EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Launch of Register of Studies & pilot phase

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Overview

- e-Register of studies
  - Demo of how to Add Study
  - Demo of Search functionality
- Pilot Phase
  - Feedback received

e-Register of Studies

- ✓ 6 May: Kick off development Register of Studies
- ✓ Sep: internal UAT
- ✓ 27 Sep: IT deployment
- ✓ Oct-Nov: Pilot phase
- ✓ 18 Nov: Launch of Database

E-Register of Studies

To ensure international standardisation

- ✓ WHO ICTRP – 20 minimum fields
- ✓ Clinicaltrials.gov
- ✓ EUDRACT
- ✓ MedDRA
- ✓ ATC

e-Register of Studies

DEMO

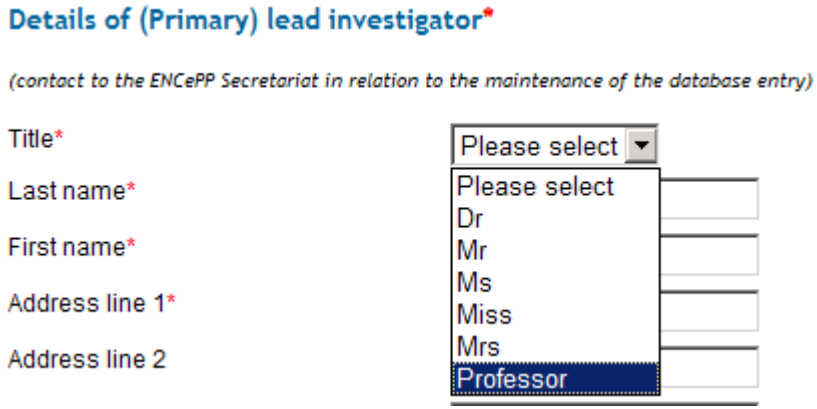
Pilot phase

- Pilot phase started in September 2010
- It involved members of ENCePP SG and EMA Staff
- Comments received are logged and tracked for future developments of the database

Pilot phase - feedback

Q2 – Title of the lead investigator

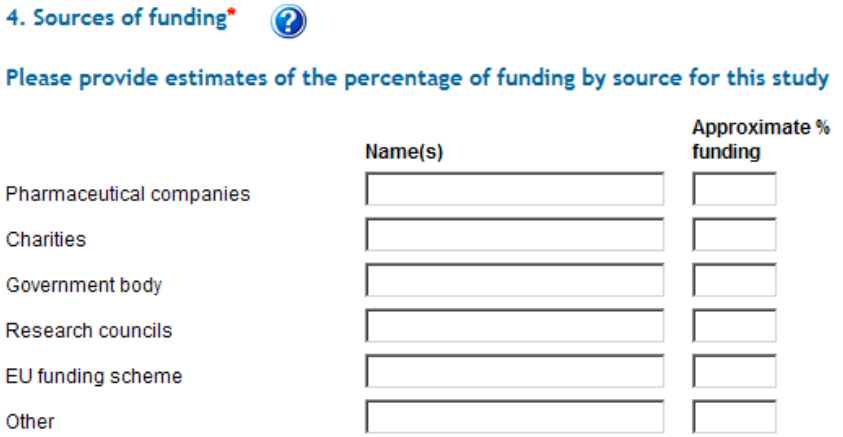
-Add more titles



Pilot phase - feedback

Q4 – Sources of funding

New option: self-funded



4. Sources of funding*

Please provide estimates of the percentage of funding by source for this study

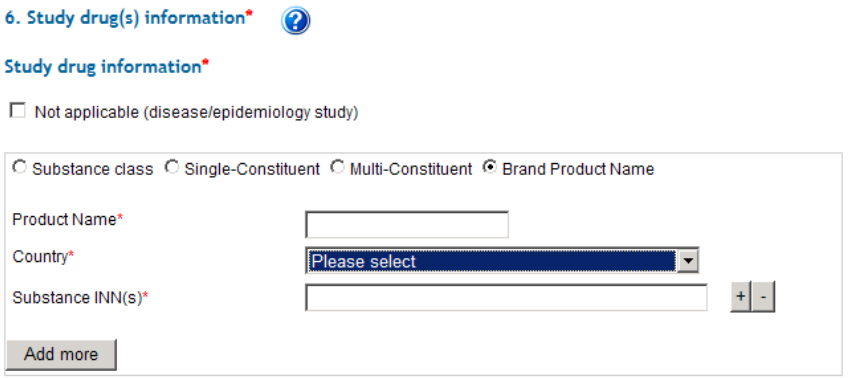
	Name(s)	Approximate % funding
Pharmaceutical companies		
Charities		
Government body		
Research councils		
EU funding scheme		
Other		

Pilot phase - feedback

Q6 – Study drug information

Brand product name

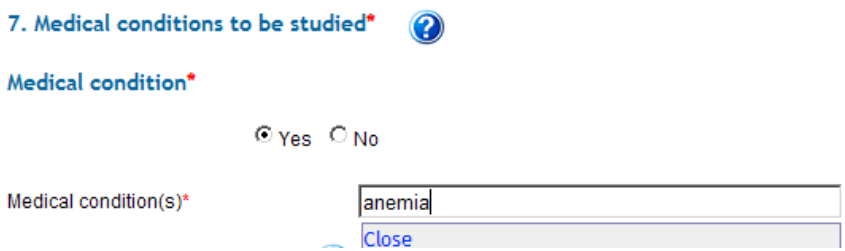
-Include option “CAP” in list of countries



Pilot phase - feedback

Q7- Medical condition

-Insert warning when term is not present in MedDRA



Pilot phase - feedback

Q2 – Countries in which this study is conducted

2 more options

-no country

-EU

Thank you!