



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

PCWP-HCPWP - February 2024

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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** 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



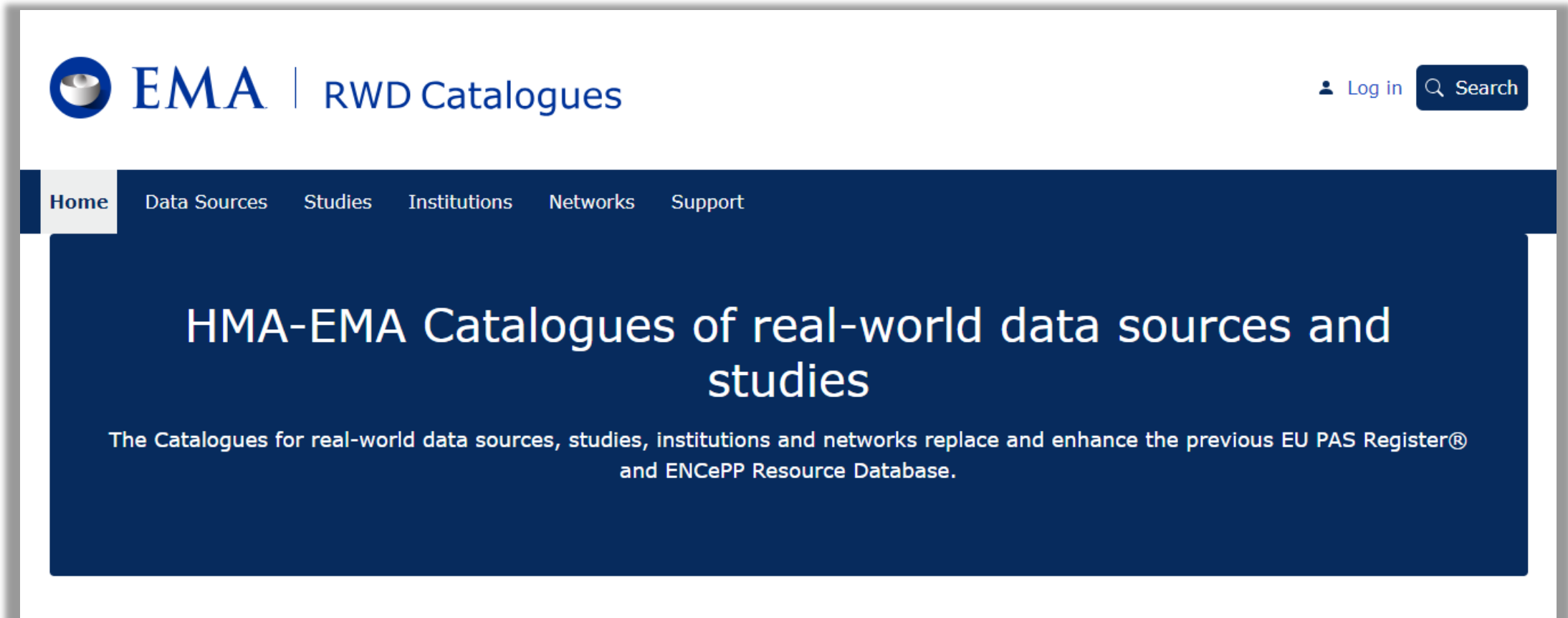
The study can be retrieved using the studies catalogue; the protocol is available. Other **similar studies** can be retrieved using studies structured metadata, and a comparison of **data sources** used in similar research is possible.

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*





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

Data source(s)	CureDRPLA Global Patient Registry Data Source Test 3 HealthData Hub: Singapore General Hospital
Data sources, if not available in the list above	SIDIAP , IPCI , CPRD

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
The value will be generated.
A globally unique and persistent identifier for an institution

Institution ID
The value will be generated.

Institution full name and acronym *
Acronym to be added in brackets after the institution name.

Institution countries *
Select Value +
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 *

