



# HMA-EMA Catalogues of real-world data sources and studies

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Patient registry workshop

Presented by Ana Cochino on 13 February 2024  
European Medicines Agency - Data Analytics and Methods Taskforce

The European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) set up a **joint task force to describe the big data landscape** from a regulatory perspective and **identify practical steps** for the European Medicines Regulatory Network to **make best use of big data in support of innovation and public health** in the European Union (EU).

The **HMA-EMA joint Big Data Task Force**, also known as the **Big Data Steering Group**, was established in December 2018. It developed Priority Recommendations to advance the use of big data in the European regulatory network, it advises EMA and HMA on prioritisation and planning of actions to implement the **Ten Priority Recommendations** in the **Big Data Task Force Final Report**.



The **HMA-EMA Catalogues of real-world data (RWD) sources and studies** will describe **real-world data sources and studies** through a set of collected **metadata** to help pharmaceutical companies and researchers **identify and use** such data when investigating the use, safety and effectiveness of medicines.

## Catalogue of RWD sources

the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Resources Database will migrate to the EMA corporate website

## Catalogue of RWD studies

will enhance the European Union electronic register of post-authorisation studies (EU PAS Register®)



- **Efficient and user-friendly platform** for researchers, regulators, and pharmaceutical companies
- **Centralised and enhanced resources** that contribute to the transparency of **observational research**
- Promotion of good practices aligning with '**FAIR**' **data principles** for **F**indable, **A**ccessible, **I**nteroperable, and **R**eusable data
- Facilitation of **search and evaluation of data sources and studies** related to medicines, ultimately supporting evidence-based decision-making
- **Integration** with other catalogues, EHDS and similar initiatives (to be further developed in coming years)

**A user would like to identify suitable data source(s) for a planned study**



The catalogue of data sources offers information (metadata) on the **data source content** (e.g.: capturing of medicinal product information, disease, demographics), availability, contact points to help the choice of data source. It allows benchmarking of different data sources referring to similar population when planning a study.

**A study protocol submitted uses a data source. The user needs to understand the suitability of the data source proposed**



The study can be retrieved using the studies catalogue; the protocol is available. Other **similar studies** can be retrieved using studies structured metadata, and a comparison of **data sources** used in similar research is possible.

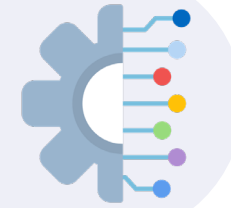
**A user reads a study report for which they need to evaluate the data source(s) used in the study**



The study report is available in the catalogue, along with details on the data source used. **Other studies** conducted using this particular data source can be consulted using the catalogues and provide orientation on the suitability of the data. The information on proposed data source used can be easily retrieved and assessed in the same context.



**Integration with EMA website content:** studies will be visible in the **relevant medicines overview page**, on the EMA website connection to summary of RMP, EPAR, PI\*



The screenshot shows the homepage of the EMA RWD Catalogues. At the top left is the EMA logo and the text 'EMA | RWD Catalogues'. On the top right, there are 'Log in' and 'Search' buttons. Below the header is a navigation menu with 'Home', 'Data Sources', 'Studies', 'Institutions', 'Networks', and 'Support'. The main content area has a dark blue background with the title 'HMA-EMA Catalogues of real-world data sources and studies' in white. Below the title is a paragraph: 'The Catalogues for real-world data sources, studies, institutions and networks replace and enhance the previous EU PAS Register® and ENCePP Resource Database.'



Home Data Sources Studies Institutions Networks Support

Home > Add content > Data source

## Add data source

Please complete the data source questionnaire to register your data source in the HMA-EMA Catalogue. Mandatory fields are marked with an asterisk (\*).

The information requested in the questionnaire needs to be kept up-to-date by the data holder. It is not the responsibility of the EMA.

The data source questionnaire contains **16** questions and is divided into **four categories**:

1. Administrative Details;
2. Data Elements Collected;
3. Quantitative Descriptors;
4. Data Flows and Management.

You will need to fill in all mandatory fields to move to the next step. A sample data source questionnaire for offline review can be found on the [support page](#).

This is a reminder that you agreed to the terms and conditions when you first logged in.

