EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Work Plan 2011-2012
Next steps for Working Groups

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Work Plan 2011-2012

The Work Plan is the document that defines the objectives and the milestones for the years 2011-2012 in the context of the implementation of the ENCePP network, as well as the means of achieving these objectives in a timely manner.

Work Plan 2011-2012

The Work Plan seeks to organise the work of the main active bodies of ENCePP, namely:

- ENCePP Plenary
- ENCePP Secretariat
- ENCePP Steering Group
- ENCePP Working Groups

Workplan 2010: deliverables achieved

Many important deliverables achieved in 2010:

- ✓ Code of Conduct
  - ✓ Implementing rules on access to data
- ✓ Checklist of methodological standards
- ✓ Guide on methodological standards
- ✓ Fully functional databases:
  - ✓ Inventory of resources
  - ✓ e-register of studies
- ✓Launch of ENCePP Studies and ENCePP Seal

Thanks to the contribution of the Working Groups

Deliverables for 2011-2012

Activities arising from previously achieved deliverables:

- Review of the Code of Conduct
  - ✓After 1 year from its adoption or 15 applications for ENCePP Seal
- Review of Checklist of Methodological Standards for ENCePP Study Protocols
  - ✓After 1 year from its adoption or 15 applications for ENCePP Seal
- Publication and dissemination of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology
  - ✓Ongoing public consultation will end January 2011

Deliverables for 2011-2012

Activities arising from deliverables achieved in 2010:

- Maintenance of the ENCePP databases and possible further developments to include:
  - ✓Overview of Post-authorisation safety studies
  - ✓Interaction with HTA bodies
  - ✓Collaboration with EnprEMA as regards paediatric medicines
- Ensuring that the ENCePP Studies database feeds in as appropriate to any discussions on standardisation of data fields

Deliverables for 2011-2012

Activities aiming at consolidating role of ENCePP:

- Defining the role of ENCePP as regards its interaction with Regulators and in light of the new PhV legislation
- Elaboration of a strategy to be used in an impact analysis
- Development of approaches to facilitate the conduct of multi-national database studies in light of existing differences in data privacy laws across the EU
- Exploring the merits of an accreditation system and its methodologies

Deliverables for 2011-2012

Activities aiming at raising the visibility of ENCePP:

- Developing a relationship with medical journals editors:
  - Meeting with journals editors to be organised by Q2 2011

- Participation in international conferences, symposia,etc.

Workplan 2011-2012 and Working Groups

- Contribution from Working Groups is crucial for the achievement of these deliverables
- Need to reactivate existing Working Groups
- Last call for volunteers plenary meeting June 2010

Workplan 2011-2012 and Working Groups

Working Group 1: ENCePP research standards and guidance

- Review of the Checklist of Methodological Standards for ENCePP Study Protocols

WG to be convened by July 2011 to discuss need for amendments and start drafting revision

Revised version of Checklist to be ready by Q3 2011

Workplan 2011-2012 and Working Groups

Working Group 1: ENCePP research standards and guidance

- Publication and dissemination of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Public consultation ends in January 2011

Final version to be published Q2 2011

- Exploring the merits of an accreditation system and its methodologies

Preliminary discussion at SG level in Q4 2011

Workplan 2011-2012 and Working Groups

Working Group 2: Independence and transparency

- Review of the Code of Conduct

WG to be convened by July 2011 to discuss need for amendments and start drafting revision on the basis of the experience gained

- Specific “task force” on access to investigational data?
- Need to refine provisions for publicly funded studies?

Draft revised version of the CoC to be ready by Q3 2011

Workplan 2011-2012 and Working Groups

Working Group 2: Independence and transparency

Working Group 3: Inventory of EU data sources and methodological approaches for multi-source studies

- Maintenance of the ENCePP databases and possible further developments

Paper outlining possible parallels between ENCePP resources databases and their possible applications in the fields of PASS, HTA and paediatric medicines to be delivered by Q2 2011

Publication of a paper on need for a registry for benefit risk and health outcome monitoring of medicines that will meet the needs of various stakeholders

Possible consultation with the two WGs

Workplan 2011-2012 and Working Groups

Working Group 3: Inventory of EU data sources and methodological approaches for multi-source studies

- Development of approaches to facilitate the conduct of multi-national database studies in light of existing differences in data privacy laws across the EU

Identification of issues and current approaches by Q4 2011

Workplan 2011-2012 and Working Groups

Working Group 3: Inventory of EU data sources and methodological approaches for multi-source studies

- Interaction between ENCePP and Regulators

Paper outlining possible funding options to support pharmacovigilance studies by Q1 2011

Discussion paper on interface between medicines regulation and ENCePP by Q2 2011

- Submission of results/time of publication
- Scrutiny of the analytical data set

Development of a detailed best practice to be followed in case researchers have findings of public health relevance by Q4 2011

Next steps

- Adoption of Work Plan by the ENCePP Steering Group on
  2 December 2010

- Adopted Work Plan published on the ENCePP Website

- First update on deliverables achieved at next Plenary meeting
  30 June 2011

Workplan 2011-2012 and Working Groups

Comments?

Suggestions?

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