

HMA-EMA Catalogues of real-world data (RWD) sources and studies

Enhancing transparency,
discoverability and supporting the
use of RWD

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Joint Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP)
Working Parties meeting

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Background & Context: RWD & RWE

- **Real-world data (RWD)** are data that describe patient characteristics in routine clinical practice
 - Data relating to **patient health status** or the **delivery of health care** from a variety of sources other than traditional clinical trials
 - e.g. claims databases, hospital data, electronic health records, patient registries, etc.
- **Real-World Evidence (RWE)** is evidence derived from the analysis of RWD
- Use of **real-world data (RWD) in regulatory decision-making** is rapidly evolving
 - RWD can be used to achieve better informed and more efficient regulatory decision-making as a complement to existing evidence
 - Challenges: data heterogeneity, varying data quality, governance diversity

Background & Context: RWD Catalogues

- The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) launched two electronic Catalogues in 2024 aiming to:
 - **Promote transparency** in non-interventional research by providing access to comprehensive information on **RWD studies**
 - **Ensure discoverability** of **RWD sources**
 - **Enhance the understanding of RWE** supporting regulatory decisions
- A **publicly accessible, centralised resource** of **metadata** on **RWD sources** and all types of **RWD studies** to enhance transparency, reproducibility, findability and collaboration in RWD research
- The Catalogues publish **metadata**, which are “**data about data**” that provide key information about a data sources (e.g.; data source’s purpose, type of content, administrative details etc.)
- **Important:** the Catalogues **do not provide access to underlying datasets** and **do not share patient-level records**
 - Transparency and discoverability are supported through metadata (and, where available, study documents)

RWD Catalogues – Timeline



(2020) The Big Data Steering Group (BDSG) workplan
Recommendation 3: Data discoverability

(2021) Data discoverability multistakeholder **workshop** followed-up by wide-reaching **surveys**

(2022) Publication of [Good Practice Guide on the use of the RWD Catalogue](#)

(2024) **Launch of HMA-EMA RWD Catalogue**

(2021) **MINERVA** project sets out the foundations of the activity in a one-year preparatory work

(2022) Adoption and publication of the “[List of metadata for data discoverability](#)”

(2023) **Migration** of ENCePP data sources and studies. Metadata collection for data sources of interest. Development of a new IT system.

(2025) The [Network Data Steering Group \(NDSG\) workplan](#). Maintenance, enhancements, publication of new resources, communication and user engagement



MINERVA: Metadata for data discoverability and study replicability in observational studies

Strengthening Use of Real-World Data in Medicines Development: Metadata for Data Discoverability and Study Replicability (EMA/2017/09/PPE/16)

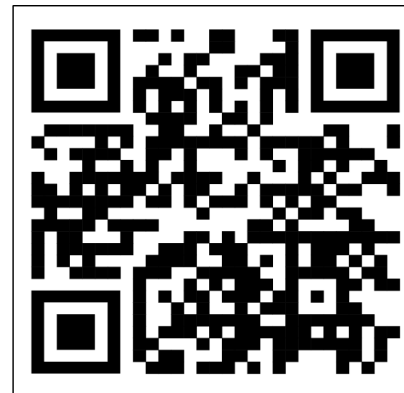
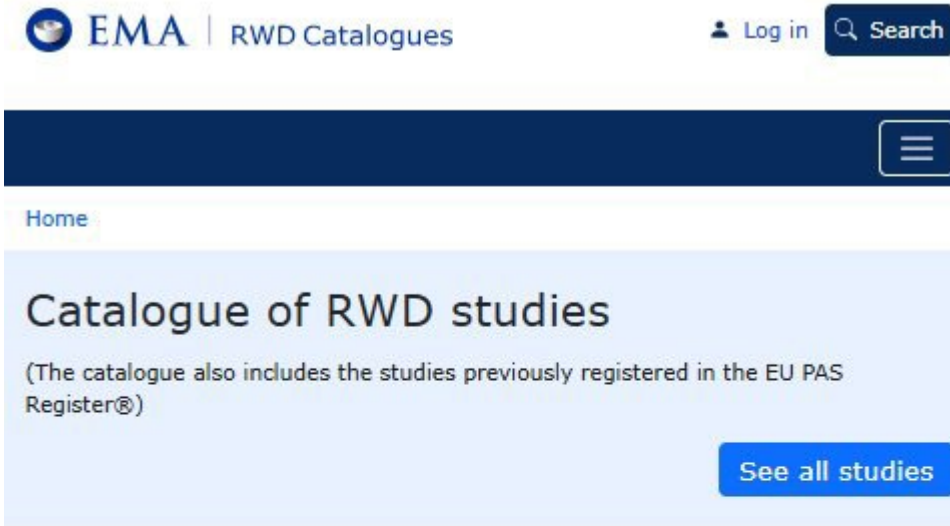