STEP 1 Administrative details

STEP 2 Data elements collected

STEP 3 Quantitative descriptors

STEP 4 Data flows and management

### Administrative details

**PURI**  
The value will be generated.  
A globally unique and persistent identifier for a data source.

**Data source ID**  
The value will be generated.

**Name of data source \***

The name of the data source, as used in European projects, must be provided. If the database is widely known by several names, these can be provided in this field, separated by a '/' sign. Where the data source has been known by different names in the past, these can be provided, using parenthesis with the note 'formerly known as'. Where the name of the data source is in a local language, the English translation should also be provided, using parentheses.

STEP 1 Administrative details

**STEP 2 Data elements collected**

STEP 3 Quantitative descriptors

STEP 4 Data flows and management

## The data source contains the following information

**Disease data**

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.  Yes

**Which disease(s) does the data source collect information on?**

+ Blastomyces pneumonia (73786)

+ Acute fibrinous organising pneumonia (84350)

Disease or diseases for which information is collected

+ Add another item

**Which disease(s) does the data source collect information on? other**

Disease or diseases for which information is collected, if not available in the above look-up

**Rare diseases**

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.  Yes

**Pregnancy and/or neonates**

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?  No

**Hospital admission and/or discharge**  Yes

Home > Data Sources > Studies > Institutions > Networks > Support

Home > Add content > Study

## Add study

Please complete the study questionnaire to register your study in the HMA-EMA Catalogue. Mandatory fields are marked with an asterisk (\*).

The information requested in the study questionnaire needs to be kept up-to-date by the study entry owner (and/or co-author). It is not the responsibility of the EMA.

The study questionnaire contains **23** questions and is divided into **three categories**:

1. Administrative Details;
2. Methodological Aspects;
3. Data Management.

You will need to fill in all mandatory fields to move to the next step. A sample study questionnaire for offline review can be found on the [support page](#).

This is a reminder that you agreed to the terms and conditions when you first logged in.

STEP 1 Administrative details STEP 2 Methodological aspects STEP 3 Data management

### Study identification

**PURI**  
The value will be generated.  
A globally unique and persistent identifier for a study.

**EU PAS number**  
The value will be generated.  
If registered in the former EU PAS Register, the EU PAS number of the study

**Study ID**  
The value will be generated.

**DARWIN EU® study**  
Study performed by DARWIN EU®  Yes

**Official title and acronym \***  
Acronym to be added in parentheses after the study title

**Study countries \***  
Countries in which this study is being conducted

**Study description**

**Link between data sources and associated studies**



Home > DARWIN EU® - DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

View [Co-authors](#) [Revisions](#)

## DARWIN EU® - DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use

Last updated: 29/11/2023

Study Finalised

[Download as PDF](#)

Administrative details   Methodological aspects   **Data management**

### Page content

- [ENCePP Seal](#)
- [Data sources](#)
- [Use of a Common Data Model \(CDM\)](#)
- [Data quality specifications](#)
- [Data characterisation](#)

### Data sources

<b>Data source(s)</b>	<a href="#">CureDRPLA Global Patient Registry</a> <a href="#">Data Source Test 3</a> <a href="#">HealthData Hub: Singapore General Hospital</a>
<b>Data sources, if not available in the list above</b>	<a href="#">SIDIAPI, IPCI, CPRD</a>

### Use of a Common Data Model (CDM)

Home > Add content > Institution

## Add institution

Please complete the questionnaire to register your institution. Mandatory fields are marked with an asterisk (\*).

The information requested in the questionnaire needs to be kept up-to-date by the record owner. It is not the responsibility of the EMA.

The questionnaire comprises **four** questions. A sample institution questionnaire for offline review can be found on the [support page](#).

This is a reminder that you agreed to the terms and conditions when you first logged in.

### Institution identification

**PURI**

A globally unique and persistent identifier for an institution

**Institution ID**

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**Institution full name and acronym \***

Acronym to be added in brackets after the institution name.

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**Institution countries \***

 +

Country where the institution head office or coordinating centre is located

## Institutions

Metadata on any contributor to the catalogue, its role and expertise (e.g., institution country, etc.)

## Add network

Please complete the questionnaire to register your network. Mandatory fields are marked with an asterisk (\*).

