EMA | RWD Catalogues

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

PCWP-HCPWP - February 2024

Presented by Ana Cochino on 28 February 2024
European Medicines Agency - Data Analytics and Methods Taskforce

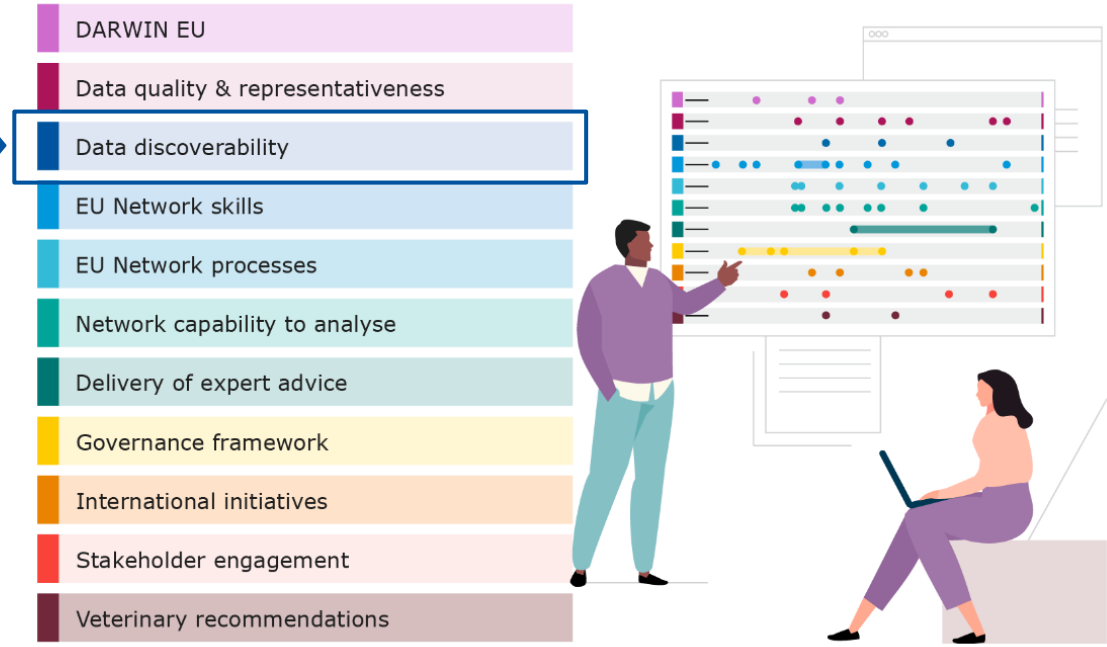
Background & Context

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**.

Recommendation 3:
Enable data discoverability

- Identify **Key Metadata for regulatory decision-making** on the choice of data source
- **Strengthen the current ENCePP** Resource Database



Catalogue of real-world data sources

Catalogue of real-world data studies

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

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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)

Use of the catalogues: Examples

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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.

Use of the catalogues: Key improvements

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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*

**This feature will be released after go-live in a second phase.*

Use of the catalogues: Add a data source

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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

