



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Launch of Register of Studies & pilot phase

Rocío Fernández
Pharmacovigilance and Risk management Sector





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

Details of (Primary) lead investigator*

(contact to the ENCePP Secretariat in relation to the maintenance of the database entry)

Title*

Last name*

First name*

Address line 1*

Address line 2

Please select ▼	
Please select	
Dr	
Mr	
Ms	
Miss	
Mrs	
Professor	



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	<input type="text"/>	<input type="text"/>
Charities	<input type="text"/>	<input type="text"/>
Government body	<input type="text"/>	<input type="text"/>
Research councils	<input type="text"/>	<input type="text"/>
EU funding scheme	<input type="text"/>	<input type="text"/>
Other	<input type="text"/>	<input type="text"/>



Pilot phase - feedback

Q6 – Study drug information

Brand product name

-Include option "CAP" in list of countries

6. Study drug(s) information*

Study drug information*

Not applicable (disease/epidemiology study)

Substance class Single-Constituent Multi-Constituent Brand Product Name

Product Name*

Country*

Substance INN(s)*



Pilot phase - feedback

Q7- Medical condition

-Insert warning when term is not present in MedDRA

7. Medical conditions to be studied* 

Medical condition*

Yes No

Medical condition(s)*

[Close](#)



Pilot phase - feedback

Q2 – Countries in which this study is conducted

2 more options

-no country

-EU

Countries in which this study is being conducted*

- National study
- International study

Please select countries

<input type="checkbox"/>	Afghanistan
<input type="checkbox"/>	Albania
<input type="checkbox"/>	Algeria
<input type="checkbox"/>	American Samoa
<input type="checkbox"/>	Andorra
<input type="checkbox"/>	Angola
<input type="checkbox"/>	Anguilla
<input type="checkbox"/>	Antarctica
<input type="checkbox"/>	Antigua and Barbuda
<input type="checkbox"/>	Argentina
<input type="checkbox"/>	Armenia
<input type="checkbox"/>	Aruba



Thank you!