The information requested in the questionnaire needs to be kept up-to-date by the record. It is not the responsibility of the EMA.

The questionnaire comprises **five** questions. A sample network questionnaire for offline review can be found on the [support page](#).

This is a reminder that you agreed to the terms and conditions when you first logged in.

## Network identification

### Networks

Metadata describing networks/consortia linking to institutions and studies in the catalogue (e.g., network name, website, etc.)

#### Network name and Acronym \*

EMS SPOR

#### Network countries \*

Countries where the network is located.

#### Network website

The format used should be <http://example.com>

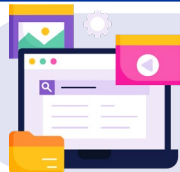
## Network description

#### Network description \*

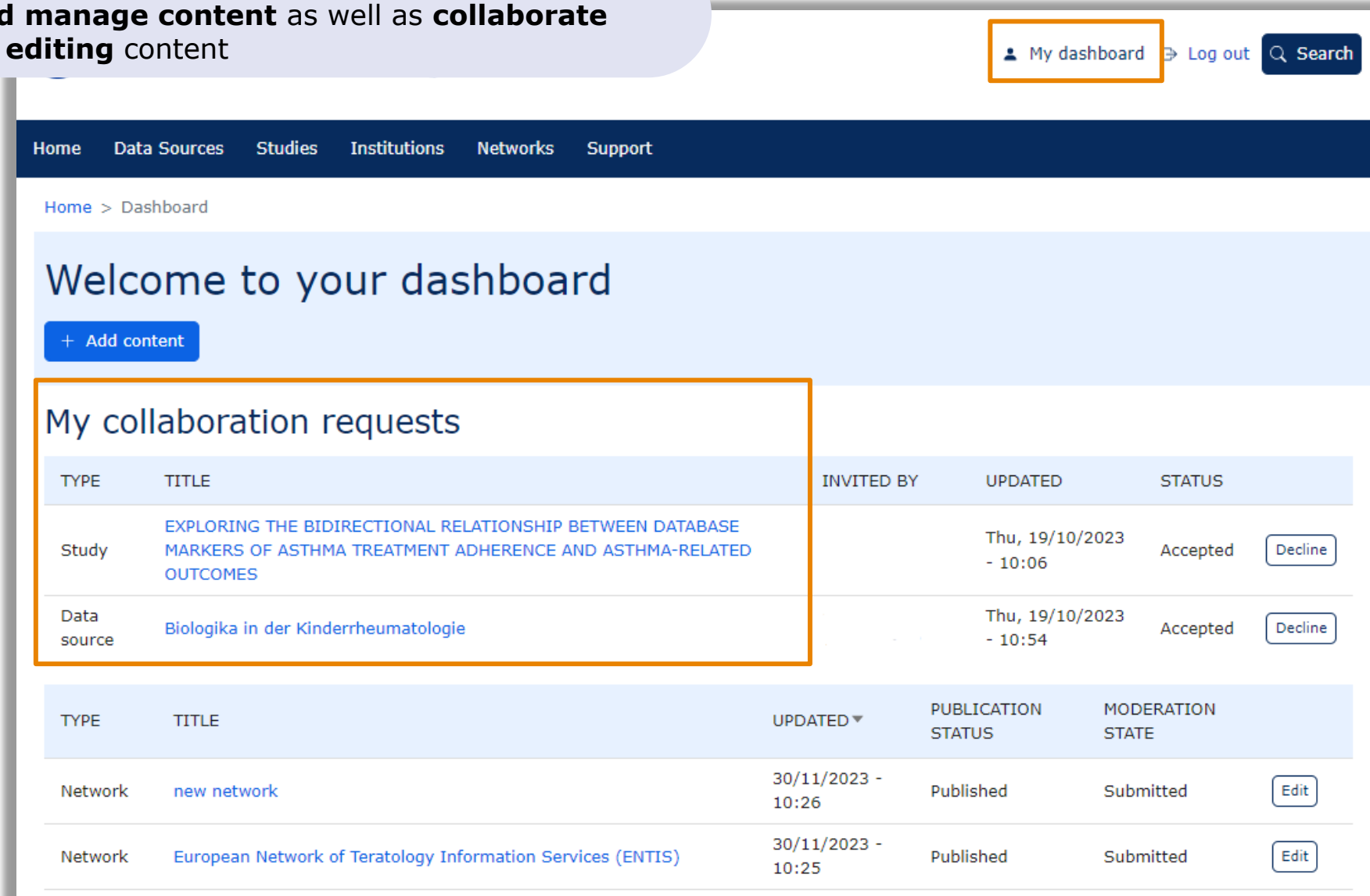
0 / 2000

#### Primary therapeutic/disease areas

#### Sources of funding \*



New platform enables users to **easily access and manage content** as well as **collaborate on editing** content



