



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Milestones in 2009

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

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





ENCePP Mandates

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

- 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

- **2 ENCePP Plenary** meetings

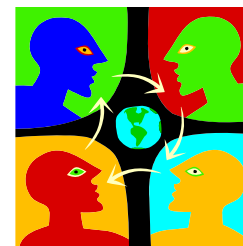
(18 September & 11 December 2009)

- **ENCIAG**

(4 x Vitero)

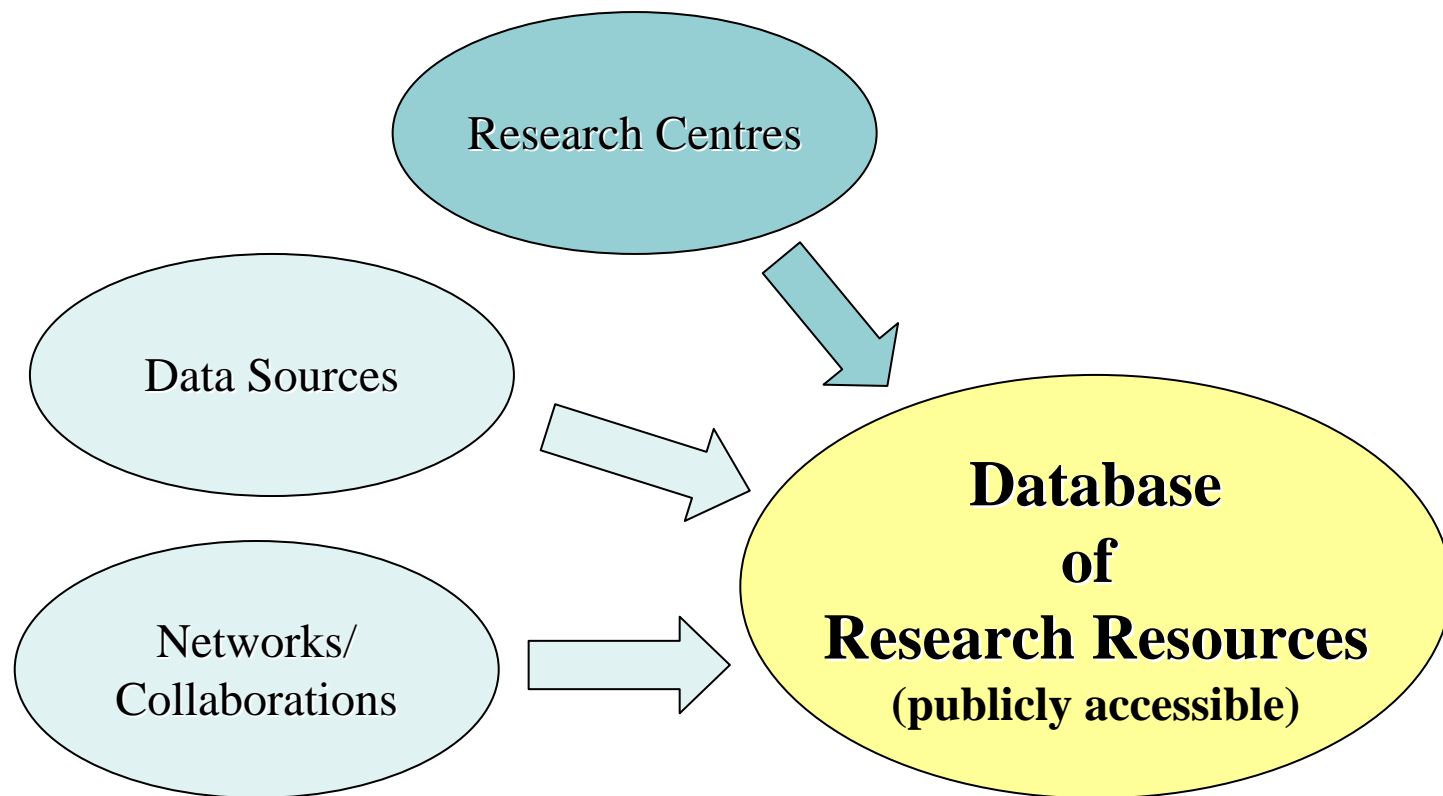
- **Working Groups**

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





Electronic Database of Research Resources





Electronic Database of Research Resources

- 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



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



Networking

- **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...

- 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...

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