



ENCePP Database of Research Resources

Research Centres participating in ENCePP

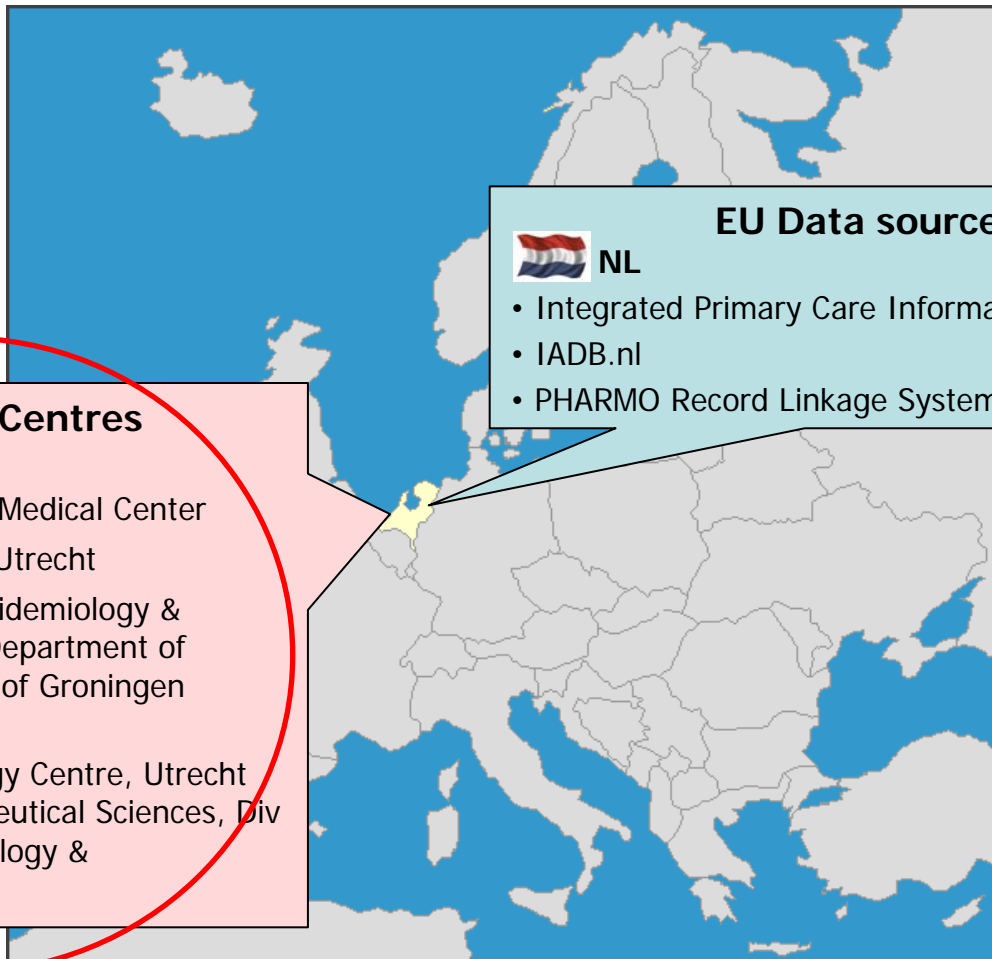
ENCePP Plenary, 18 September 2009

Mary Teeling
Stefanie Prilla




ENCePP is a European Medicines Agency initiative

ENCePP Research Resources Database



EU Data sources

 NL

- Integrated Primary Care Information (IPCI)
- IADB.nl
- PHARMO Record Linkage System (PHARMO RLS)

ENCePP Centres

 NL

- Erasmus University Medical Center
- PHARMO Institute, Utrecht
- Unit of Pharmacoepidemiology & Pharmacoecconomy, Department of Pharmacy, University of Groningen
- Utrecht University Pharmacoepidemiology Centre, Utrecht Institute for Pharmaceutical Sciences, Div of Pharmacoepidemiology & Pharmacotherapy