WORKSTREAM OVERVIEW

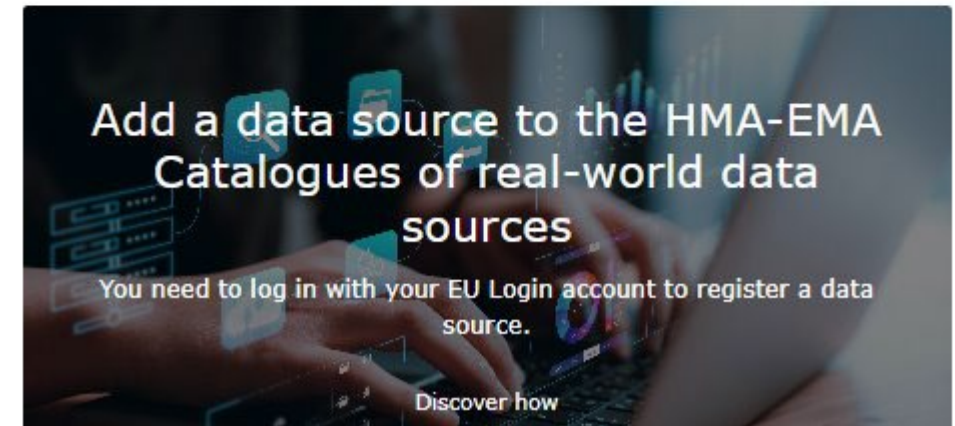
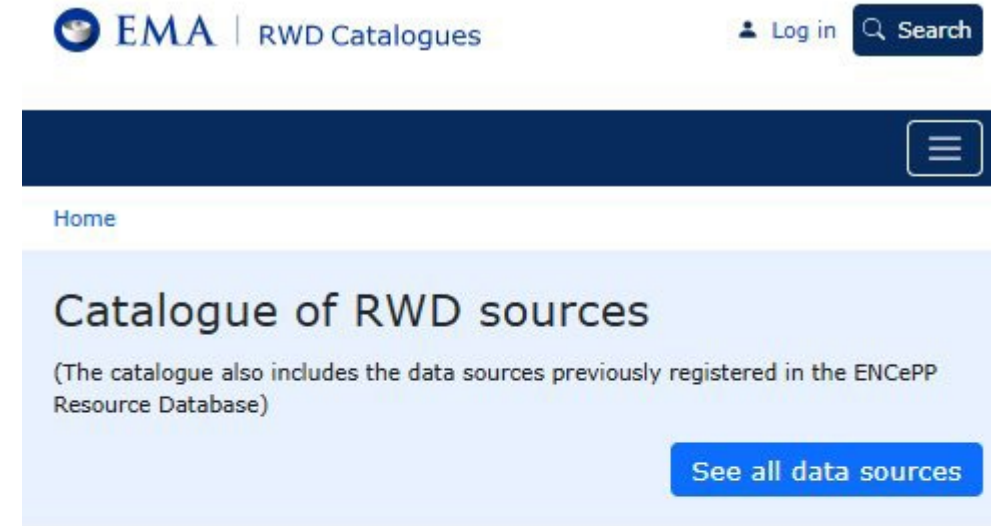
Data interoperability

	Q1/Q2 - 2025	Q3/Q4 - 2025	Q1/Q2 - 2026	Q3/Q4 - 2026	Q1/Q2 - 2027	Q3/Q4 - 2027	Q1/Q2 - 2028	Q3/Q4 - 2028
Data asset discovery, cataloguing and metadata management	HMA EMA catalogues of real-world data sources & non-interventional studies							
	Integration of veterinary data sources into the catalogue (v)				Discuss place of catalogues in prep. of EHDS Data Catalogue			
	Engage with stakeholder to populate HMA EMA catalogues (v)							
	Catalog EMRN Data Assets, in preparation of EHDS and EMRN use cases (v)							
	Agree Network critical data assets and strategic recommendation to catalogue EMRN data assets				Population of EMRN Data Assets catalogue (v)			

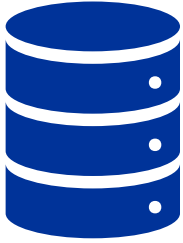
HMA-EMA Catalogues of RWD sources and studies



