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SCIENCE MEDICINES HEALTH

EMA-HMA Catalogues of data sources and non-interventional studies

ENCePP Plenary 2023

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slido.com
#catalogues

Presented by Ana Cochino on 1 December 2023
European Medicines Agency - Data Analytics and Methods Taskforce

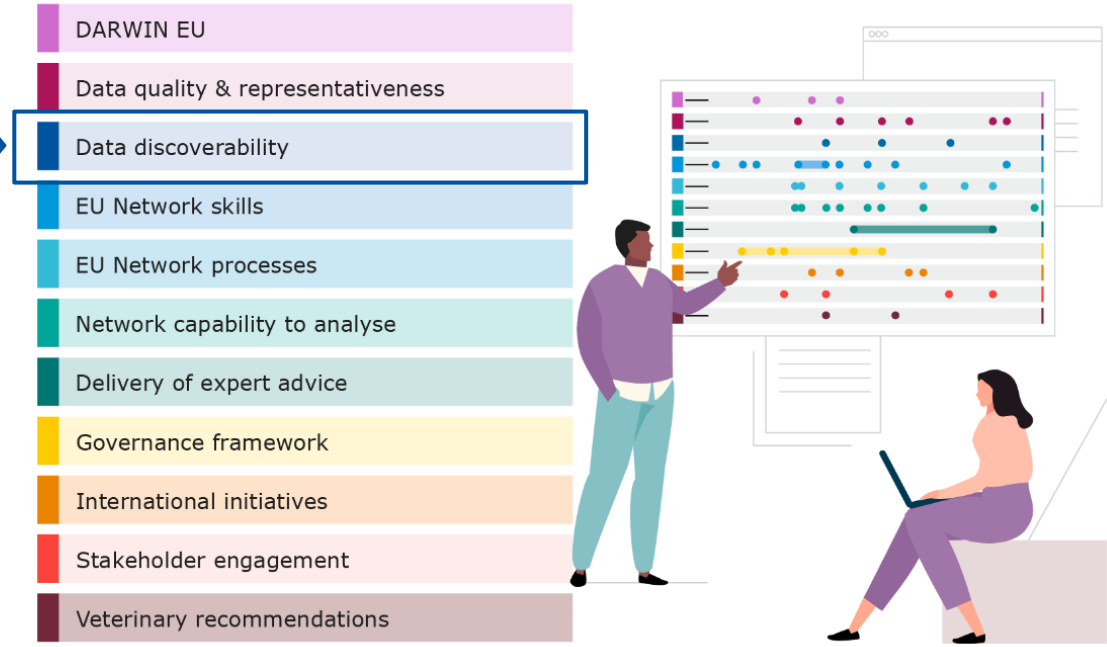
Background & Context

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 data sources

Catalogue of non-interventional studies

EMA-HMA Catalogues of data sources & non-interventional studies

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The **EMA-HMA Catalogues of data sources and non-interventional 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 data sources

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

Catalogue of 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)

Send us your **proposals** for a **short name/acronym** for the new EMA-HMA catalogues of data sources and non-interventional studies

Slido will remain open for proposals until 4 December

"At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool Slido. Please go to Slido and enter the event code 'catalogues'. Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, you consent to the processing of your personal data as explained in the EMA Data Privacy Statement for Slido."