Working Group: *EU PhV & PhEpi research centres in ENCePP*

Chair: Mary Teeling

Mandate

- Develop a questionnaire allowing collection of essential information on the research centres/organisations. (The information gathered through the questionnaire should allow at a later stage complex searches of the Inventory.)
- Identify additional existing EU Ph'Epi and Ph'V research resources; define exclusion/inclusion criteria for participating centres/organisations, e.g. source of funding, size of CROs, etc.
- Develop an electronic Inventory: Identify needs and deliverables of such a tool; liaise with EMEA IT project manager
- Input to the design of the EMEA web page

Objectives

- Comprehensively catalogue the **existing European research centres** participating in ENCePP.
- Collect and present information about the centres' expertise and capacity for conducting a study in response to a particular research question.
- Facilitate access to research centres to potential study sponsors/funders and to promote the recruitment of these centres to conduct studies commissioned by any sponsor/funder.

Scope

- European research centres participating in ENCePP.
- Networks and research collaborations

The Database should be...

- ... up-to-date
- ... fully searchable
- ... open to the general public

Information to be
entered remotely by
the centre's
representative(s)



Milestones

- Identification of key information of the centres to be collected
- Preparation of a Questionnaire = data fields
 - Pre-defined data fields, i.e. tick boxes and drop-down lists
 - free text avoided wherever possible
 - Identification of mandatory data fields
- Define search criteria/fields
- Develop the database

Drafting Group

Drafting
Group &
Working
Group;
approved by
ENCIAG

Questionnaire for research centres

-

Data fields

1 Contact details

Name of organisation

1) Department/ research group

2) Organisation/Affiliation

Contact person (contact 1)

Title:

Address line 1

Address line 2

City

Postcode

Country

Phone number incl. country code

+ - -

Alternative phone number plus country code

+ - -

Fax number plus country code

+ - -

Email address for contact 1

Alternative contact person (contact 2)

Title:

Email address for contact 2

Website/Homepage

2. Please provide a short description of your organisation*

(max. 1000 characters incl. space)

3. Under which category would you classify your organisation (please tick all that apply):

University based

Hospital based

Government based

Charity or non-profit organisation

For profit organisation

Other

(please specify) _____

4. Do you have access to the following resources (please tick all that apply):

	In house	Via contacts / network
Epidemiologist/Pharmacoepidemiologist	<input type="checkbox"/>	<input type="checkbox"/>
Statistician	<input type="checkbox"/>	<input type="checkbox"/>
Clinician	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Pharmacologist	<input type="checkbox"/>	<input type="checkbox"/>
Pharmacist	<input type="checkbox"/>	<input type="checkbox"/>
Geneticist/Pharmacogeneticist	<input type="checkbox"/>	<input type="checkbox"/>
IT specialist	<input type="checkbox"/>	<input type="checkbox"/>
Ethics expertise	<input type="checkbox"/>	<input type="checkbox"/>
Legal expertise	<input type="checkbox"/>	<input type="checkbox"/>
Regulatory expertise	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify other relevant resources below)		
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>

5. In the past 5 years, has your centre performed drug safety/risk-benefit research in the following therapeutic/disease areas (please tick all that apply):