Use of the catalogues: Add a study and linkage functionality

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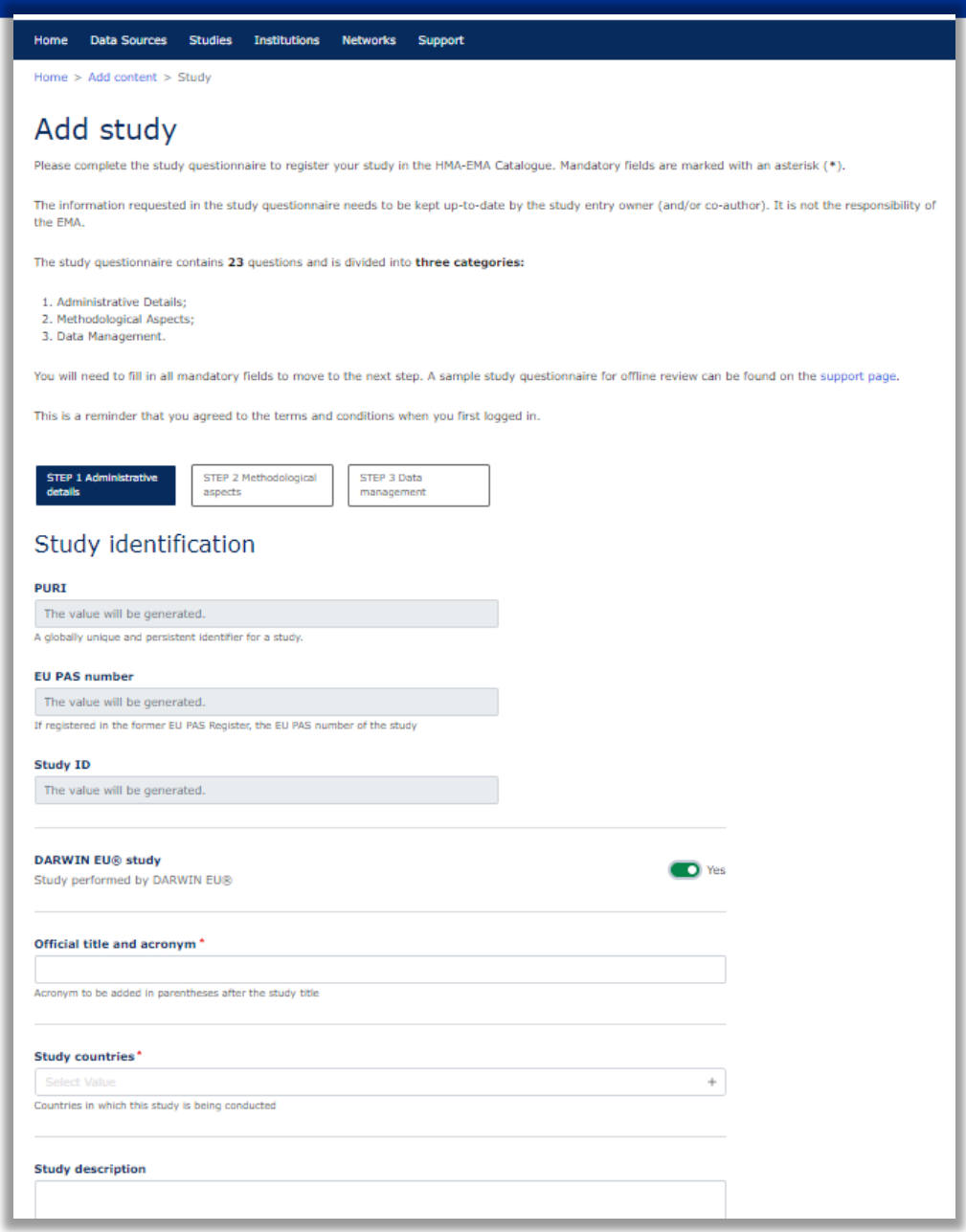
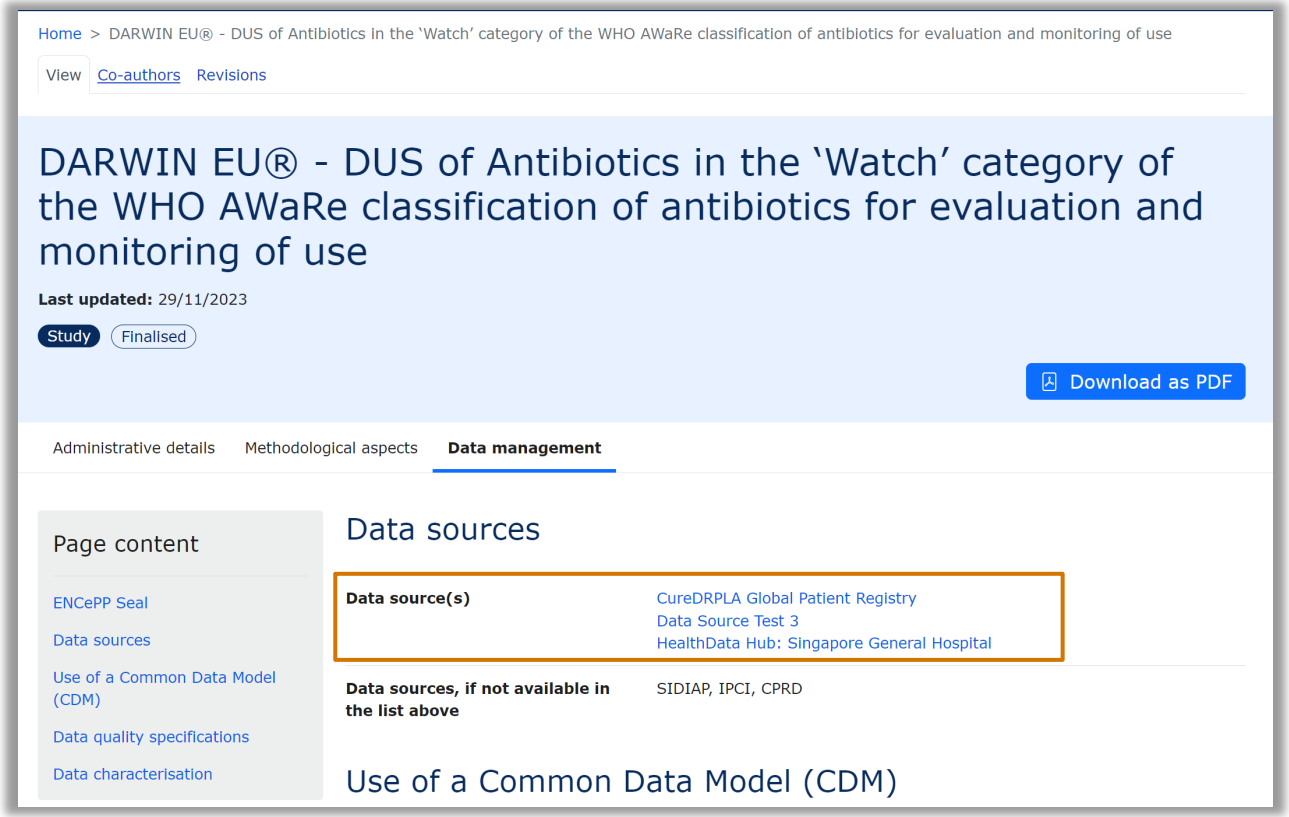
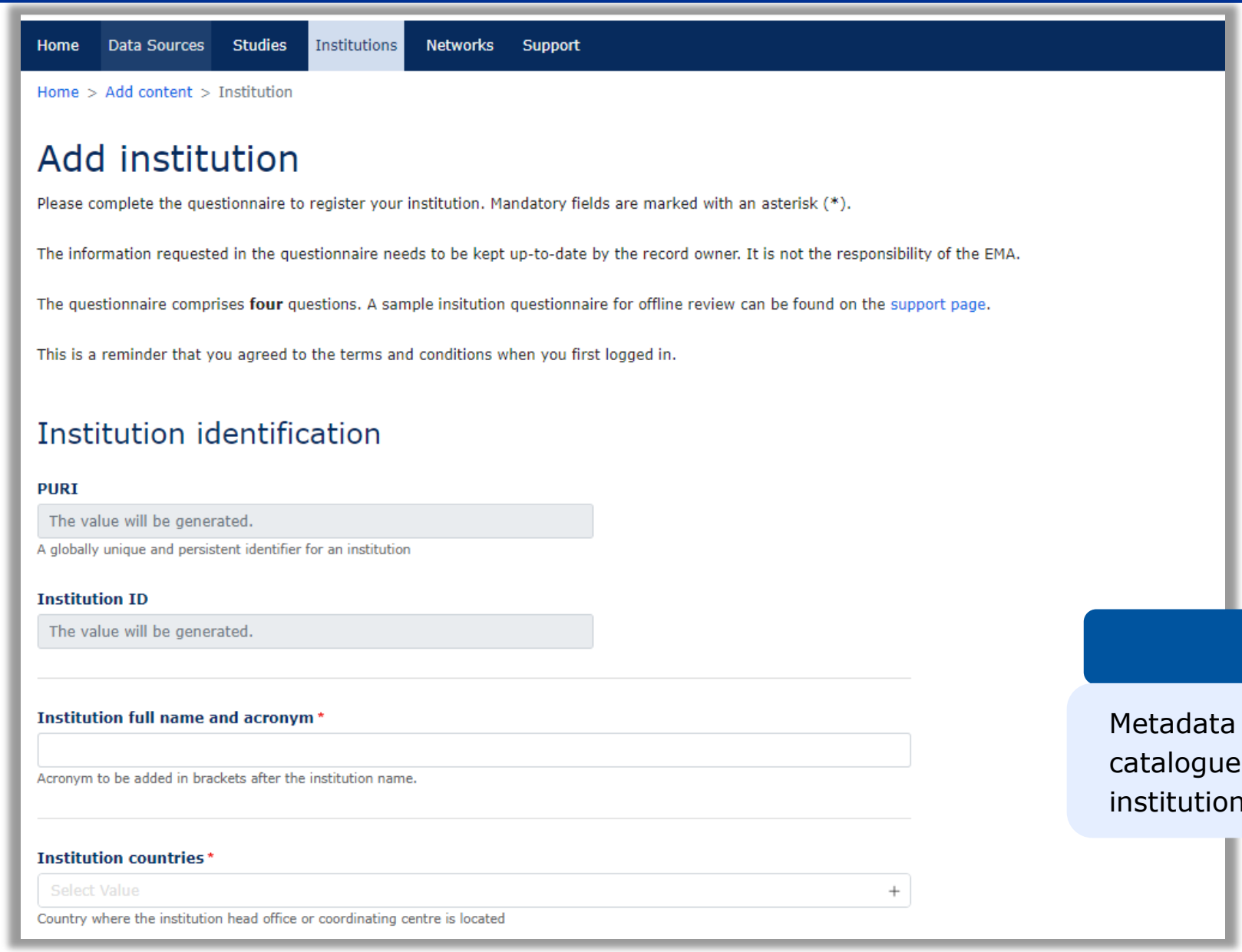