***Scan to
access and explore
the RWD Catalogues***



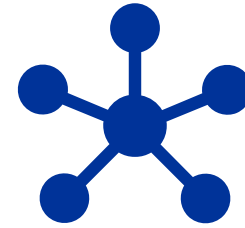
Key functionalities



Standardised metadata structure



Enhanced search functionalities



Linkage between data sources and study records



Open access



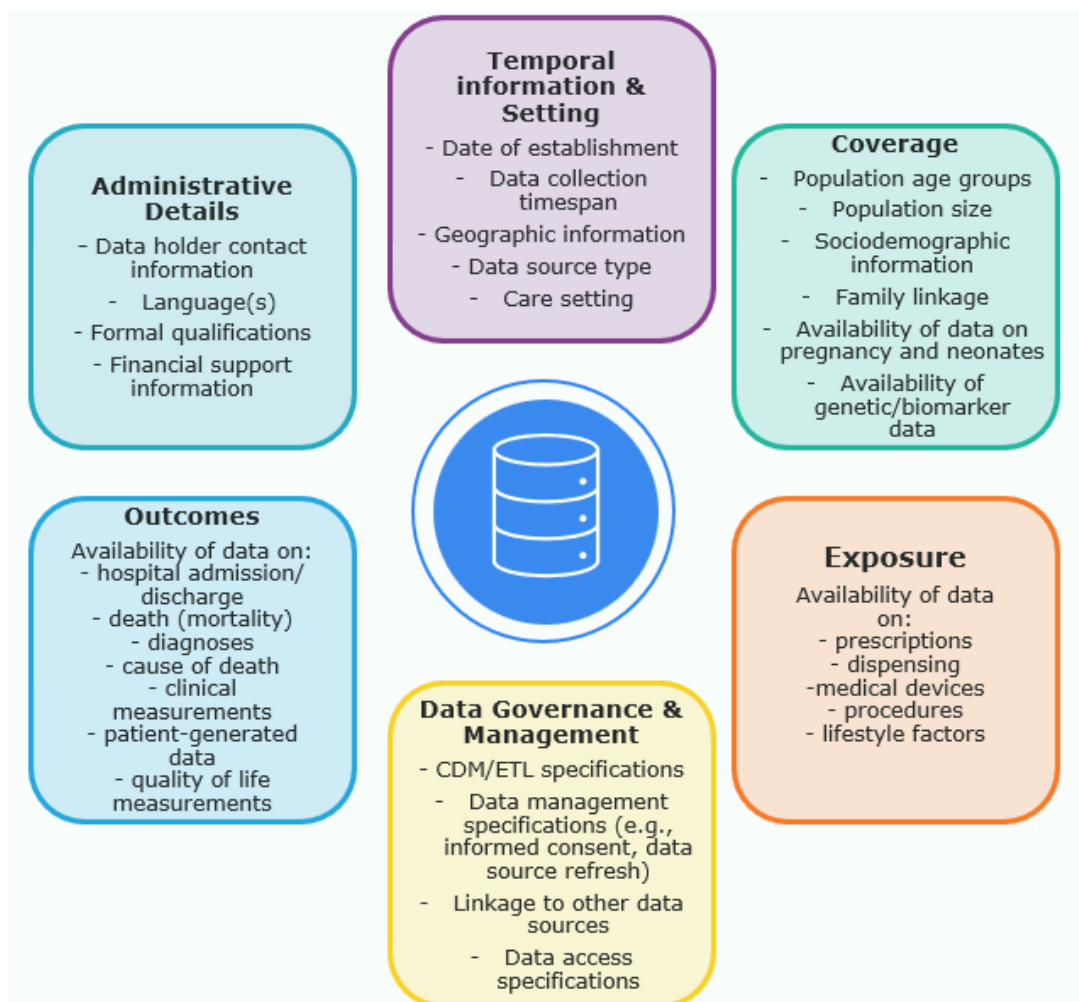
Study documents accessible



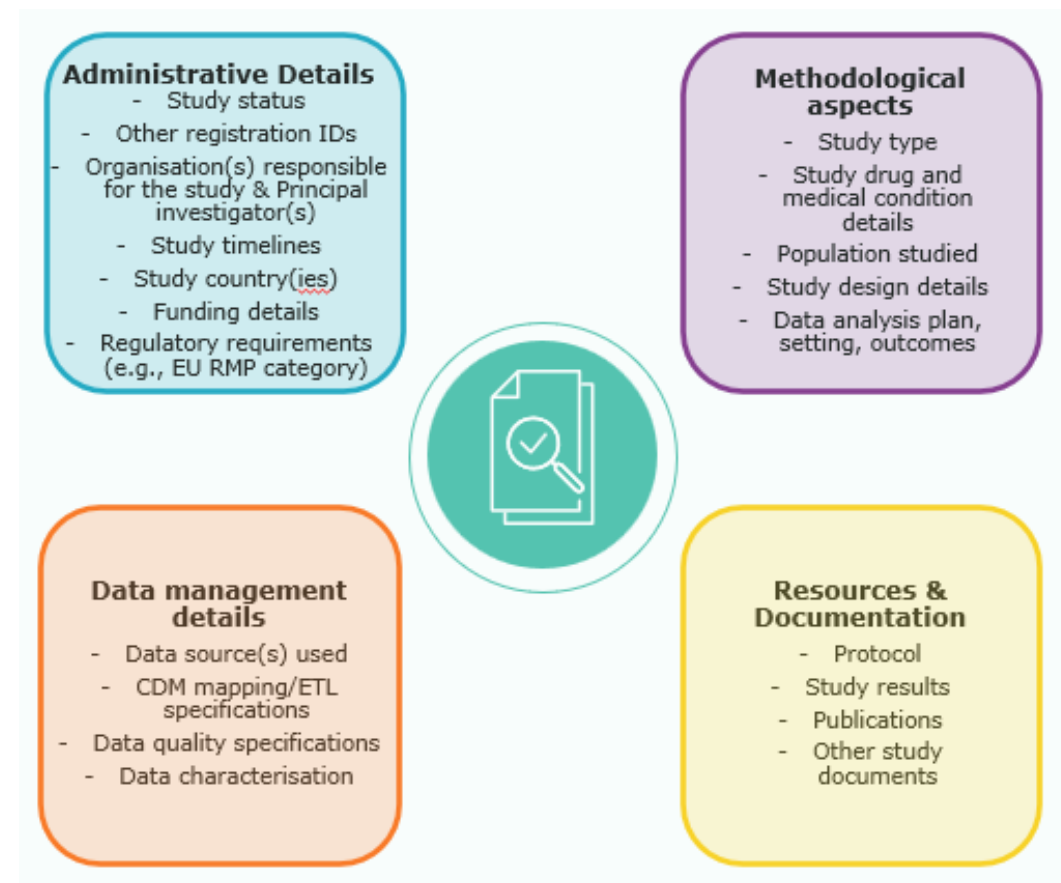
Steady increase of number of records

Data collected

Data source record

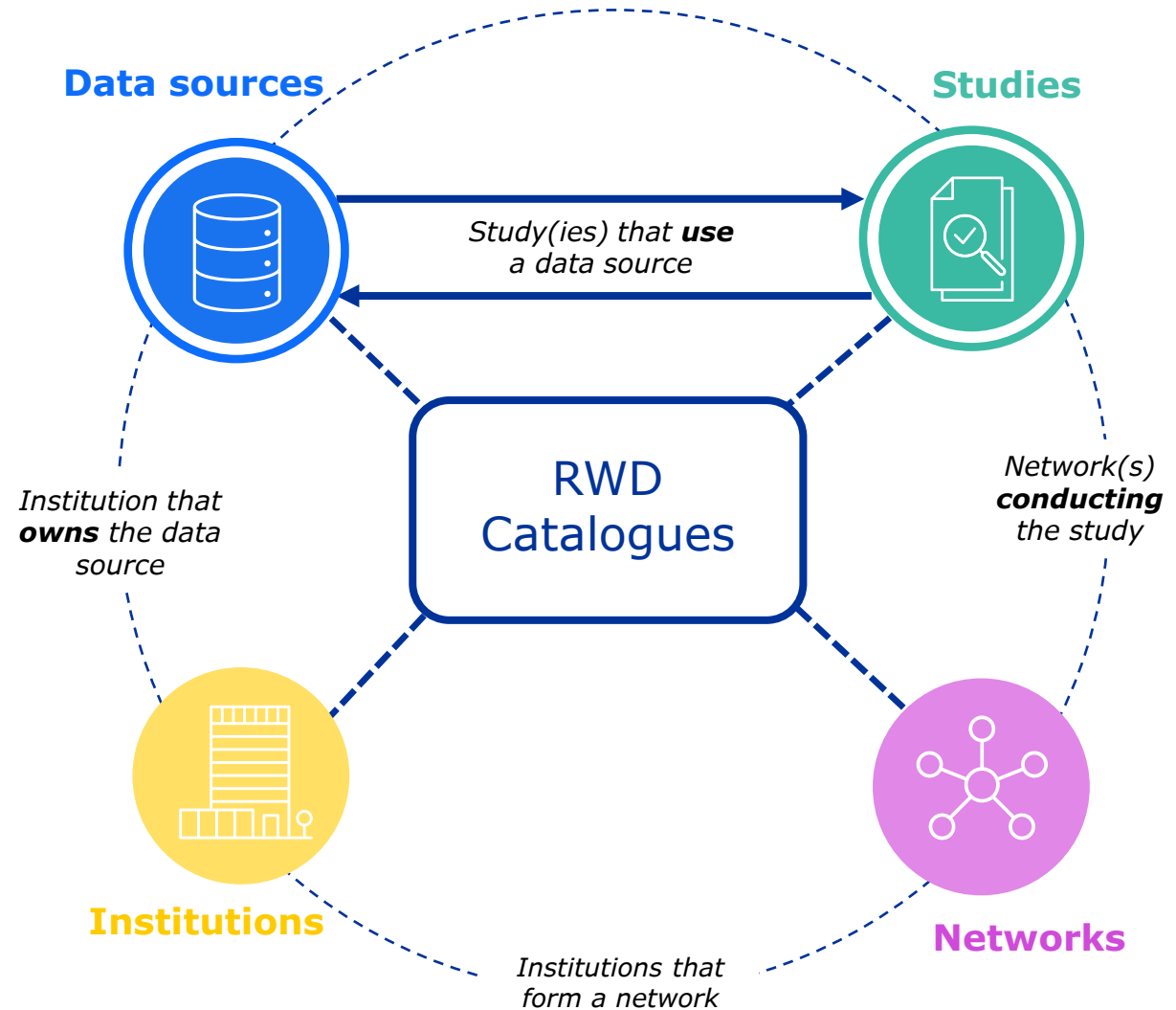


Study record



How the RWD Catalogues connect data

Possibility to view
information about **data
sources used in a study** and
vice versa



Data flow example

Data source

The Cancer Registry of Norway

First published: 01/02/2024 Last updated: 04/08/2025

Data source Human Cancer registry Disease registry

Administrative details Data elements collected Quantitative descriptors Data flows and management

Page content

