



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## ENCePP Milestones in 2009

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ENCePP Plenary Meeting  
London, 11 December 2009

Henry Fitt



ENCePP is a European Medicines Agency initiative

An agency of the European Union





## *ENCePP Work Plan 2009*

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- First ever ENCePP Work Plan
- Agreed by ENCIAG
- Published on ENCePP website





## *ENCePP Mandates*

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### 1. Mandate of the ENCePP Steering Group



- Endorsed by ENCIAG & Plenary
- Published on ENCePP website
- ***Inaugural Meeting*** of ENCePP SG: January 2010

### 2. Mandate of the ENCePP Plenary



- Endorsed by ENCIAG & Plenary
- Published on ENCePP website



## *Draft ENCePP Code of Conduct & Draft Checklist of Methodological Research Standards*

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- Developed over several months by dedicated working groups
- Endorsed by ENCIAG & Plenary
- Released for Public Consultation on 16 November 2009 (open until 5 January 2010)



## Meetings

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- **2 ENCePP Plenary** meetings

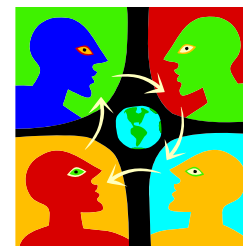
(18 September & 11 December 2009)

- **ENCIAG**

(4 x Vitero)

- **Working Groups**

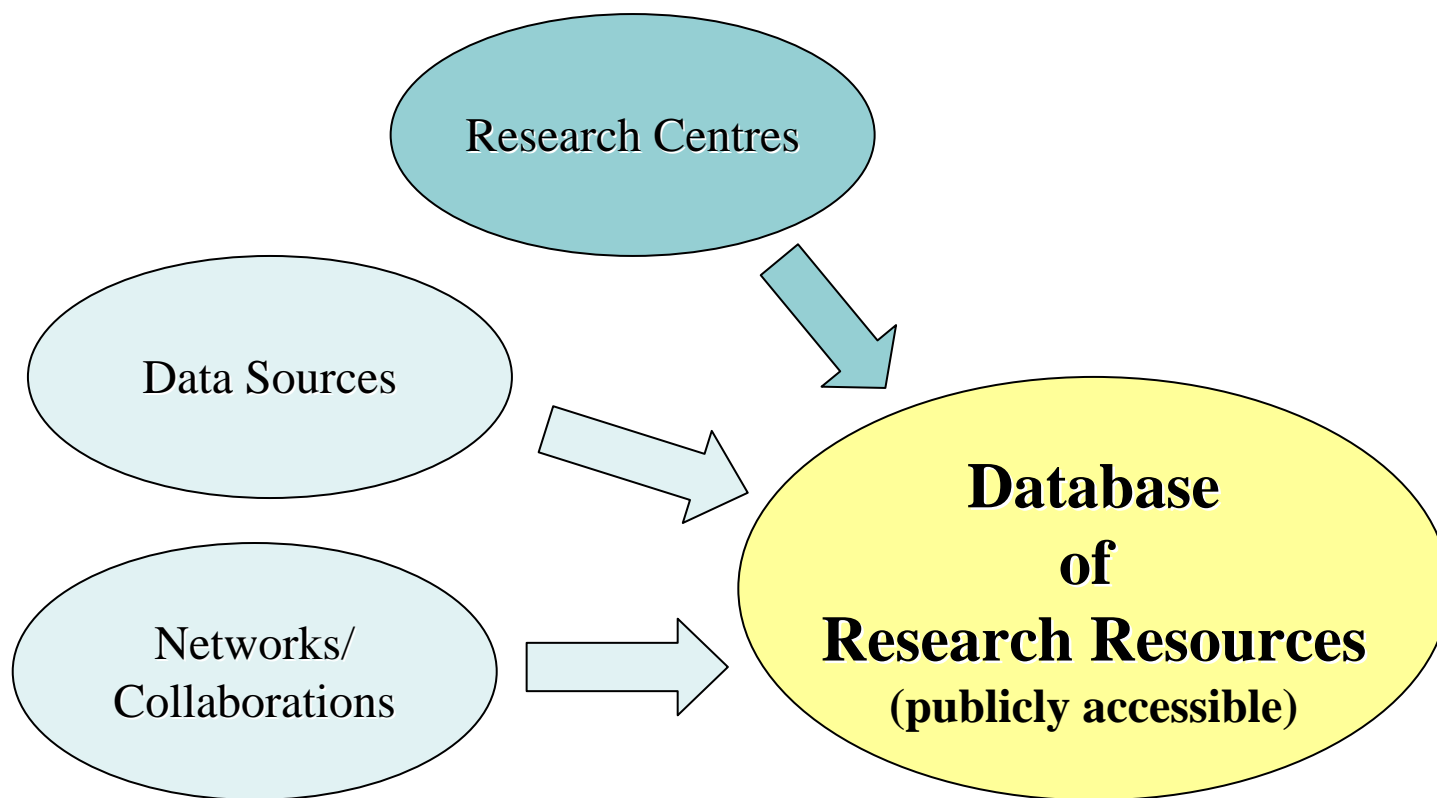
(TC, Vitero and face-to-face, total no. of meetings: 11)





# *Electronic Database of Research Resources*

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## *Electronic Database of Research Resources*

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- Development of web-based questionnaires for centres/networks and data sources by dedicated Working Groups
- Questions endorsed by ENCIAG and Plenary
- Database of ***research centres***: Launch of database December 2009



## *International Collaborations*

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- Regular TC with **US FDA** (discussions on synergies with Sentinel Project)
- Collaboration with **DSEN** (Drug Safety and Effectiveness Network) / **Health Canada**





## *Networking*

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- **AHRQ**: Search for partners in research project on use of epoetins in patients with chronic kidney disease through ENCePP
- Contribution to inventory of examples of research activities and data sources relevant for **A/H1N1 benefit/risk monitoring** in Europe



## *Plenty more to do in 2010...*

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- Work Plan 2010
- Finalisation of CoC and MRS Checklist following Public Consultation
- Research resources database – Stage 2
- Fully-functional web-page (member forum, FAQ)
- Database for post-authorisation studies



## *Plenty more to do in 2010...*

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- Development of guidance on methodological research standards
- Promoting ENCePP
- Plenaries 2010:
  - 08 June 2010
  - 18 November 2010
- ..... **1<sup>st</sup> of many ENCePP studies!!!!**