Link between **data sources and associated studies**



Use of the catalogues: Add an institution



Institutions

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

Use of the catalogues: Add a network

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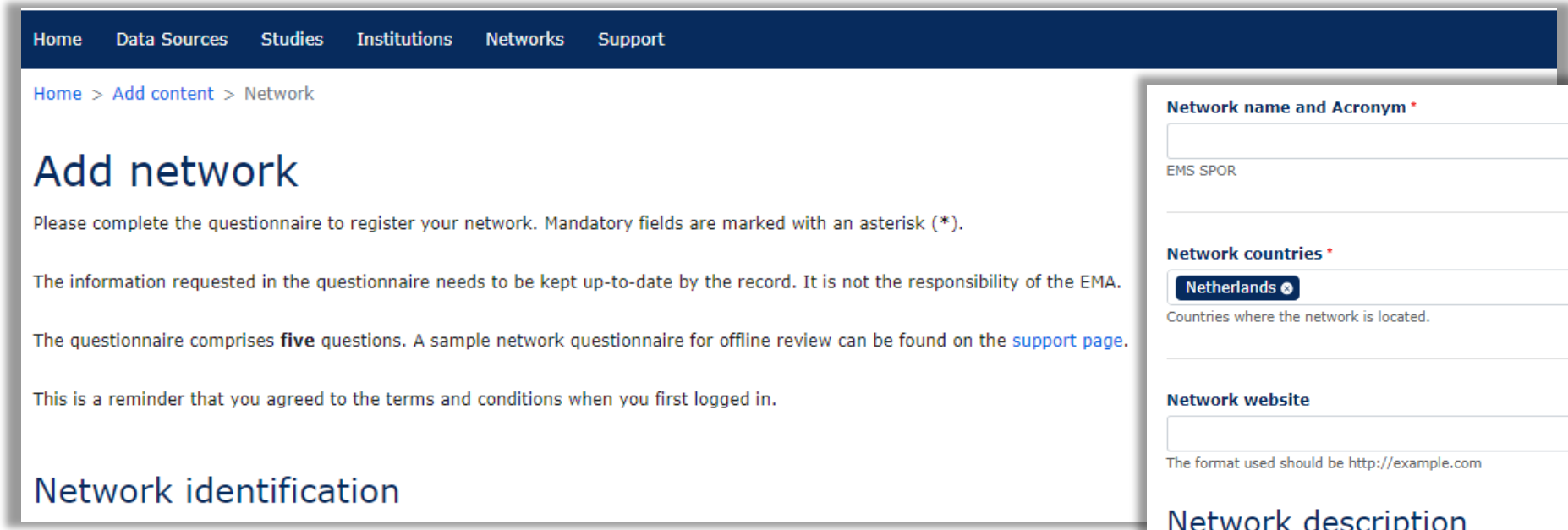

