15 December 2017
EMA/526382/2017
Inspections, Human Medicines, Pharmacovigilance and Committees Division

ENCePP Resource Database

Inventory of Patient Registries
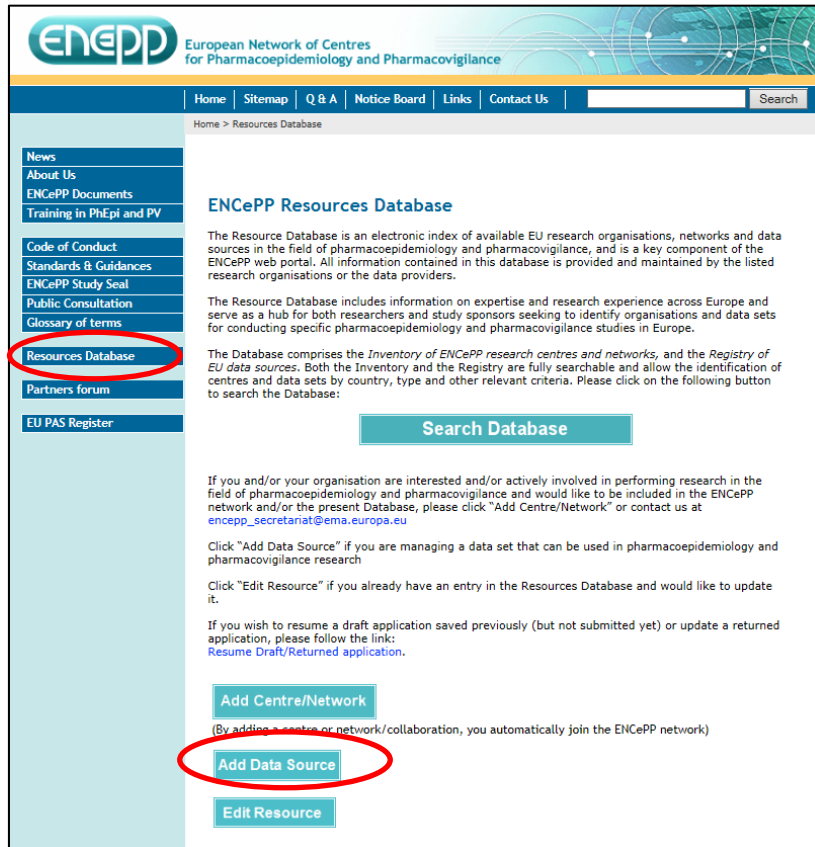
Table of Contents

Introduction

The aim of this document is to provide key points on:

- **How to <u>enter</u> patient/disease registries**.

- **How to <u>search</u> patient/disease registries.**

The main objective of the ENCePP inventory of registries is to be a network tool for disease and patient registries.

A.   How to <u>enter</u> your registry in the ENCePP Resources Database

1. Go to the ENCePP website Resources database:
   http://www.encepp.eu/encepp/resourcesDatabase.jsp

2. Select "Add Data Source"

3. After selecting "Add Data Source", you will have to choose a database classification (Centre/Network/Data Source). Select "Data source".

4. Register data source question: "Is data source maintained by a centre registered in the ENCePP inventory of research centres?" Select as appropriate (yes/no/don't know)

5. Questionnaire

Fields marked with (*) are mandatory. They must be completed in order to move forward to the next question.

1. Contact details

1. Name of data source*: complete name (long name)

2. Name under which the data source should be displayed in the inventory (max 50 characters)*: short name – *add disease*

Please note that the patient registry disease must appear next to the short name. This is to ensure that at least the disease appears in one of the two above mentioned fields (that will help when searching specific disease patient registries). Please see the following example:

1. Contact details	
Name of data source	European Register for Multiple Sclerosis
Name under which the data source should be displayed in the inventory (e.g short name if one exists)	EUReMS - Multiple Sclerosis

3. Name of organisation holding the data.

    1. Department/research group

    2. Organisation/affiliation*

    3. Website/Homepage

    4. Administrative contact *

    5. Scientific contact *

2. How would the data source be most appropriately described? (Please choose all that apply):

Patient registries should have <u>disease/case registries</u> **and** <u>exposure registry</u> selected.

Sections 3.1 to 3.4 are optional

(Please complete all that apply)

4. Which kinds of events are covered?

This field is very important when searching for a specific disease registry stakeholder.

'Specific event' should be selected.

The disease/s and/or the field disease must be included as this assists in searches. The row on the specific event should be for the field disease, and the free box text for all the diseases included in the registry, if more than one disease is included.

☑	Specific event	☐	☑	Renal diseases
	Please describe:			Acute kidney injury (AKI), Chronic kidney disease (CKD), Established renal failure (ERF)

Sections 5 to 12 are optional.

(Please complete all that apply)

13. Is there a written policy governing data access?*

Yes / No. If yes, please specify

14. Is there a committee to evaluate requests for data access?*

Yes / No

15. Is a charge made for data access?*

Yes / No. If yes, please specify.

16. Please list at least 1 of the 5 most relevant publications using the data for the last five calendar years. If there is a publication explicitly reporting on assessment of data quality, please include first

Please provide a link to relevant recent publications

B.   How to <u>search</u> for a registry in the ENCePP Resources Database

1. Go to search database section: http://www.encepp.eu/encepp/search.htm

2. Select "Data Source"

    It is recommended to search the following 3 options:

    -   *2.1 Search a registry by name*
    -   *2.2. Search a registry by disease*
    -   *2.3. Obtain the entire data sources list*

    The above options are described below:

2.1. Search a registry by name

Type the complete name (long name) or short name (acronym) on the "name of data source" field.

2.2. Search a registry by disease

There are 2 different steps to find all the registries by disease:

1. Type the disease in the search field "name of data source

2. You will retrieve registries with the disease on their "name of data source" or "short name" field (acronym) field.

3. Then another new search should be done. Select "specific event" from the list of events. Type the disease in the "specific event" field:

2.3. Obtain the entire data sources list

1. Select "data source"

2. Select "search"

3. The complete list of data sources will be displayed.

C. Other relevant links

- *Patient registries initiative from the European Medicines Agency (EMA)*

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000658.jsp

- *European Commission*

  https://ec.europa.eu/commission/index_en

- *RD Connect Network*

  http://catalogue.rd-connect.eu/