Use of the catalogues: Examples

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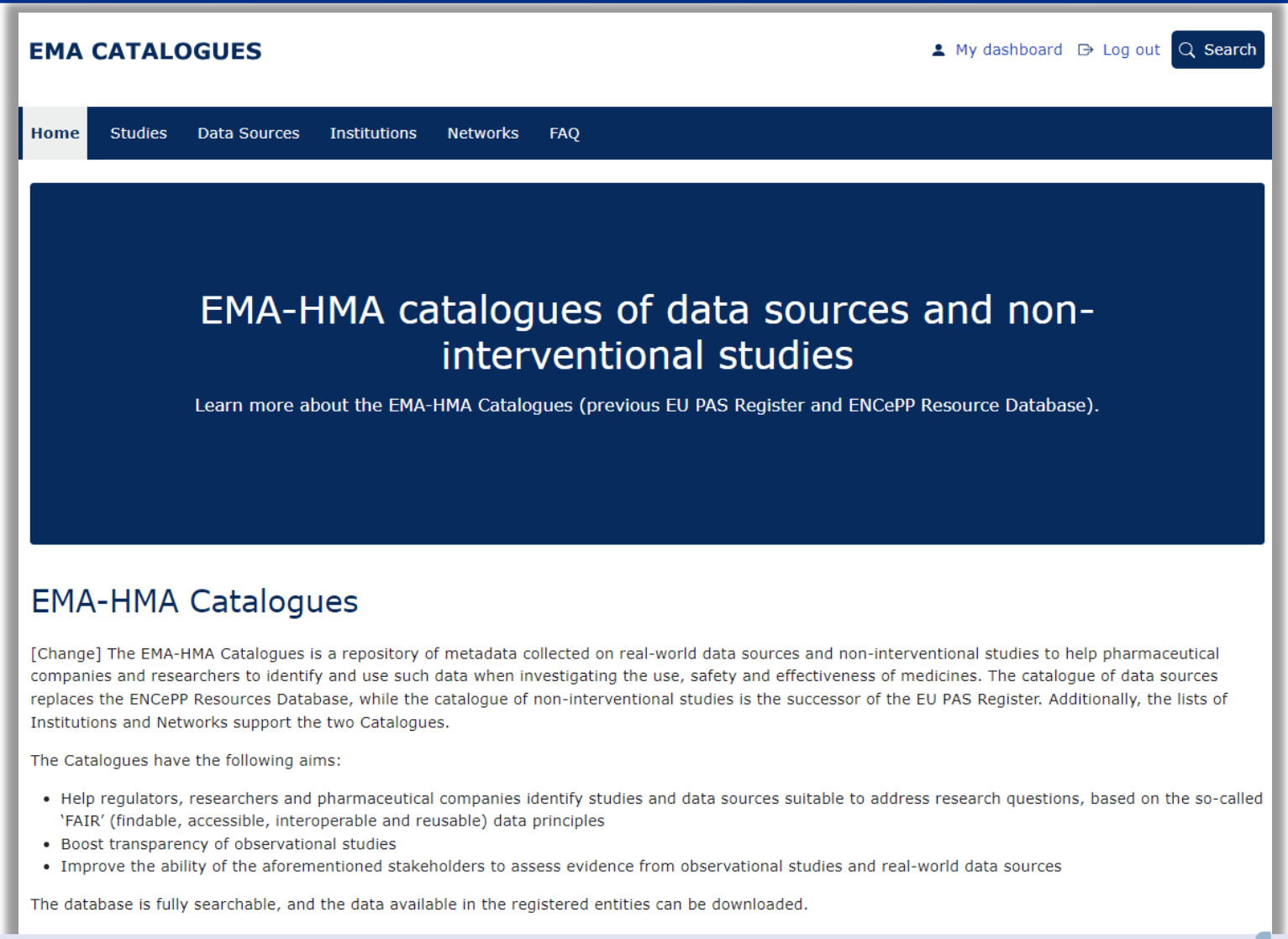
A user would like to identify suitable data source(s) for a planned study	The catalogue of data sources offers information (metadata) on the **data source content** (e.g.: capturing of medicinal product information, disease, demographics), availability, contact points to help the choice of data source. 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: Home page



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 Studies Data Sources Institutions Networks FAQ

Home > Add content > Data source

Add data source

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

The information provided in the questionnaire needs to be kept up-to-date by the editor of this entry, and this is not the responsibility of the EMA.

The questionnaire's 16 questions are divided into 4 steps: 1. Administrative Details, 2. Data Elements Collected, 3. Quantitative Descriptors and 4. Data Flows and Management. A sample questionnaire for offline review only, can be downloaded using the following link: (FILE TO BE ADDED)

You agreed with the terms and conditions when you joined the EMA-HMA Catalogues.

STEP 1 Administrative details | STEP 2 Data elements collected | STEP 3 Quantitative descriptors | STEP 4 Data flows and management

Administrative details

Name *

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.