- | | | | |
|---|--------------------------|--------------------------------|---|
| Anaesthesia | <input type="checkbox"/> | | |
| Cardiovascular diseases | <input type="checkbox"/> | | |
| Congenital Malformations | <input type="checkbox"/> | | |
| Devices | <input type="checkbox"/> | | |
| Disorders of the central nervous system | <input type="checkbox"/> | | |
| Ear, nose and oropharynx disorders | <input type="checkbox"/> | | |
| Endocrine disorders | <input type="checkbox"/> | | |
| Eye disorders | <input type="checkbox"/> | | |
| Gastrointestinal tract | <input type="checkbox"/> | | |
| Geriatrics | <input type="checkbox"/> | | |
| Gynaecology | <input type="checkbox"/> | | |
| Immunological products and vaccines | <input type="checkbox"/> | | |
| Immunosuppression | <input type="checkbox"/> | | |
| Infectious diseases | <input type="checkbox"/> | | |
| Liver disease | <input type="checkbox"/> | | |
| Malignant disease | <input type="checkbox"/> | | |
| Musculoskeletal and joint diseases | <input type="checkbox"/> | | |
| Neonates | <input type="checkbox"/> | | |
| Nutrition and blood | <input type="checkbox"/> | | |
| Osteoporosis | <input type="checkbox"/> | | |
| Paediatrics | <input type="checkbox"/> | | |
| Poisoning/Overdose | <input type="checkbox"/> | | |
| Pregnancy | <input type="checkbox"/> | | |
| Psychiatry | <input type="checkbox"/> | | |
| Renal impairment | <input type="checkbox"/> | | |
| Respiratory diseases | <input type="checkbox"/> | Other, including rare diseases | <input type="checkbox"/> (please specify) |
| Skin disorders | <input type="checkbox"/> | | <input type="checkbox"/> (please specify) |
| Urinary tract disorders | <input type="checkbox"/> | | <input type="checkbox"/> (please specify) |

6. In the past 5 years have you carried out drug safety / risk-benefit studies that have been published with the following design (please tick all that apply):

- | | | |
|-------------------------------|--------------------------|------------------|
| Cohort study | <input type="checkbox"/> | |
| Case-control study | <input type="checkbox"/> | |
| Drug utilisation study | <input type="checkbox"/> | |
| Interventional clinical trial | <input type="checkbox"/> | |
| Meta-analysis | <input type="checkbox"/> | |
| Other | <input type="checkbox"/> | (please specify) |
| | <input type="checkbox"/> | (please specify) |

7. Are you experienced in studies collecting data directly from individual patients/respondents?

Yes No

If yes,

5 or fewer studies (≤ 5)

more than 5 studies (> 5)

If yes, how many patients/respondents were involved in the study(ies) (if you have conducted > 1 study you are likely to tick more than one box):

< 150

150 – 1,499

1,500 – 14,999

$\geq 15,000$

8. Are you experienced in secondary research and meta-analysis?

Yes No

9. Please indicate whether you have access to the following data collection resources (please tick all that apply):

Capacity to conduct face-to-face interviews

In a clinic

In the community

Electronic data capture systems

If yes, system used: _____

Interactive voice response systems

Call centre

10 What existing data resources have you worked with in the past 3 years and how many projects have you conducted with them?

Name of data resource No. of studies

11 Please indicate whether your centre currently participates in research networks:

Name of network national international Link to webpage

_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____

12. Have you established Registries (e.g. disease, drugs, etc) in your centre?

Yes No

If yes, please specify:

Drug Registry/ies if yes, please specify the drug(s) / drug class _____

[▶ click here to add further Registries](#)

Disease Registry/ies if yes, please specify the disease / disease area _____

[▶ click here to add further Registries](#)

Other if yes, please specify _____

[▶ click here to add further Registries](#)

13. In principle, would you be interested in carrying out research that is funded, i.e. contract research (please tick all that apply):

- By pharmaceutical companies
- By charities
- By government
- By research councils
- By EU funding schemes

14. Do you only conduct contract research if you have the freedom to publish the results?

Yes No

15. Are you experienced in collaborating with other centres in a study team (please tick all that apply):

Yes No

If yes, are you experience in leading a study team as

Principal Investigator

Collaborating Investigator

16. Please list the 5 most relevant publications from your research unit for the last five calendar years:

Reference

Link to web-publication (if available)

Next steps

September/
October 2009

- Development of database and search tool/fields

November 2009

- Population with first data sources:
user testing

December 2009

- Launch & presentation of Database
on 11 December 2009