Administrative details
Contact details
Data source regions and languages
Data source establishment

Administrative details

Data source ID	1111128
Name of data source	The Cancer Registry of Norway
Data source acronym	CRN
Data holder	The Norwegian Institute of Public Health

linked Institution

The Norwegian Institute of Public Health

First published: 01/02/2024 Last updated: 22/07/2024

Institution Hospital/Clinic/Other health care facility Other

Page content

Institution identification
Institution description
Institution details
Contact
Network(s) of which the

Institution identification

Institution ID	3331163
Institution full name and acronym	The Norwegian Institute of Public Health
Institution countries	Norway
Type of institution	Hospital/Clinic/Other health care facility Other

linked Study

DARWIN EU® – Prevalence of selected cancers

First published: 19/08/2025 Last updated: 19/08/2025

EU PAS number: EUPAS1000000715

Study Ongoing

Subscribe

Administrative details Methodological aspects Data management Resources

Page content

Study identification
Research institutions and networks
Contact details

Study identification

EU PAS number	EUPAS1000000715
Study ID	1000000715
Official title and acronym	DARWIN EU® – Prevalence of selected cancers

linked Network

Data Analysis and Real World Interrogation Network (DARWIN EU®)

First published: 01/02/2024 Last updated: 30/04/2025

Network

Download as PDF

Page content

Network identification
Network description
Network details
Contact
Institutions that are part of this network

Network identification

Network ID	49628
Network name and Acronym	Data Analysis and Real World Interrogation Network (DARWIN EU®)
Network website	https://www.darwin-eu.org/
Network countries	Belgium Croatia Denmark Estonia Finland

linked Network

Where are we now?