Acronym

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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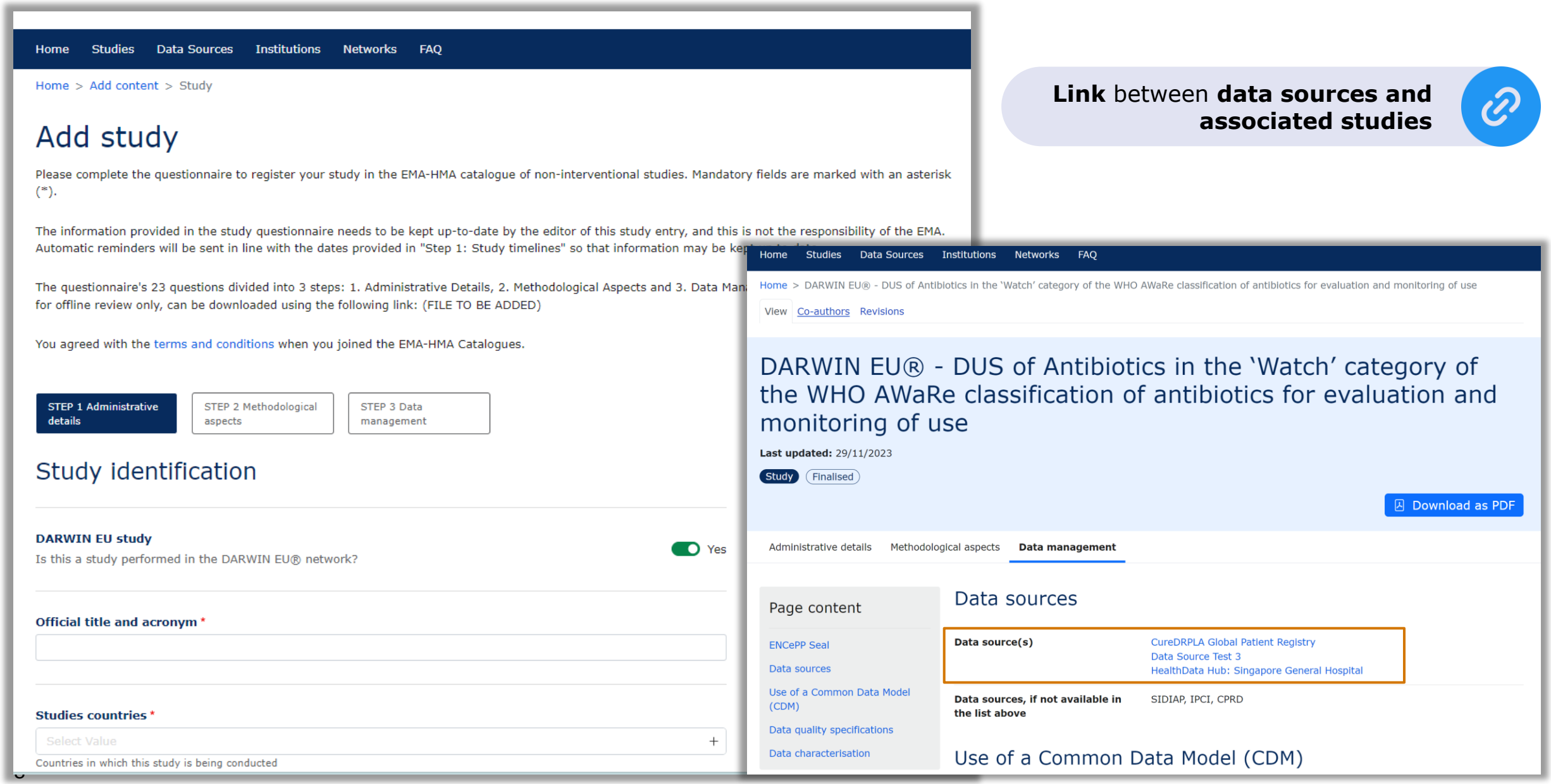
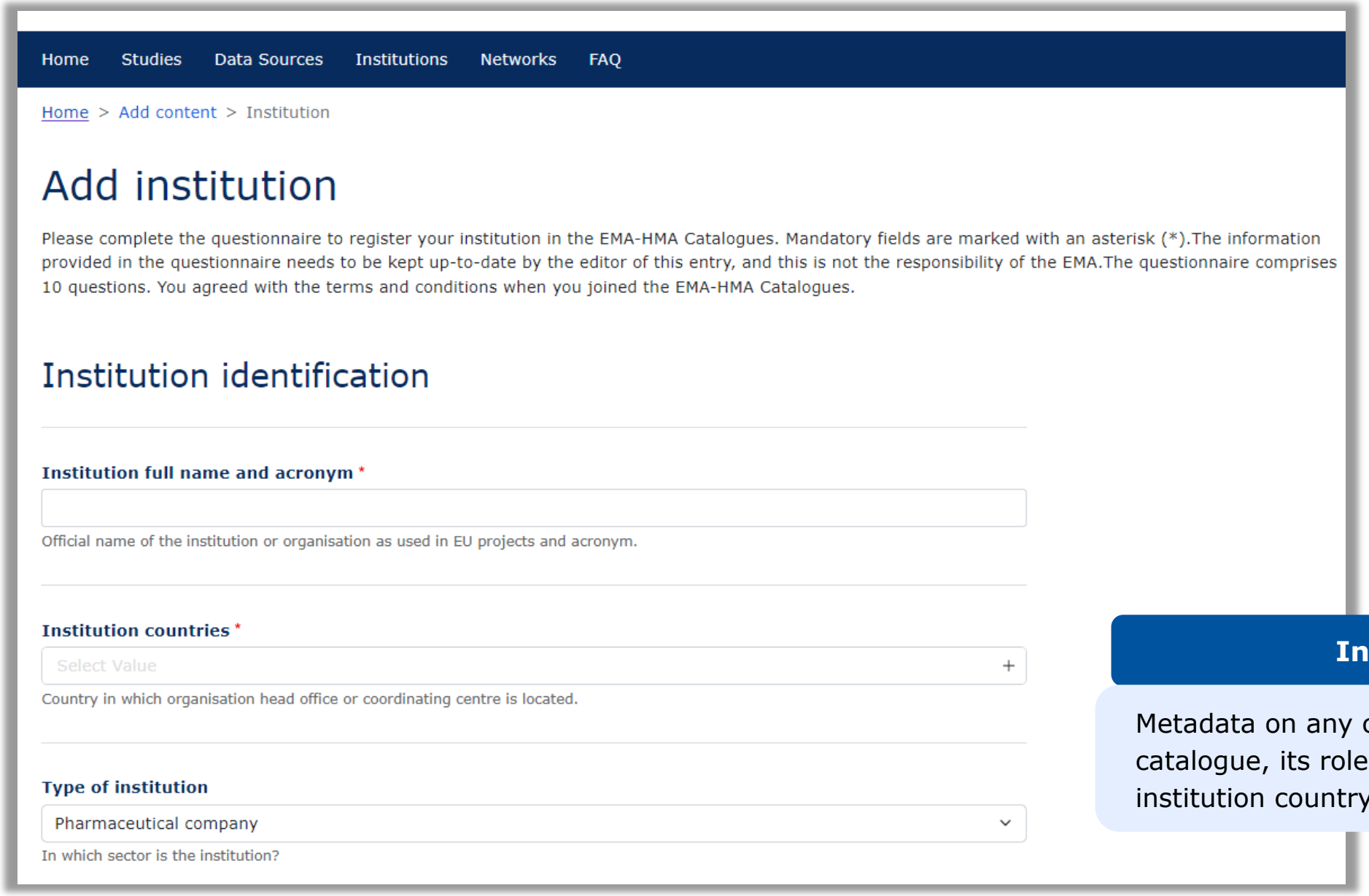
Link between **data sources and associated studies**