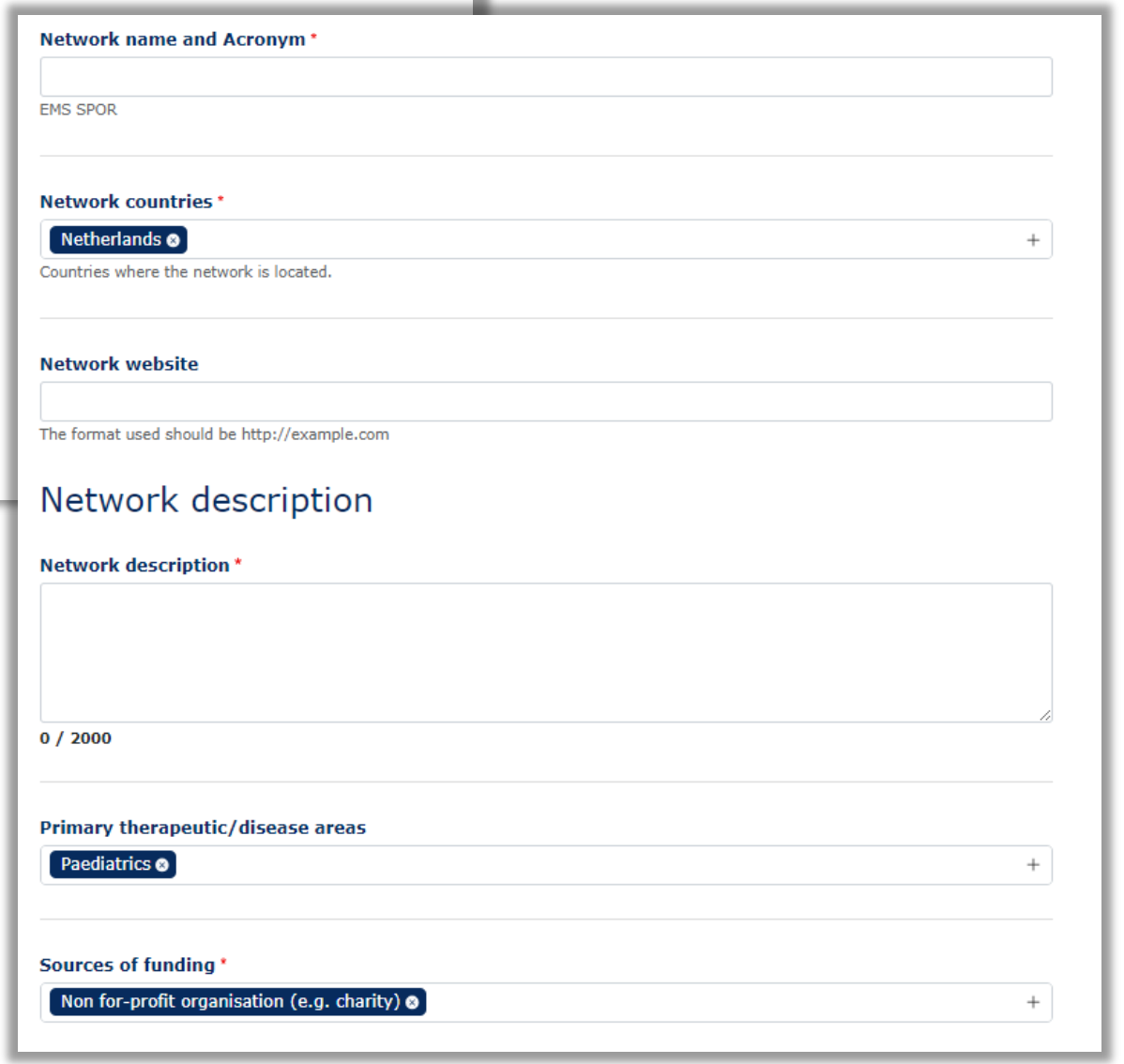

Networks

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

Use of the catalogues: My dashboard and Co-authorship

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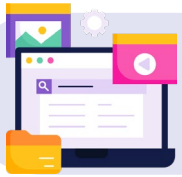
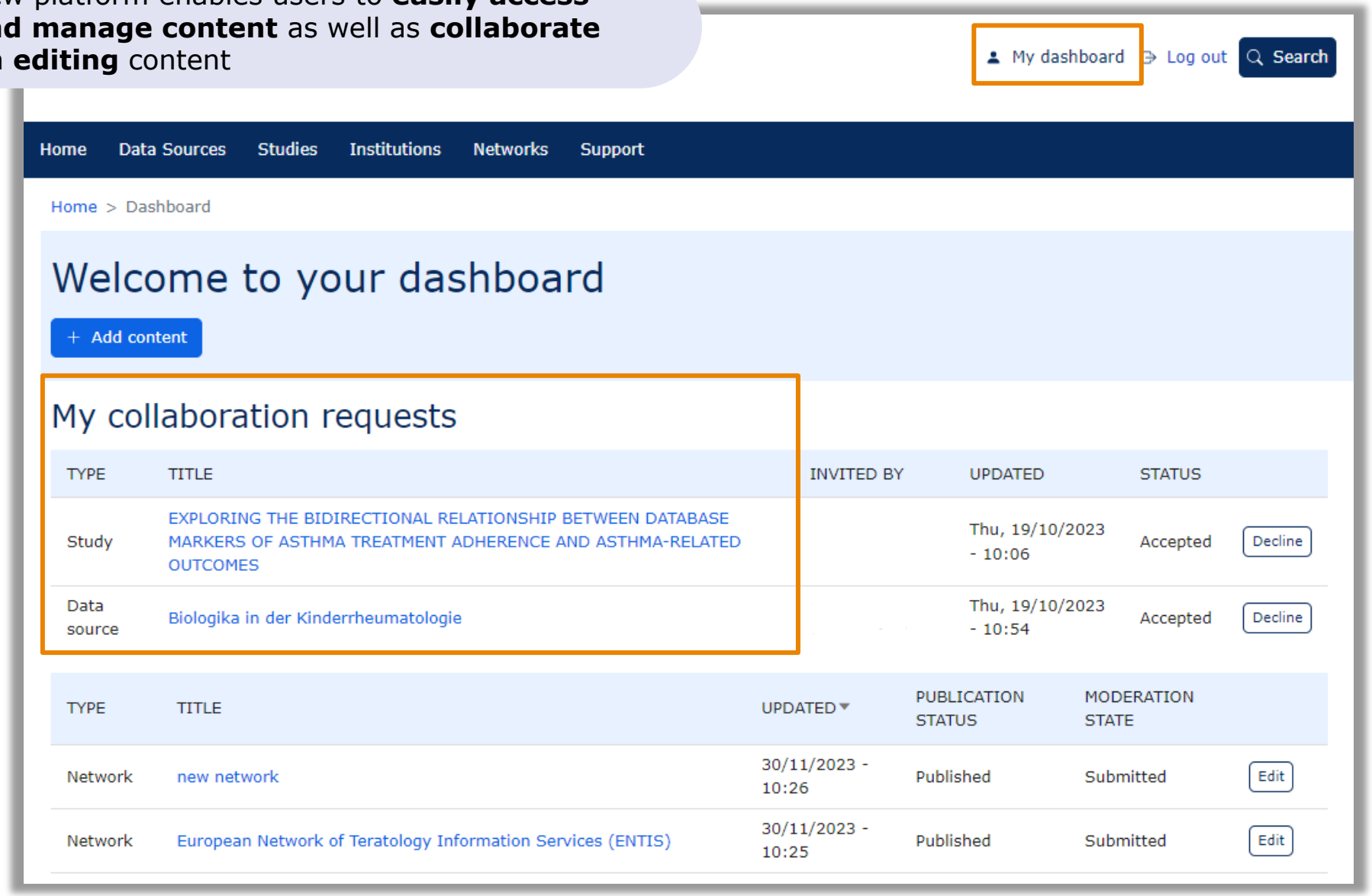
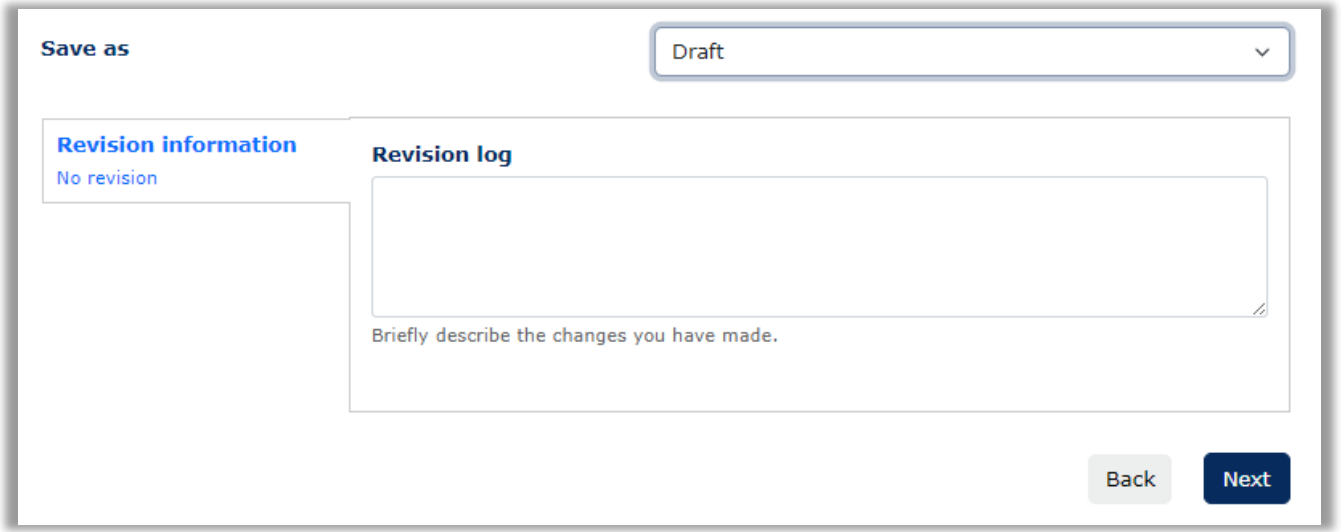


New platform enables users to **easily access and manage content** as well as **collaborate on editing** content