272

Data sources

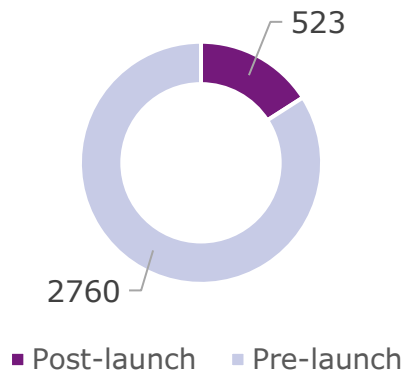
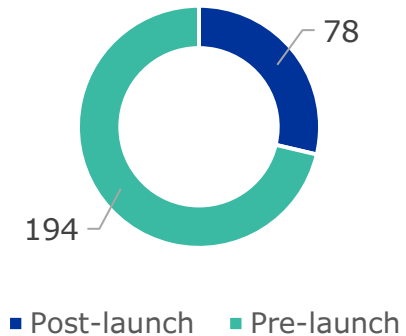
↑ **+40%**
since launch



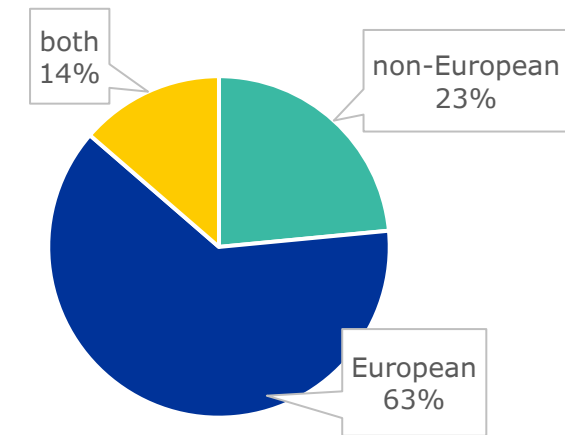
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Studies

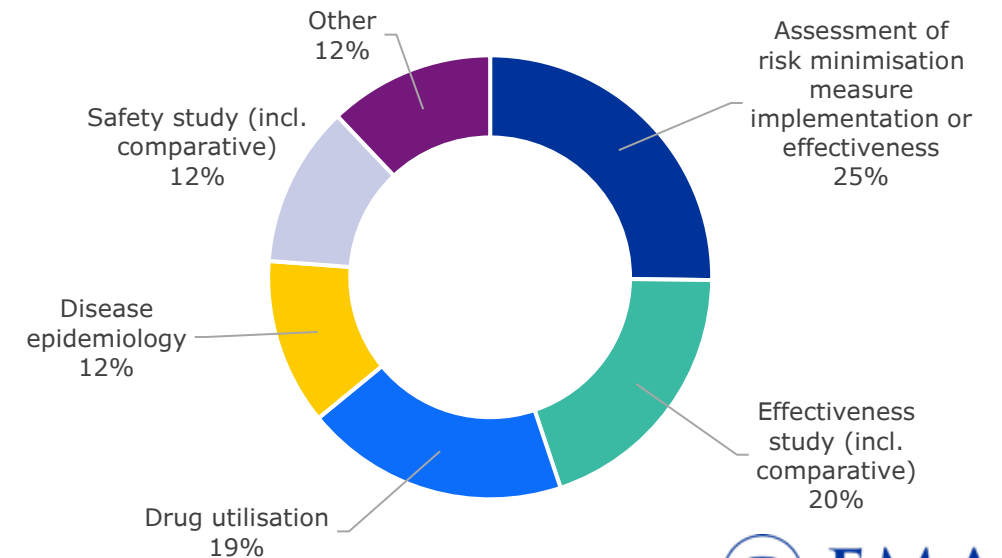
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Proportion of Studies by Region: EU vs. Non-EU