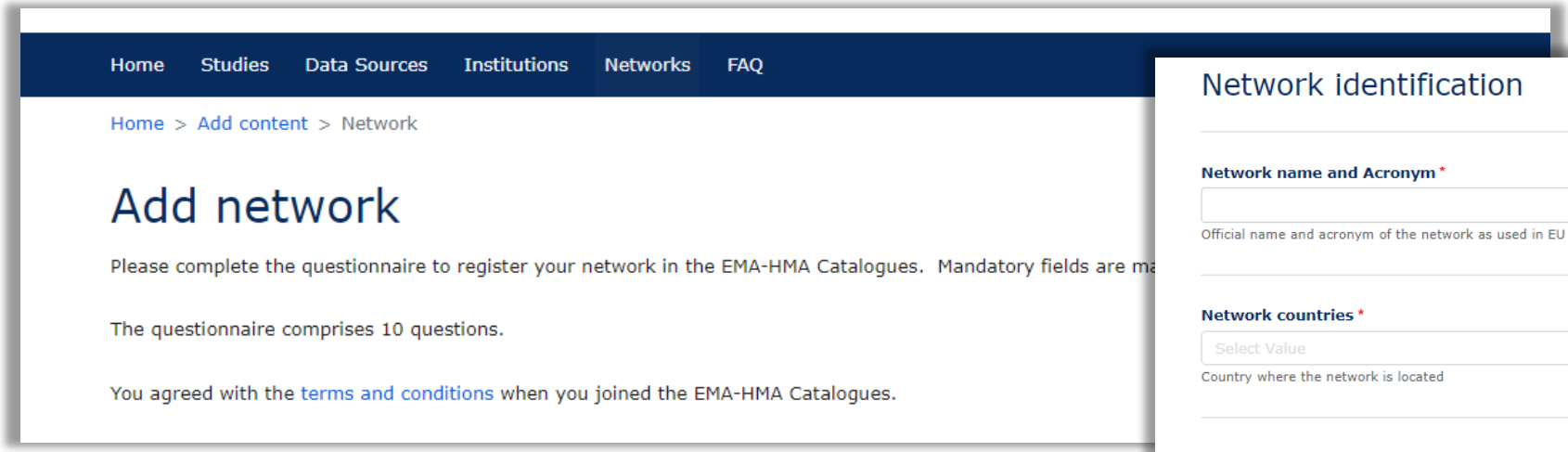
Use of the catalogues: add an institution

