ENCePP
Database of Research Resources

Data sets used for PE and PhV Research

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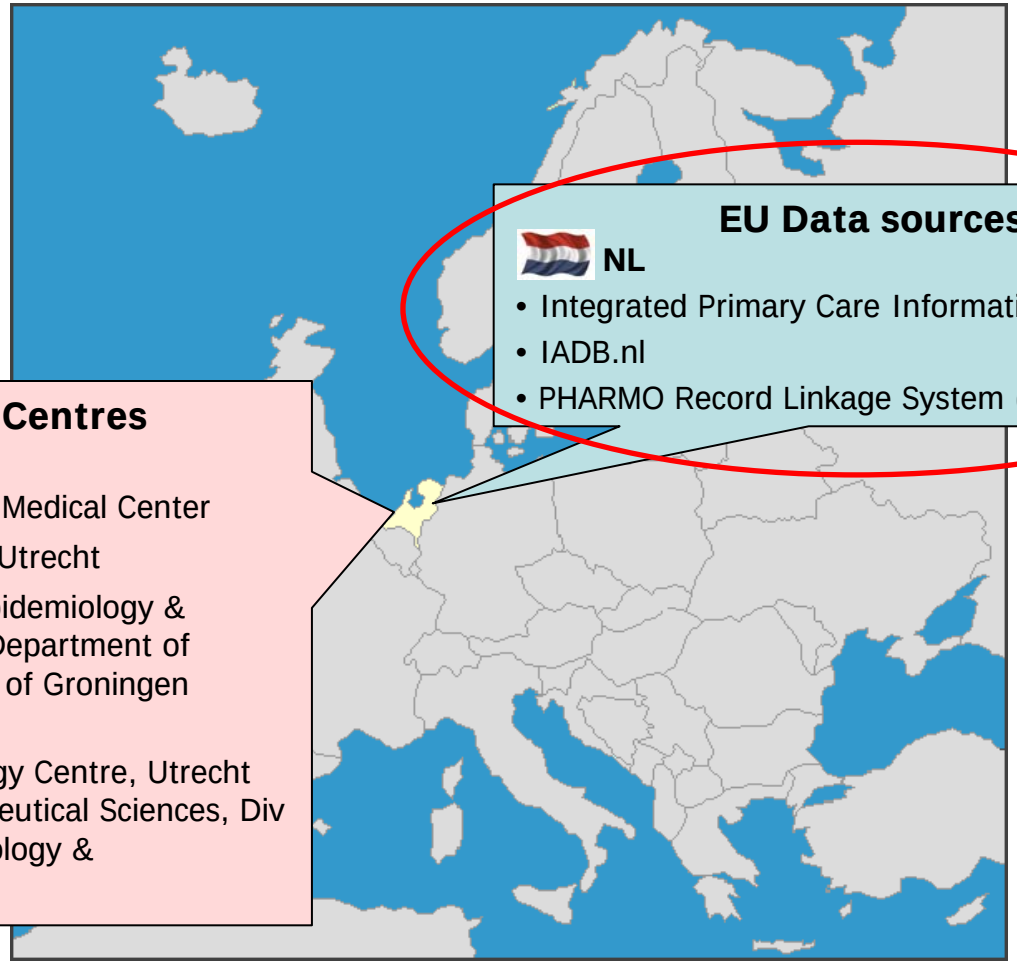
ENCePP Research Resources Database



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 data sources and methodological approaches for multi-source studies

Chair: Miriam Sturkenboom

Mandate

- Define the element that the EU Inventory of data sources should have
- Explore approaches & processes for interoperability and sharing of European epidemiology data sources
- Address Data Privacy restrictions for PE/PV research
- Input to the design of the EMEA web page

EU Database of **Data sets**

Purpose

provide a means for researchers to locate existing datasets containing information likely to resolve their question.

Scope

maximum coverage of available data sources in Europe, non-European resources not excluded [incl. e-healthcare databases, disease registries, exposed registries, case-control surveillance…]

EU Database of **Data sets**

Must be…

… comprehensible

… accurate

… easy to maintain

… clear regarding access restrictions to data access and costs

Principles

- Provide access to data providers, not excessive detail on structure
- But give sufficient detail to substantially reduce effort of finding data
- Not just for ENCePP researchers
- Open access for all genuine data providers but moderated in response to comments from users.

Developing the database… Milestones & timelines

- List of key points for the Database
- First draft questionnaire: March 2009
- Consultation process:
    1. Drafting Group WG3 (April 2009)
    2. Working Group (May 2009)
    3. ENCePP (June 2009)
- Final draft: July 2009

1. Contact details

Is this data source maintained by a centre registered in the ENCePP inventory of research centres?