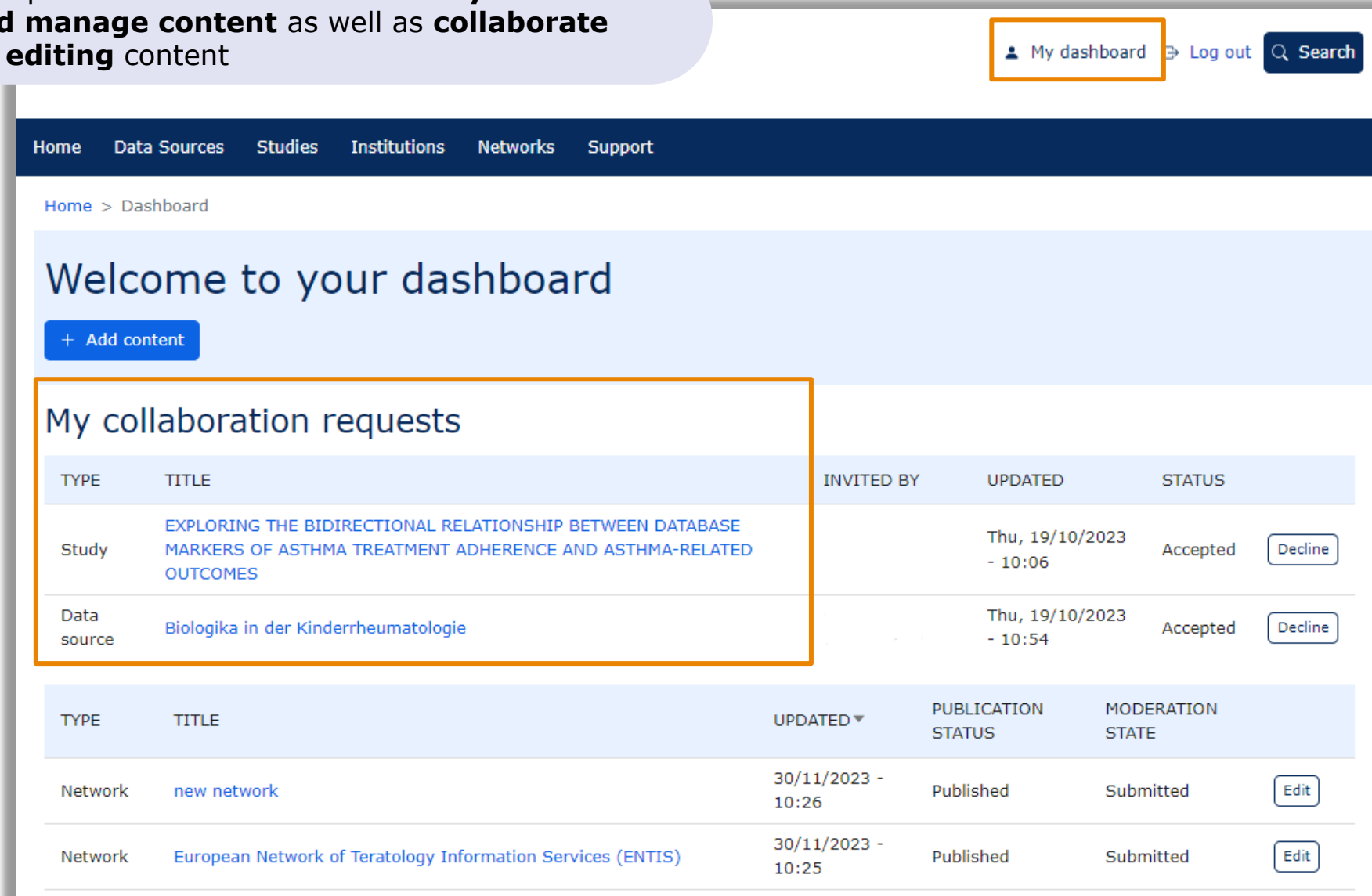
0 / 2000

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 <input type="button" value="Decline"/>
Data source	Biologika in der Kinderreumatologie		Thu, 19/10/2023 - 10:54	Accepted <input type="button" value="Decline"/>

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

Use of the catalogues: Content moderation flow



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'Watch' category of the WHO AWaRe classification of antibiotics for evaluation and monitoring of use	29/11/2023 - 12:11	Unpublished	Submitted	Edit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

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

Data source: Hospital inpatient records Hospital outpatient visit records Primary care medical records

Hospital Medical Records Database DE

Austria Germany

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


Data source: Hospital inpatient records

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

Data source: Hospital inpatient records Hospital outpatient visit records Primary care medical records

 **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 Newest first ▾

[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

Study **Finalised**

[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

Network **ENCePP partner**



Filter options

- Data source
- Institution
- Network
- Study

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](#) ↓

[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](#)

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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](#)

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

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



Multistakeholder webinar for the launch: 4 March 2024 – live broadcast on EMA website

Survey to collect feedback on the usability of the RWD Catalogues

Continuous engagement with stakeholders to use and populate the catalogues

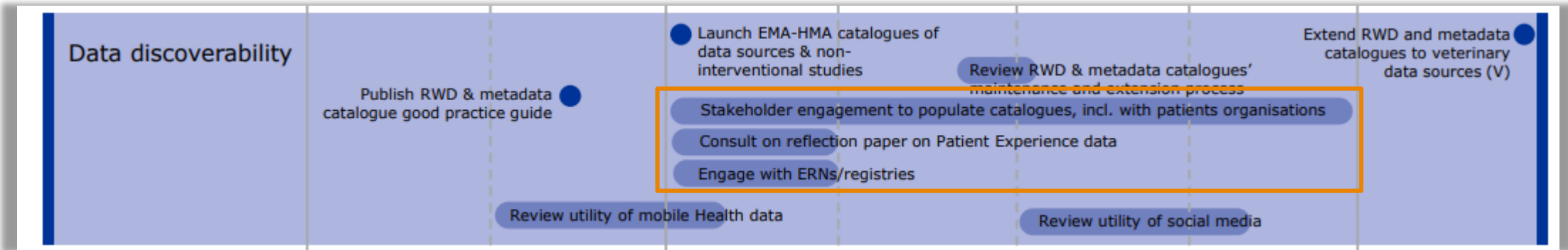
Revised draft of the Good Practice Guide publication (Q2 2024)

New release for enhanced search functionalities, re-direction of previous EU PAS Register study links, and bug improvements

Integration of information on EMA website (e.g., EPARs, product information, qualification opinions, PRAC decisions)

Continue refinement of the fields collected, look-up values, and the search criteria

Integrate characterisation of data-quality elements



Call to action! We invite you (PCOs and HCPOs) to populate the catalogue with patient data sources

1. Create an [EU Login](#) account
2. Log in to the [RWD Catalogues website](#)
3. Add data source
4. Fill in the [metadata](#) fields
5. Submit!



The RWD Catalogues are:



15 February 2024



Publicly available

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



Data sources and studies integrated

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

Any questions?

Further information

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Send us a question Go to www.ema.europa.eu/contact