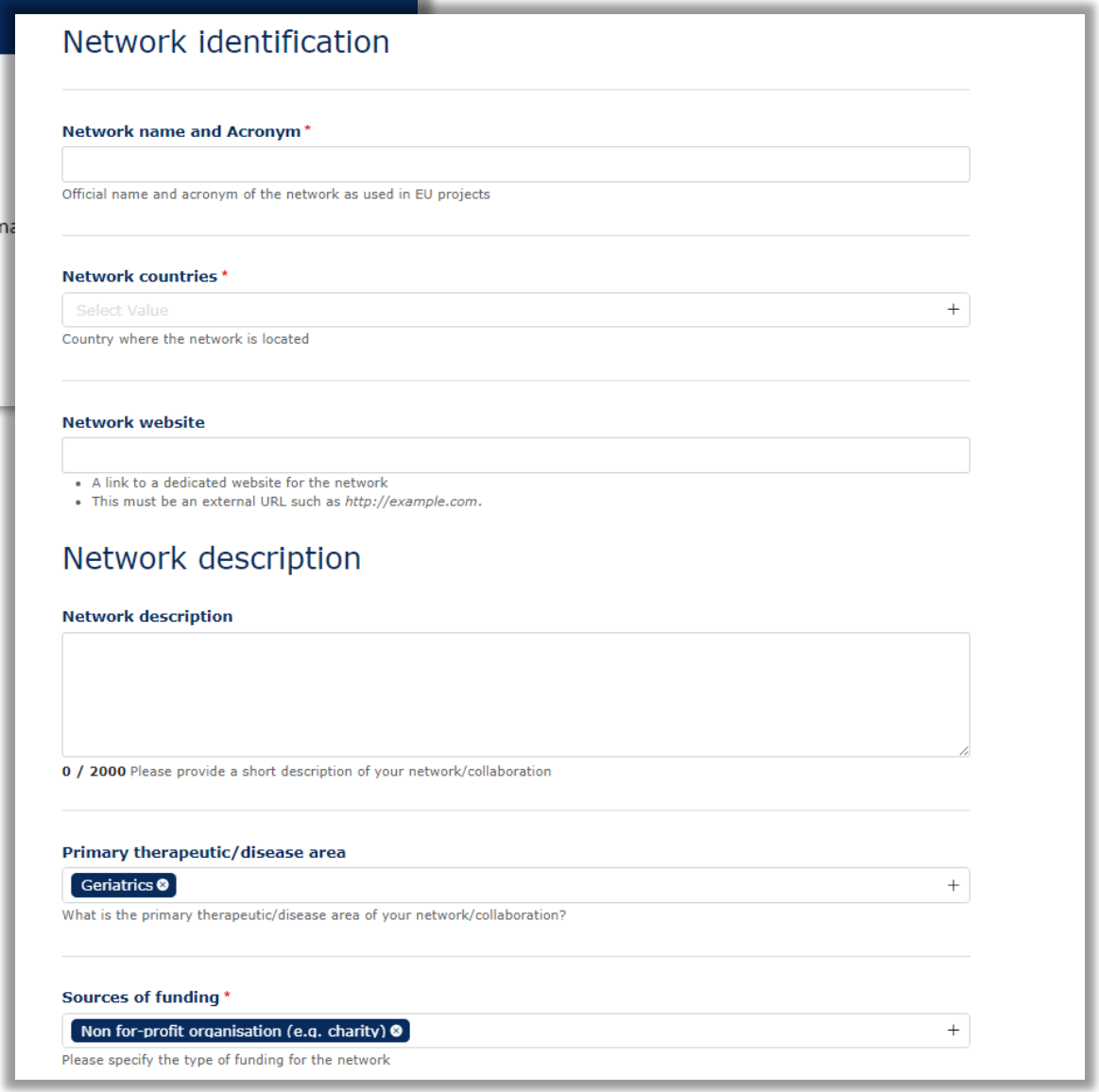


Institutions

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

Use of the catalogues: Add a network





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

My dashboard | Log out | Search

Home | Studies | Data Sources | Institutions | Networks | FAQ

Home > Dashboard

Welcome to your dashboard

+ Add content

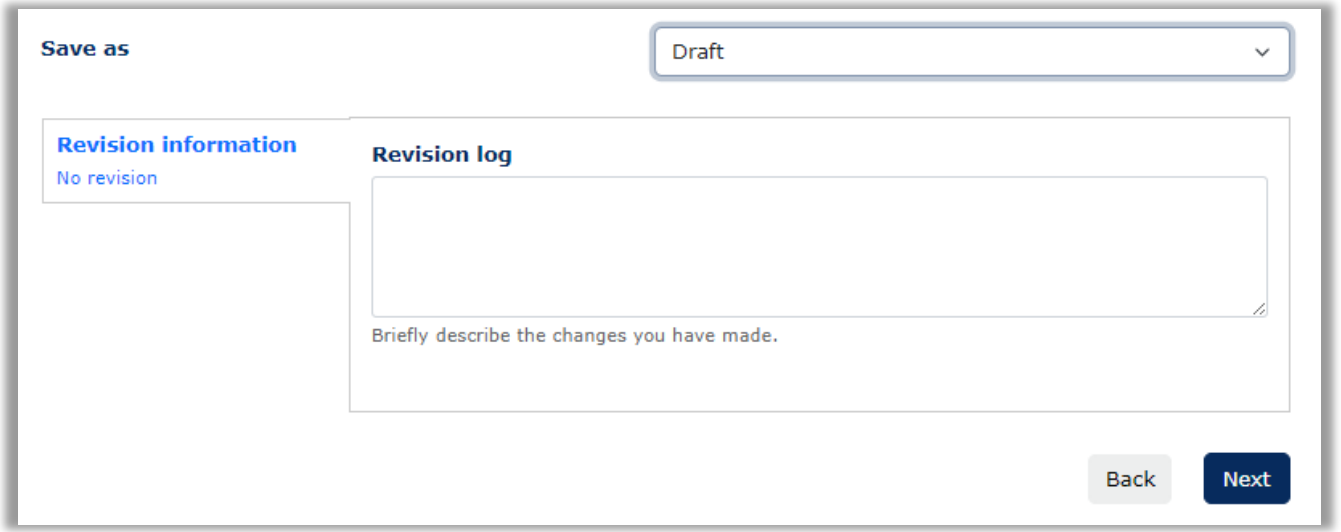
My collaboration requests