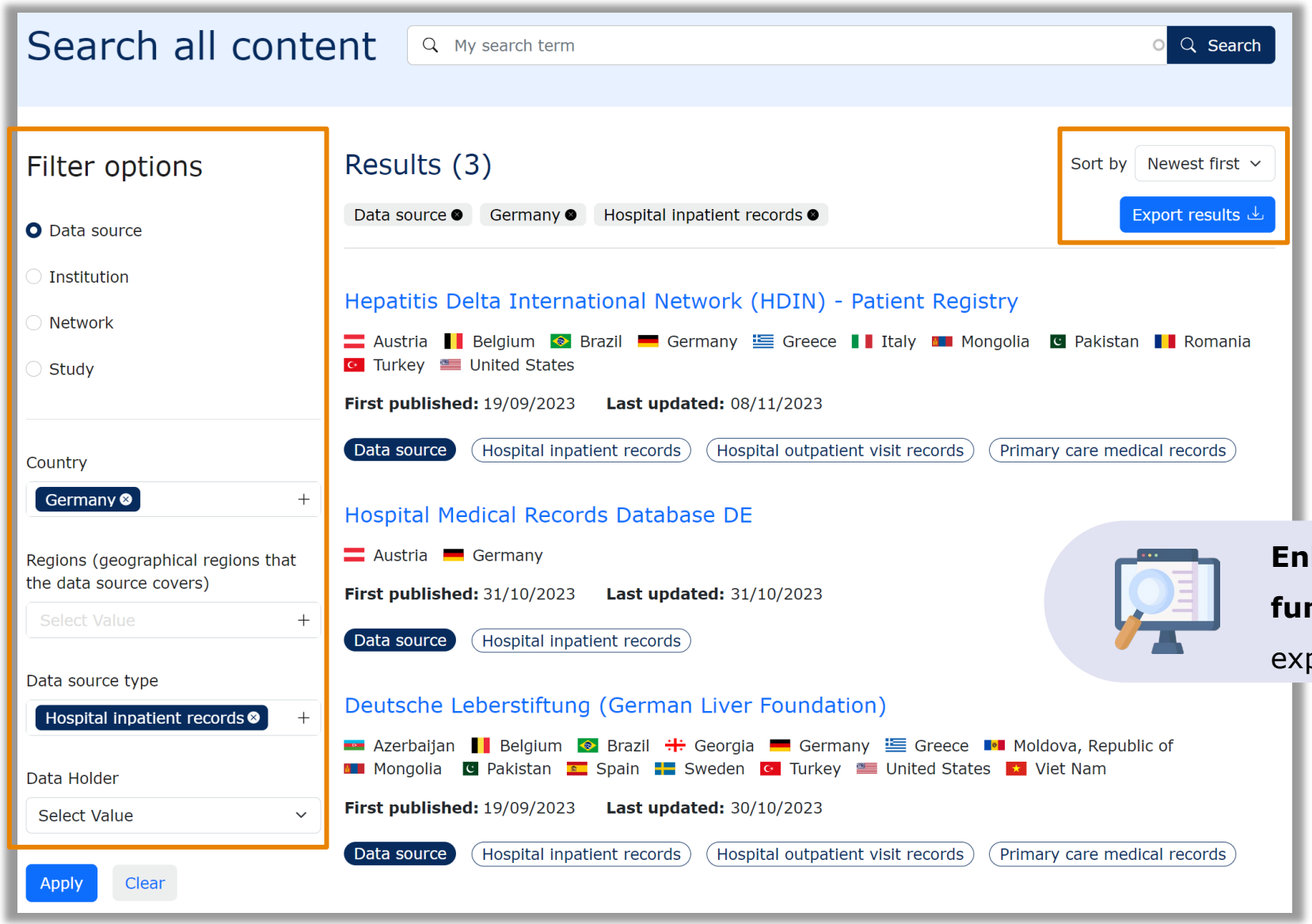


Use of the catalogues: Content moderation flow

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

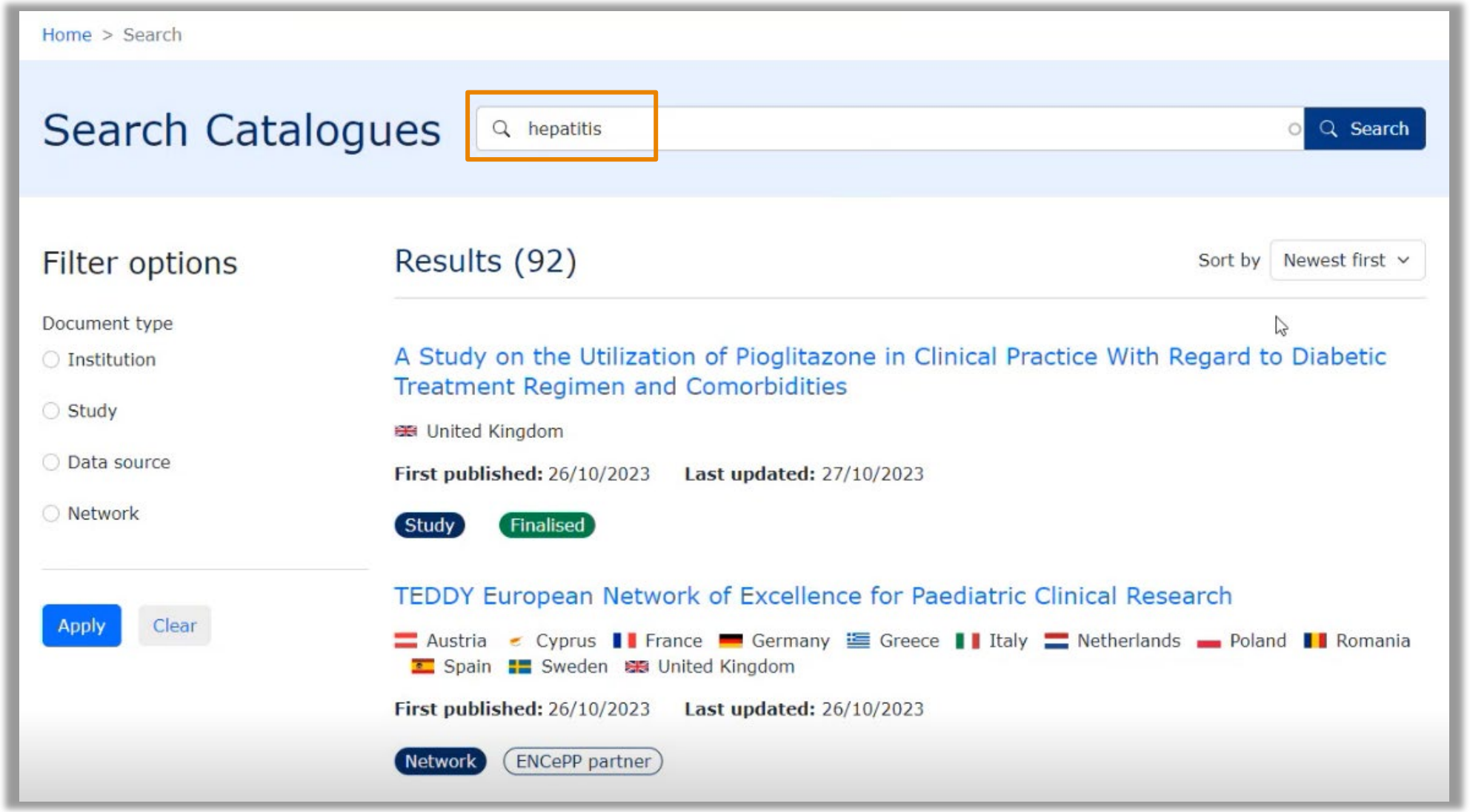


Use of the catalogues: Search functionality



