EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

18 March 2015
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ENCePP Secretariat

Minutes - ENCePP Steering Group Meeting

4 March 2015, 15.00 to 17.00 (TC), chaired by Peter Arlett

List of participants	
Present:	Morten Andersen (MA), Peter Arlett (PAR), Ana Corrêa Nunes (ACN), Marieke De Bruin (MDB), Corinne de Vries (CdV), Pierre Engel (PE), Henry Fitt (HF), Teresa Herdeiro (TH), Tom MacDonald (TMD), Viola Macolić Šarinić (VMS), Nicholas Moore (NM), Yola Moride (YM), Susana Perez-Gutthann (SPG) Principal Scientific Adviser to ENCePP SG: Xavier Kurz Statistical Adviser to ENCePP SG: Jim Slattery EMA: Fergus Sweeney (FS) ENCePP Secretariat: Thomas Goedecke (TG), Eeva Rossi, Dagmar Vogl
Apologies:	David Haerry, Nawab Qizilbash, Hubert Leufkens, Patrice Verpillat, Kevin Blake

1. Welcome & Adoption of draft agenda

The agenda was adopted without changes.

2. ENCePP Work Plan

TG presented the main objectives and deliverables of the ENCePP Work Plan 2015-2016 for adoption by the Steering Group.

PAR stated that the work plan should be considered a living document which is likely to undergo further review over the next months. This is due to the need for further discussion at SG level on strategic issues, particularly ENCePP's contribution to regulatory decision-making and interaction of the network with industry. Further discussions are envisaged for the next SG face-to-face meeting.

Subject to some minor editorial amendments, the Work Plan 2015-2016 was adopted by the Steering Group and will be published on the ENCePP website.

3. ENCePP Info Day 2015

TG presented a proposal for the organisation of an '*Information Day on Post-Authorisation Studies (PAS)*'. The event will be organised by DIA in early June 2015 and hosted by EMA. He presented a short summary of the proposed scope of the Info Day which is targeted at industry, academia and CROs as main stakeholders. The objective is to emphasize the benefits of the ENCePP network as an interface between these stakeholders for the conduct of PAS to support regulatory decision-making, while putting this in the context of the regulatory requirements for PAS.

He also invited SG members to express their interest in being a member of the programme committee or participating as chairs or speakers.

There was unanimous agreement by the Steering Group on the proposal, and the majority of SG members offered their support, depending on their availability.

SPG suggested considering to include a presentation on GVP Module VI and adverse event reporting; she also stressed the importance of reaching out to SMEs without dedicated in-house PhEpi resources.

YM suggested including a presentation on health technology assessment (HTA), and the need for adapting protocols according to national HTA requirements for studies requested by PRAC.

4. New Clinical Trial Regulation

FS provided a brief orientation on the new Clinical Trial Regulation (EU) 536/2014, in particular the definition of the terms clinical study, clinical trial, low intervention clinical trial and non-interventional status. He confirmed that the new Regulation will come into force in May 2016 at the earliest, and that this date is dependent on the availability of the EMA clinical trials portal. He also confirmed that the new rules will only apply to new clinical trials started after the coming into force date of the Regulation.

He referred to the Q&A document published by the European Commission which includes an algorithm for determining the clinical trial status of a given study.

During the ensuing discussion concerns were raised over some of the new definitions of the CTR (art. 2) in particular on 'low interventional clinical trial', 'investigational product' and 'non-interventional studies' and the potential impact of them on current PASS conduct and on non-interventional research in general. Additionally PE and SPG emphasized that per the new definition low interventional clinical trial, numerous observational studies capturing primary data collection (e.g Patient Reported Outcomes) will fall under the new CTR. The SG was assured that the issues raised will be raised with those coordinating the implementation of the CTR.

In conclusion it was acknowledged that there is a need for information and training on this topic. In this context it was proposed to provide an update on the new CTR to the ENCePP plenary meeting in November 2015.

5. A.O.B.

None.