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	Decline
Data source	Biologika in der Kinderrheumatologie		Thu, 19/10/2023 - 10:54	Accepted	Decline

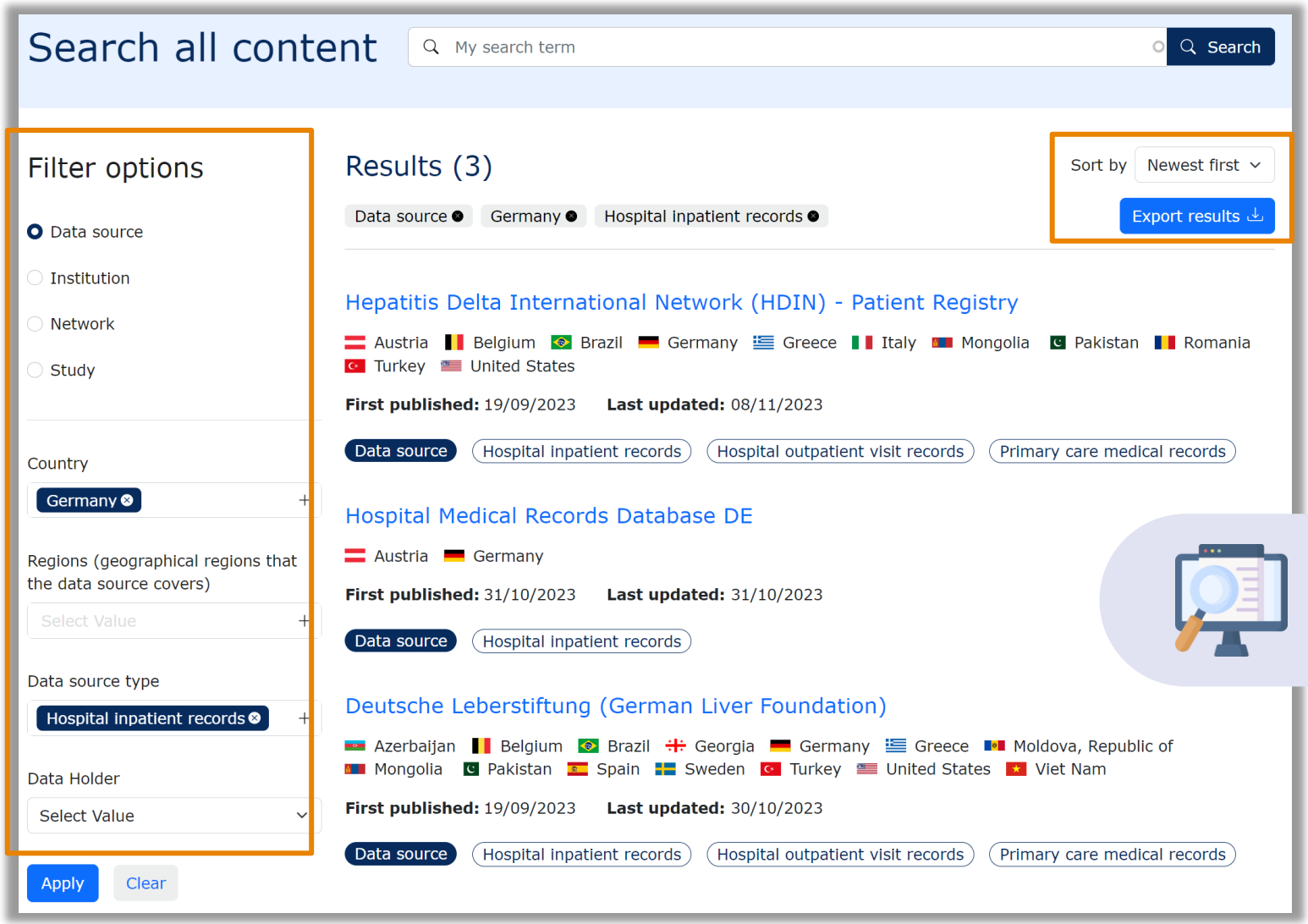
TYPE	TITLE	UPDATED	PUBLICATION STATUS	MODERATION STATE	
Network	new network	30/11/2023 - 10:26	Published	Submitted	Edit
Network	European Network of Teratology Information Services (ENTIS)	30/11/2023 - 10:25	Published	Submitted	Edit