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

Use of the catalogues: Search functionality



Patient registries: examples of specific data

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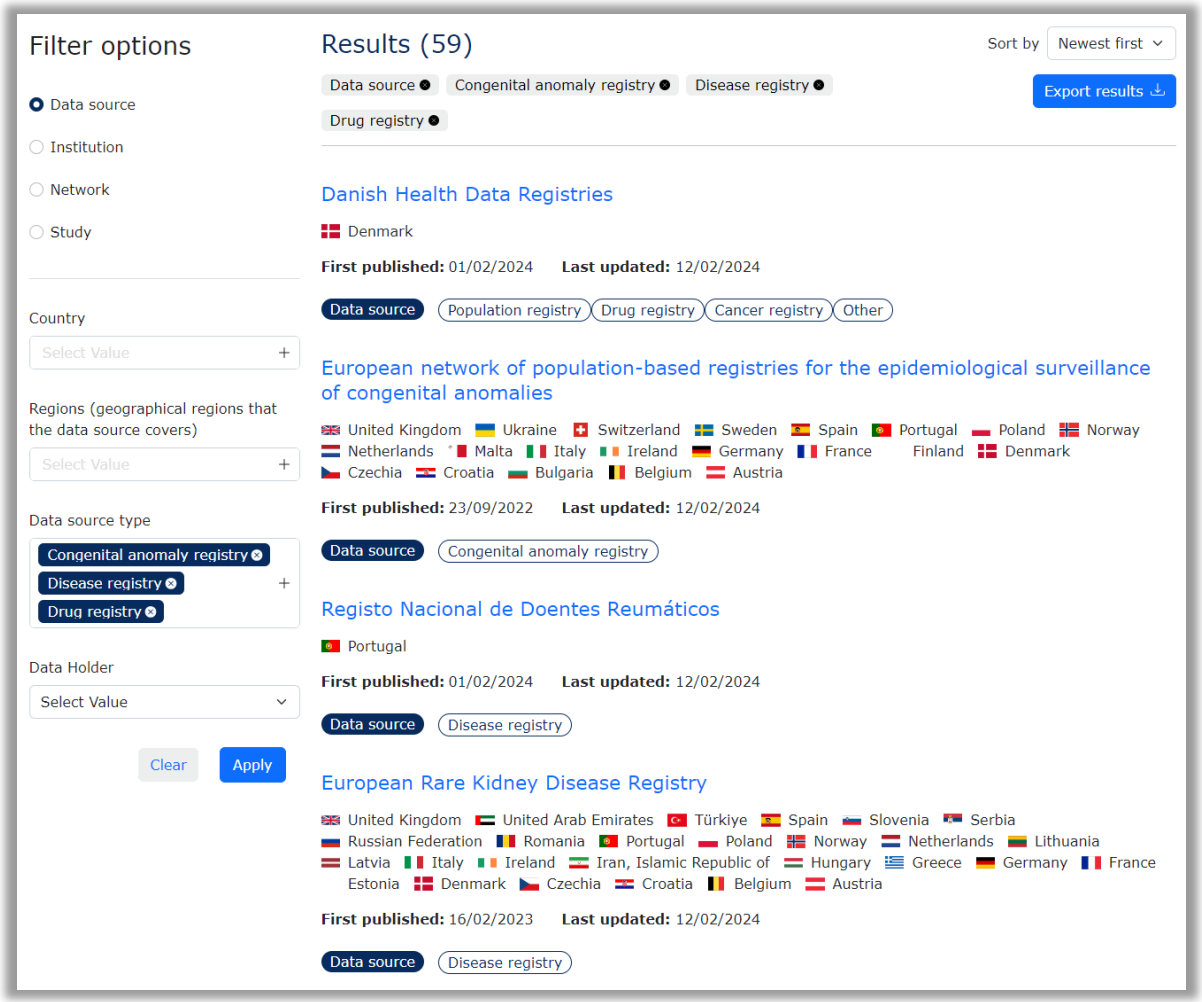
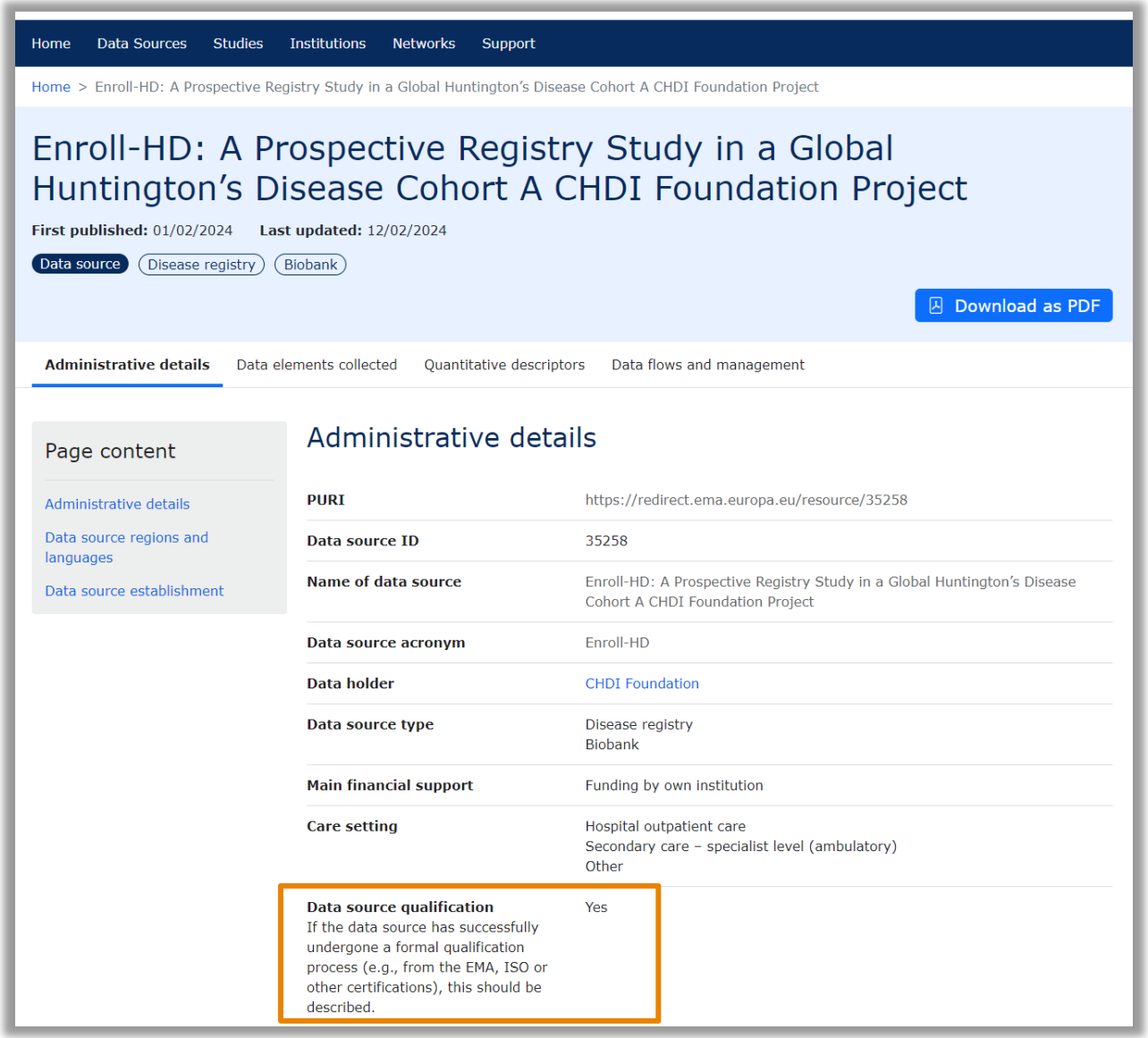