☐	Yes	If Yes → Pick list of centres→ Fill in contact details from registry of centres
☐	No	If No → Collect contact details in same format as registry of centres

/Note: Drop-down list from registry of research centres to be included.
The contact details from the Inventory of research centres will be automatically transferred./

2. How would your data source be most appropriately described?

- Disease/case registry ☐
- Spontaneous reporting database ☐
- Prescription event monitoring ☐
- Administrative database, e.g. claims database ☐
- Routine primary care electronic patient registry ☐
- Exposure registry ☐
- Pharmacy dispensing database ☐
- Prospective studies database ☐
- Case-control surveillance database ☐

Other (please describe):

3.1 What kinds of licensed medicinal products are covered?

Please choose all that apply:

		Comment:
Hospital data	☐	
Community / general practice data	☐	
OTC	☐	
Vaccines	☐	
None	☐	

Other (please describe):

3.2 Is the ATC code (5th level) available?

☐ Yes

☐ No

3.3 Are other product dictionaries used?

☐ Yes

☐ No

If YES → Please specify:

3.4 Is the indication for use recorded? ☐ Yes ☐ No

Is a coding dictionary being used? ☐ Yes ☐ No

If YES → please specify:

Comments:

4. Which kinds of events are covered?

Please choose all that are relevant:		Does coding conform to a medical dictionary?		
Pls check	**Event**	**Medical Dictionary Yes**	**No**	**If yes, please specify**
☐	No events			
☐	Adverse events (for PV DBs)	☐	☐	
☐	Symptoms/Signs	☐	☐	
☐	Diagnosis in primary care	☐	☐	
☐	Specialist Diagnosis	☐	☐	
☐	Discharge Diagnosis	☐	☐	
☐	Laboratory values	☐	☐	
☐	Death	☐	☐	
☐	Procedures	☐	☐	
☐	Overdoses	☐	☐	
☐	Teratogenic events	☐	☐	
☐	Specific event (*pls describe)	☐	☐	

*Description:

5. Year in which data source was set up?

6. Geographical origin of data?

List of countries

7. Is data collection nation-wide or a regional sub-set of the population?

☐ Nation-wide

☐ Regional sub-set → if sub-set, please describe: free text

8. From which age groups do your data come?

Age group

- 17 years and under [Paediatrics] ☐
  - preterm newborn infants ☐
  - term newborn infants (0 to 27 days) ☐
  - infants and toddlers (28 days to 23 months) ☐
  - children (2 to 11 years) ☐
  - adolescents (12 to 17 years) ☐
- 18 – 45 years ☐
- 46 – 64 years ☐
- 65 years and over ☐
  - 65 – 75 years ☐
  - 76 years and over ☐

9. What is the size of the source/catchment population of the database (all types of databases)?

10. a. What is the total (cumulative) number of persons with actual data in the database (e.g. in registries/ GP databases)?

b. What is the number of persons with active data collection in the past year (e.g. in registries/ GP databases)?

11. a. What is the total number of reports in the database (e.g. in Pharmacovigilance databases)?

b. What is the number of reports over the last year in the database (e.g. in Pharmacovigilance databases)?

12. Is it possible (both legally and practically) to obtain the following additional information on the patient:

a) Clinical information from treating physician? Yes ☐ No ☐

b) Questionnaire data from the patient? Yes ☐ No ☐

c) Genetic information or samples Yes ☐ No ☐

13. Can the data source be linked to other sources of data?

☐ Yes

☐ No

If YES → please describe method and type of data that can be linked to:

14. Is there a written policy governing data access?

☐ Yes

☐ No

If yes → Give web address if available:

15. Do you have a committee to evaluate requests for data access?

☐ Yes

☐ No

16. Is a charge made for data access?

☐ Yes

☐ No

☐ Special arrangements for academic purposes

If yes → Give web address for charging structure if available:

17. Please list the 5 most relevant publications using your data for the last five calendar years. If there is a publication explicitly reporting on assessment of data quality, please include first:

Reference

1. Link to web publication (if available)
2. Link to web publication (if available)
3. Link to web publication (if available)
4. Link to web publication (if available)
5. Link to web publication (if available)

Next steps

September/ October 2009	• Development of database and search tool
November 2009	• Population with first data sources: user testing
11 December 2009	• Presentation of electronic Inventory to ENCePP Plenary on 11 December 2009