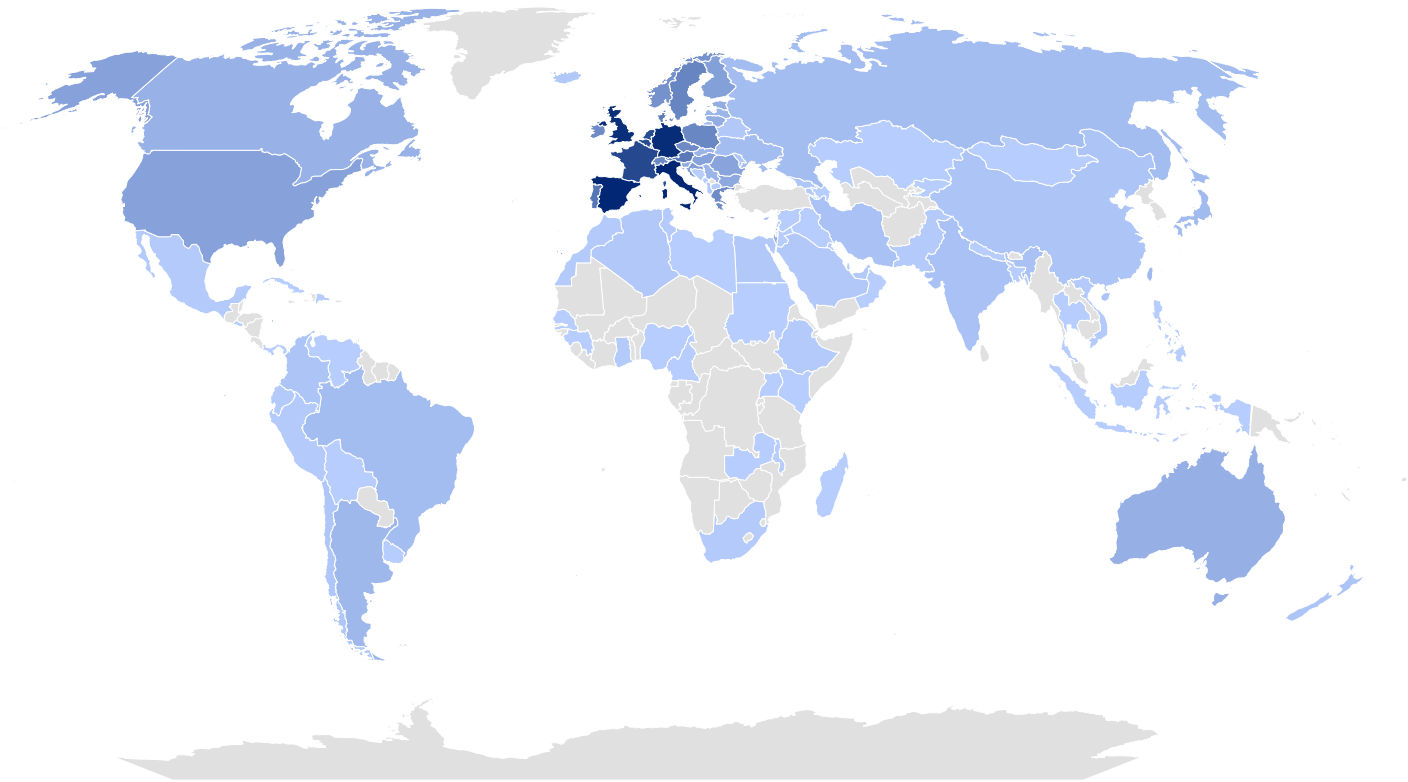
Distribution of Study Scope



Where are we now?

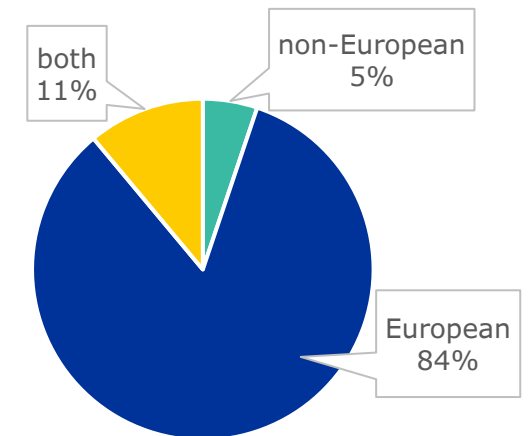
Geographical distribution of RWD sources registered in the RWD Catalogues

Series1
0 75



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Powered by Bing

Proportion of Data sources by Region:
EU vs. Non-EU



Use cases for Patients & Healthcare professionals

Find studies in a disease area

by medical condition, medicine, population, country

Find data sources for a disease area

by disease, key characteristics, population, country

Identify studies or data sources by organisation type

*patient organisations, hospitals, clinics, networks
including studies led/co-led by a patient organisation*

Identify responsible parties for a data source or study

institution, network, sponsor/lead investigator, contact point(s)

