



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Register of Studies

Progress Report

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ENCePP Plenary Meeting, 8 June 2010

An agency of the European Union





Structure of database

It will have 4 sections (or Tabs):

1. Administrative information
2. Targets of the study
3. Methodological aspects
4. ENCePP Seal and relevant documents

Total: 19 questions



Tab 1 – Administrative information

- Q1. Study identification:** official Study title incl acronym, Study type, brief Study description and whether study was requested by a regulator
- Q2. Research centres and Investigator details:** coordinating study entity, investigator's details, link to Networks, other centres and countries
- Q3. Study timelines:** planned and actual dates
- Q4. Source(s) of funding:** expressed in %
- Q5. Contact details:** scientific and public queries



Tab 2- Targets of the Study

Q6. Study drug information: <ATC codes/substance name>

Q7. Medical conditions to be studied: <MedDRA terms>

Q8. Population under study: age and sex

Q9. Number of patients: estimated total

Q10. Source of data: <link to ENCePP data sources>



Tab 3 – Methodological aspects

Q11. Scope of the Study

Q12. Main objective: objective, primary and secondary outcomes

Q13. Study design

Q14. Follow-up of patients

Q15. Data analysis plan: summary



Tab 4 – ENCePP Seal and relevant docs

Q16. ENCePP Seal

Q17. Full protocol

Q18. Study results

Q19. Other relevant information (pdf): conflicts of interest, composition of Steering Group and Observers, other docs



Next steps

- Currently under development by IT team
- Release expected for Q4 2010
- Interim solution developed