My dashboard Log out Search

Home Data Sources Studies Institutions Networks Support

Home > Dashboard

## Welcome to your dashboard

+ Add content

### My collaboration requests

TYPE	TITLE	INVITED BY	UPDATED	STATUS
Study	EXPLORING THE BIDIRECTIONAL RELATIONSHIP BETWEEN DATABASE MARKERS OF ASTHMA TREATMENT ADHERENCE AND ASTHMA-RELATED OUTCOMES		Thu, 19/10/2023 - 10:06	Accepted <button>Decline</button>
Data source	Biologika in der Kinderreumatologie		Thu, 19/10/2023 - 10:54	Accepted <button>Decline</button>

TYPE	TITLE	UPDATED	PUBLICATION STATUS	MODERATION STATE
Network	<a href="#">new network</a>	30/11/2023 - 10:26	Published	Submitted <button>Edit</button>
Network	<a href="#">European Network of Teratology Information Services (ENTIS)</a>	30/11/2023 - 10:25	Published	Submitted <button>Edit</button>

# Use of the catalogues: content moderation flow



Study	<a href="#">DARWIN EU® - DUS of Antibiotics in the 'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use</a>	29/11/2023 - 12:11	Unpublished	Submitted	Edit
Data source	<a href="#">Translational Research in Europe - Assessment and Treatment of Neuromuscular Diseases</a>	26/10/2023 - 14:58	Published	Draft	Edit ▾
Network	<a href="#">Medicys Limited, MEDICYS</a>	26/10/2023 - 11:46	Unpublished	Returned	Edit ▾

Save as Draft ▾

**Revision information**  
No revision

**Revision log**

Briefly describe the changes you have made.

Back Next

Search all content

**Filter options**

- Data source
- Institution
- Network
- Study

Country

+

Regions (geographical regions that the data source covers)

+

Data source type

+

Data Holder

▾

**Results (3)**

Data source ● Germany ● Hospital inpatient records ●

Sort by  ▾

↓

**Hepatitis Delta International Network (HDIN) - Patient Registry**

Austria Belgium Brazil Germany Greece Italy Mongolia Pakistan Romania Turkey United States

**First published:** 19/09/2023 **Last updated:** 08/11/2023

**Hospital Medical Records Database DE**


Austria Germany

**First published:** 31/10/2023 **Last updated:** 31/10/2023

**Deutsche Leberstiftung (German Liver Foundation)**

Azerbaijan Belgium Brazil Georgia Germany Greece Moldova, Republic of Mongolia Pakistan Spain Sweden Turkey United States Viet Nam

**First published:** 19/09/2023 **Last updated:** 30/10/2023

 **Enhanced search & export functionalities** possibility to filter, sort and export search results and records

Home > Search

## Search Catalogues

### Filter options

Document type

- Institution
- Study
- Data source
- Network

### Results (92)

Sort by

[A Study on the Utilization of Pioglitazone in Clinical Practice With Regard to Diabetic Treatment Regimen and Comorbidities](#)

 United Kingdom

**First published:** 26/10/2023 **Last updated:** 27/10/2023

[TEDDY European Network of Excellence for Paediatric Clinical Research](#)

 Austria  Cyprus  France  Germany  Greece  Italy  Netherlands  Poland  Romania  
 Spain  Sweden  United Kingdom

**First published:** 26/10/2023 **Last updated:** 26/10/2023



### Filter options

- Data source
- Institution
- Network
- Study

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Country

Select Value +

Regions (geographical regions that the data source covers)