Connect using listed contact details

for studies, data sources, institutions and networks

Use cases for researchers

Identify suitable data
sources for study
planning

Compare data sources

Understand how a data
source was used in a
study

Use standardised
metadata to streamline
study documentation

Guidance & Resources

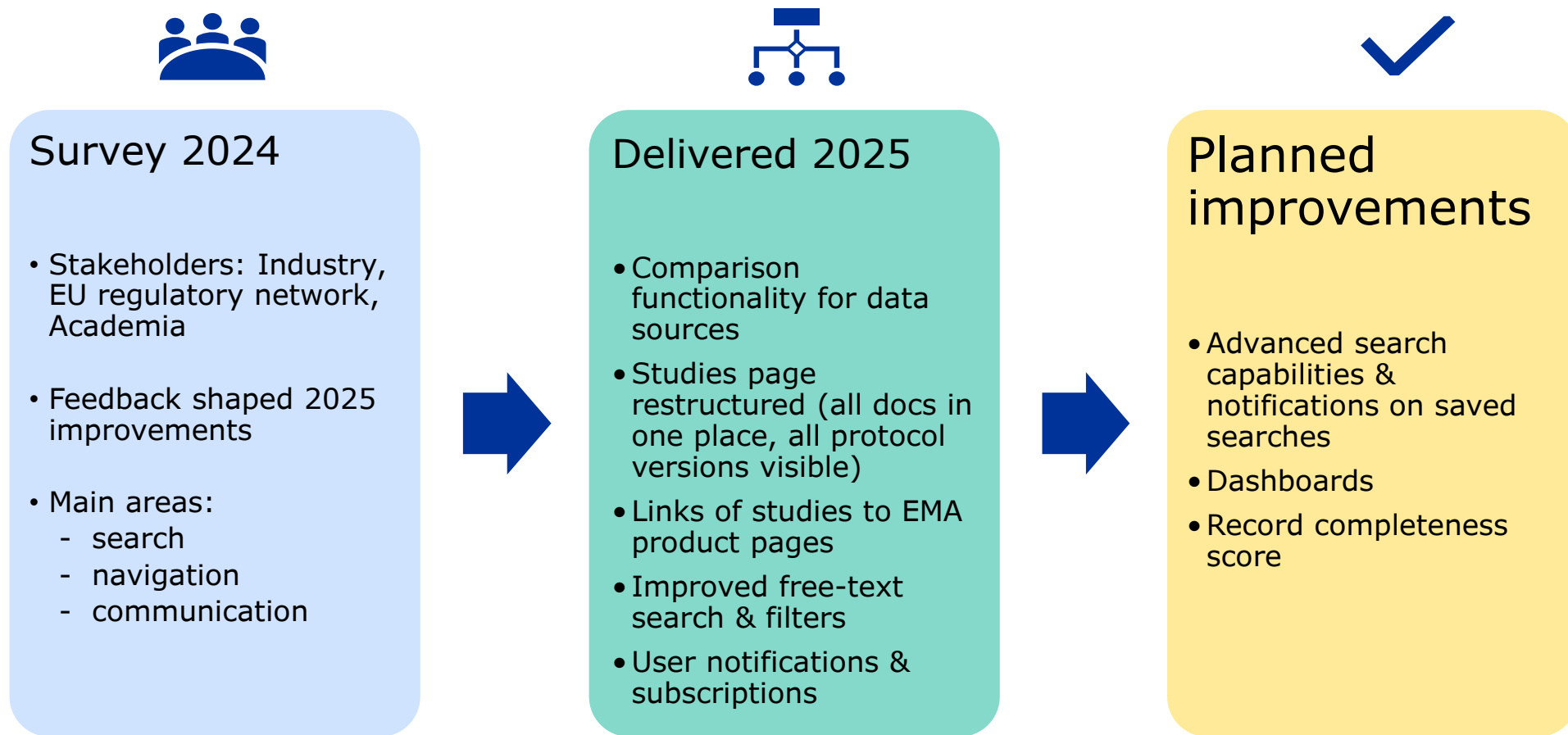
Related to the RWD Catalogues:

- [Good Practice Guide for the use of the Metadata Catalogue of Real-World Data Sources](#)
- [User guide](#)
- [List of metadata for the HMA-EMA Catalogues of real-world data sources and studies](#)

Other useful resources:

- [Guideline on registry-based studies - Scientific guideline | European Medicines Agency \(EMA\)](#)
- [Draft of Data Quality Framework for EU medicines regulation application to real-world data | European Medicines Agency \(EMA\)](#)

Improvements delivered and ahead - guided by user feedback



Help enhance the RWD Catalogues



- **Data holders** and **study investigators** are invited to contribute information on data sources and studies to improve **transparency** and **collaboration**
- **Promote submissions** to the catalogues through your networks
- **Suggest data sources** for inclusion

DEMO



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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Engagement with European & Global Initiatives



ICH E23 Working Group

International **convergence** and where possible, **harmonisation** on:

- RWD and RWE terminologies
- List of core metadata
- General principles for assessment of RWD/RWE (focus on effectiveness studies)
- EC, Europe rapporteur of the WG



TEHDAS2 Joint Action

- Development of guidelines & technical specifications to support the practical implementation of the EHDS framework for the secondary use of health data
- EMA provides input in public consultation of draft deliverables & participates in HealthData@EU EC Advisory Board