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

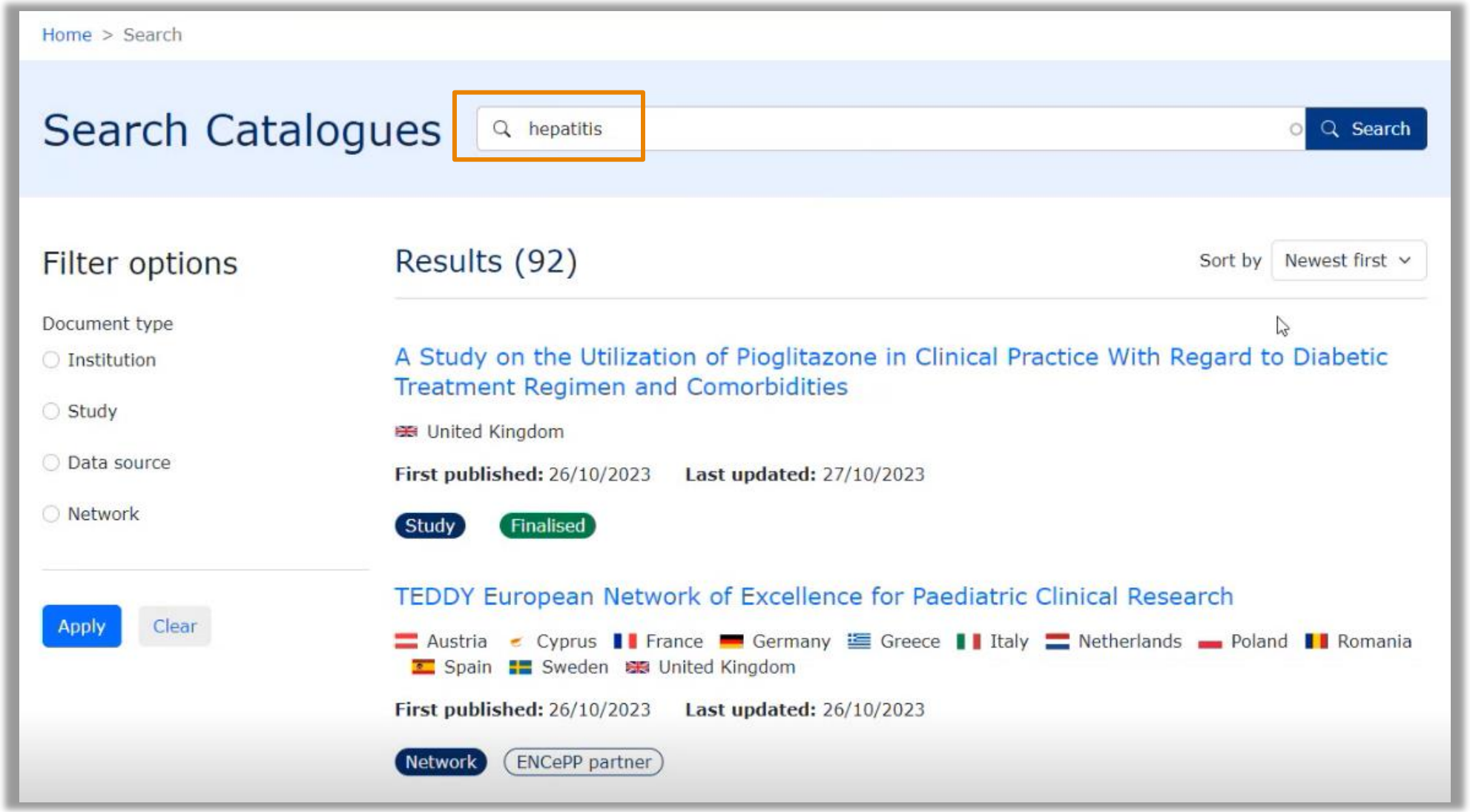


Use of the catalogues: Search functionality



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

Use of the catalogues: Search functionality



External Validation: Preliminary results

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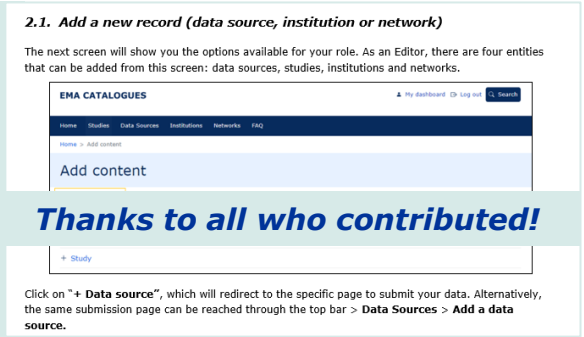
Scope: to explore the functionalities, overall content, and provide feedback on the catalogues.

