ENCePP
Database of Research Resources

Research Centres participating in ENCePP

ENCePP Plenary, 18 September 2009

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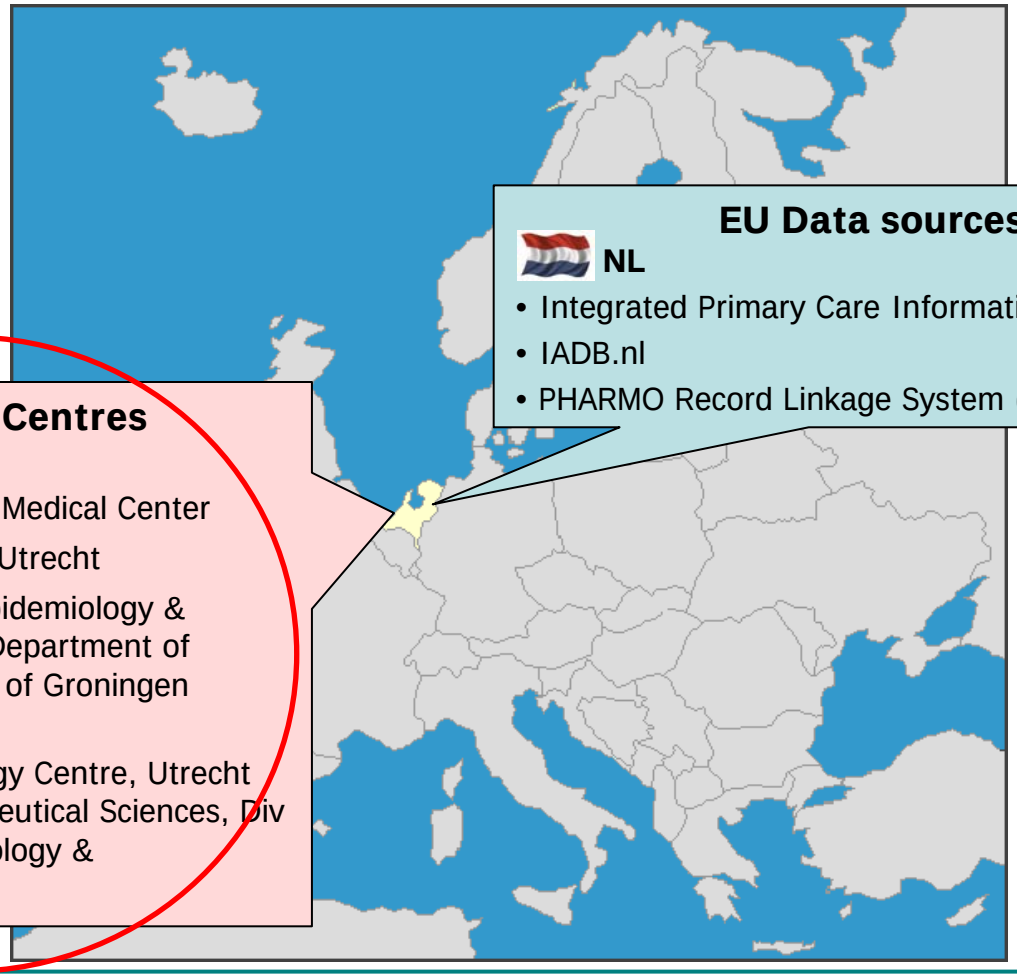
ENCePP Research Resources Database



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 & Pharmacoeconomy, 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)

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Milestones

- Identification of key information of the centres to be collected

Drafting Group

- 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

Drafting Group & Working Group; approved by ENCIAG

- Develop the database

Questionnaire for research centres

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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	☐	☐
Statistician	☐	☐
Clinician	☐	☐
Clinical Pharmacologist	☐	☐
Pharmacist	☐	☐
Geneticist/Pharmacogeneticist	☐	☐
IT specialist	☐	☐
Ethics expertise	☐	☐
Legal expertise	☐	☐
Regulatory expertise	☐	☐
Other (please specify other relevant resources below)		
_____	☐	☐
_____	☐	☐
_____	☐	☐

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
- ☐ Cardiovascular diseases
- ☐ Congenital Malformations
- ☐ Devices
- ☐ Disorders of the central nervous system
- ☐ Ear, nose and oropharynx disorders
- ☐ Endocrine disorders
- ☐ Eye disorders
- ☐ Gastrointestinal tract
- ☐ Geriatrics
- ☐ Gynaecology
- ☐ Immunological products and vaccines
- ☐ Immunosuppression
- ☐ Infectious diseases
- ☐ Liver disease
- ☐ Malignant disease
- ☐ Musculoskeletal and joint diseases
- ☐ Neonates
- ☐ Nutrition and blood
- ☐ Osteoporosis
- ☐ Paediatrics
- ☐ Poisoning/Overdose
- ☐ Pregnancy
- ☐ Psychiatry
- ☐ Renal impairment
- ☐ Respiratory diseases
- ☐ Skin disorders
- ☐ Urinary tract disorders

☐ Other, including rare diseases

☐ (please specify)
☐ (please specify)
☐ (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
- ☐ Case-control study
- ☐ Drug utilisation study
- ☐ Interventional clinical trial
- ☐ Meta-analysis

Other
- ☐ (please specify)
- ☐ (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 ☐
≥ 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
_____	☐	☐	_____
_____	☐	☐	_____
_____	☐	☐	_____

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