Next steps

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)

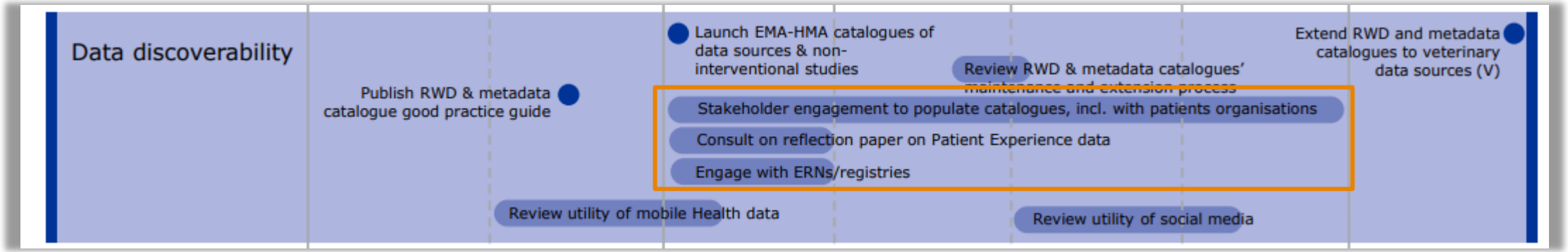
New release for enhanced search functionalities, re-direction of previous EU PAS Register study links, and bug improvements

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

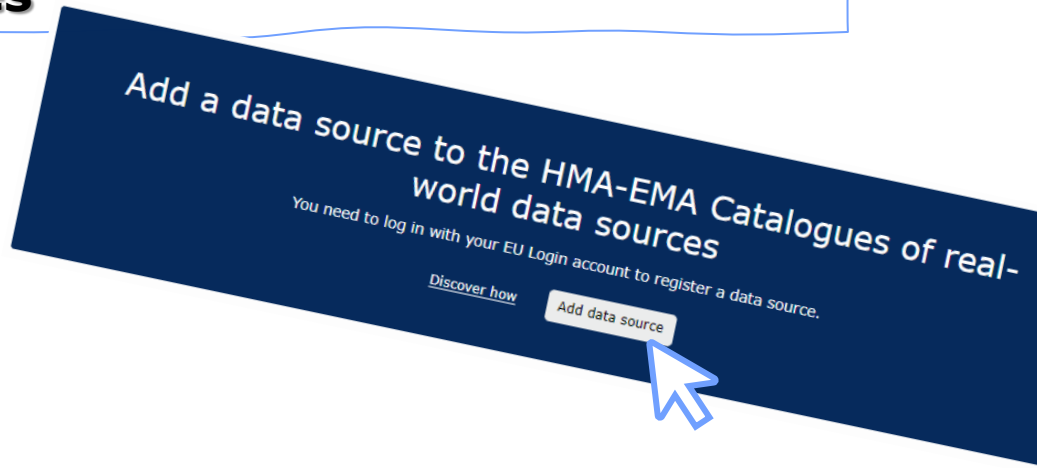
Integrate characterisation of data-quality elements

Next steps for Data Discoverability



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!



Take home messages

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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