Volunteers to this exercise from the Industry, data holders, DARWIN EU Coordination Centre, institutions, NCA, academics etc. **Thanks to ENCePP Partners for their contributions!**



Thanks to all who contributed!

Comments were mainly related to:

Data entry and visualisation
- Navigation between steps/pages and visibility of buttons
- Dashboard visualisation improvements
- % complete metric for data entry

Co-authorship and moderation flow
- Status change from draft to submitted to returned
- Co-authorship functionalities tested
- Completing all three steps of the form before being able to save the draft

Search functionalities and look ups
- Filters working
- Various limitations in the search functionality
- Additional filter options proposed

Content
- Data quality and completeness
- Interpretation of fields and instructions → FAQ
- Alignment between sections and other platforms such as CTIS

Export (of search and documents)
- Not all details are provided in the exported pdf
- Some issues with Excel export of search results
- Additional Word Export version for review of draft

Bug reporting
- Errors when submitting entries
- Error with collaboration requests

Changes & Improvements

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Main highlights

The replacement of the current ENCePP Resource database and EU PAS Register with a **new platform** with a **revised list of data elements** captured. It will require users to have an **EU Login account** to submit and manage their content.

Download of data will be possible, along with the possibility to **link such data to other EMA regulatory documents** (after go-live). The information on data sources and studies will be **publicly available** on the EMA website.

Summary of changes:

- The Catalogues of Data Sources and Studies will be moved from current ENCePP website to **EMA website**.
- **Updated user-friendly platform**, with a data manegement dashboard, better search functionalities and the possibility to download data.
- **Revised data elements** collected for both data sources and studies.
- An integration of EMA website content with studies and data source information (to follow after go-live).
- New look and feel & URL address for the rest of the content on the **ENCePP website** (e.g.: guidance, news etc.).
- A **downtime** of 2-3 weeks will be needed for the transfer between the two systems.

Upcoming communication

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Upcoming communications

Communication to users*

- Create **EU Login accounts**
- EU PAS Register **hidden protocols** will not be migrated unless published before 1 January
- **All (published) studies** are being migrated (incl. finalised, ongoing and planned)
- Data sources that have not confirmed migration can still submit their data after go-live!
- **All Networks and Institutions** (aka Centres) are being migrated

Communication about expected downtime (of current ENCePP databases)

- **Downtime**/freeze submission **2-3 weeks** in January.
- Industry, regulators, and ENCePP users will be informed of downtime.
- Any updates to be made **prior to 1 January** or **after go-live.**

Exact timelines TBC

Upcoming events

- HMA/EMA Big Data Stakeholder Forum on 4 December
- EMA Quarterly system demo - Q4 2023 on 19 December
- Multistakeholder workshop on Patient Registries on 12-13 February 2024

Expected go live: early 2024!

*Users= ENCePP database users, i.e. primary lead investigators for studies, contact points for data sources, centres and networks etc.

Use of the catalogues: notable points

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1 Catalogues are primarily aimed at **medicine regulation** and usefulness in this particular context

The metadata elements are tailored to this scope and have been **agreed within the network** 2

3 The technical development is in line with **FAIR principles** , taking advantage of a modern approach to cataloguing, while building on data collected for over 10 years (ENCePP)

At Go-live (early 2024) the catalogue will be pre-populated with information: 4

- Data sources collected from RWE use cases and exploratory pilots (e.g.: DARWIN EU, ENCePP, MINERVA)
- Studies migrated from EU PAS Registry (e.g.: post-authorisation safety studies, other observational studies) - protocols, results and structured information included

5 A data management system built in ensuring ease of **maintenance** and a **data validation** module ensuring reliable data published

Integration with **other regulatory documents** from EMA corporate website (to be further developed throughout next year, post go-live) 6

7 Integration with other catalogues, EHDS and similar initiatives (to be further developed in the coming years)

Take home messages

The EMA-HMA Catalogues will:

Go-Live in early 2024

Be publicly available

Data sources and studies integrated

More information

For more information about the new system, you may want to refer to the product "**Real World Metadata Catalogues (RWMC)**" included in the EMA quarterly system demos listed below:

- Demo: data source form (Q2 2023)
- Demo: studies form and user dashboard (Q3 2023)
- List of metadata elements
- Catalogues good practice guide (draft version)

Join at
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For questions related to the new catalogues: metadata@ema.europa.eu

Upcoming events

- HMA/EMA Big Data Stakeholder Forum on 4 December
- Quarterly system demo - Q4 2023 | European Medicines Agency (europa.eu) on 19 December