Select Value +

Data source type

- Congenital anomaly registry
- Disease registry
- Drug registry

Data Holder

Select Value v

Clear Apply

### Results (59)

Data source ● Congenital anomaly registry ● Disease registry ● Drug registry ●

Sort by Newest first v Export results ↓

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#### Danish Health Data Registries

🇩🇰 Denmark

First published: 01/02/2024 Last updated: 12/02/2024

Data source Population registry Drug registry Cancer registry Other

[European network of population-based registries for the epidemiological surveillance of congenital anomalies](#)

🇬🇧 United Kingdom 🇺🇦 Ukraine 🇨🇭 Switzerland 🇸🇪 Sweden 🇪🇸 Spain 🇵🇹 Portugal 🇵🇱 Poland 🇳🇴 Norway 🇳🇱 Netherlands 🇲🇹 Malta 🇮🇹 Italy 🇮🇪 Ireland 🇩🇪 Germany 🇫🇷 France 🇫🇮 Finland 🇩🇰 Denmark 🇨🇪 Czechia 🇦🇷 Croatia 🇧🇬 Bulgaria 🇧🇪 Belgium 🇦🇹 Austria

First published: 23/09/2022 Last updated: 12/02/2024

Data source Congenital anomaly registry

#### Registo Nacional de Doentes Reumáticos

🇵🇹 Portugal

First published: 01/02/2024 Last updated: 12/02/2024

Data source Disease registry

#### European Rare Kidney Disease Registry

🇬🇧 United Kingdom 🇦🇪 United Arab Emirates 🇹🇷 Türkiye 🇪🇸 Spain 🇸🇯 Slovenia 🇷🇸 Serbia 🇷🇺 Russian Federation 🇷🇴 Romania 🇵🇹 Portugal 🇵🇱 Poland 🇳🇴 Norway 🇳🇱 Netherlands 🇱🇮 Lithuania 🇱🇻 Latvia 🇮🇹 Italy 🇮🇪 Ireland 🇮🇷 Iran, Islamic Republic of 🇭🇺 Hungary 🇬🇷 Greece 🇩🇪 Germany 🇫🇷 France 🇪🇪 Estonia 🇩🇰 Denmark 🇨🇪 Czechia 🇦🇷 Croatia 🇧🇪 Belgium 🇦🇹 Austria

First published: 16/02/2023 Last updated: 12/02/2024

Data source Disease registry

Home Data Sources Studies Institutions Networks Support

Home > Enroll-HD: A Prospective Registry Study in a Global Huntington's Disease Cohort A CHDI Foundation Project

## Enroll-HD: A Prospective Registry Study in a Global Huntington's Disease Cohort A CHDI Foundation Project

First published: 01/02/2024 Last updated: 12/02/2024

Data source Disease registry Biobank

[Download as PDF](#)

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**Administrative details** Data elements collected Quantitative descriptors Data flows and management

Page content

- [Administrative details](#)
- [Data source regions and languages](#)
- [Data source establishment](#)

### Administrative details

<b>PURI</b>	https://redirect.ema.europa.eu/resource/35258
<b>Data source ID</b>	35258
<b>Name of data source</b>	Enroll-HD: A Prospective Registry Study in a Global Huntington's Disease Cohort A CHDI Foundation Project
<b>Data source acronym</b>	Enroll-HD
<b>Data holder</b>	<a href="#">CHDI Foundation</a>
<b>Data source type</b>	Disease registry Biobank
<b>Main financial support</b>	Funding by own institution
<b>Care setting</b>	Hospital outpatient care Secondary care – specialist level (ambulatory) Other
<b>Data source qualification</b>	Yes

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

- Go live: 15 February
- Multistakeholder webinar for the launch: 4<sup>th</sup> March
- Continue communication activities and raising awareness
- Finalise the integration of information with EMA website content (e.g.: EPARs, product information, qualification opinions, PRAC decisions)
- Follow actively the maintenance process and collection of new data
- Continue refinement of the fields collected, look-up values and the search criteria
- Integrate characterisation of data-quality elements

The RWD Catalogues will:



**Go-Live  
in February 2024**



**Be publicly available**

<https://catalogues.ema.europa.eu/>



**Data sources and studies integrated**

Once launched, support is available here: [Support | HMA-EMA Catalogues of real-world data sources and studies \(europa.eu\)](#)