Data Integration and Pooling of Studies.	Consolidate the membership and scope of the Drafting Group established Q4 2012.	Completed
	Deliver scope document including proposal for expertise to be involved.	Completed
	The Drafting Group to compile and review existing guidances.	Ongoing
	Finalise and publish a guidance document following expert peer review.	Due in Q4 2014

2. Summary of activities:

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

As detailed in table above.

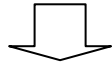
3. Next steps / Milestones:

The WG is progressing well and contributions have been received by the lead author for each section of a guidance. To steer the lead author towards harmonizing the approach in their individual sections, a dedicated reviewer has also been appointed for each section. The group has agreed an aggressive approach to finalising the guidance with at least monthly TCs and the timing of the face-to-face meeting to be decided. At this stage this is most likely once a mature draft has been agreed with input from WG1 for external/public. The aim is to have at least an almost final guide at the time of the next ENCePP Plenary meeting in November 2014.

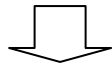
The following are the key steps involved to this end:

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.

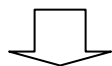
- To continue writing and refining the guidance document



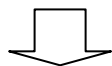
- Contact with other groups involved in developing related guidances: CIOMS, FDA, EFPIA



- Document for internal review by the ENCePP Methods Working Group



- Face-to-face meeting to finalise the guidance document prior to review by others



- Document for review by selected external reviewers