

Enhancing transparency & discoverability: HMA-EMA Catalogues of real-world data (RWD) sources and studies

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Healthcare Data, Data Data Analytics and
Methods Task Force

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2025



Background & Context

- The use of real-world data (RWD) in regulatory decision-making is rapidly evolving
- Challenges: data heterogeneity, varying data quality, governance diversity
- The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) launched two electronic Catalogues in 2024 aiming to:
 - Enhance the understanding of RWE supporting regulatory decisions
 - Promote transparency in non-interventional research by providing access to comprehensive information on RWD studies
 - Ensure discoverability of RWD sources

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

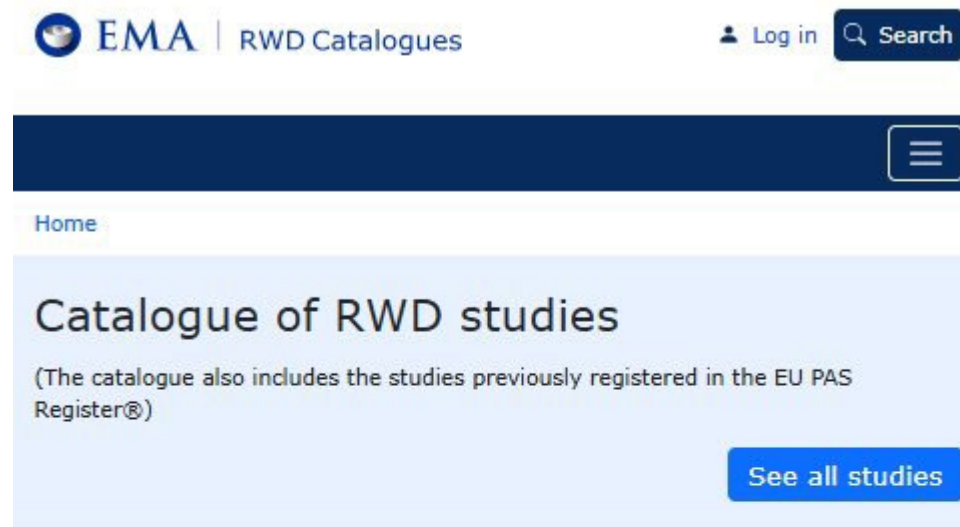
Data interoperability

Data asset discovery, cataloguing and metadata management

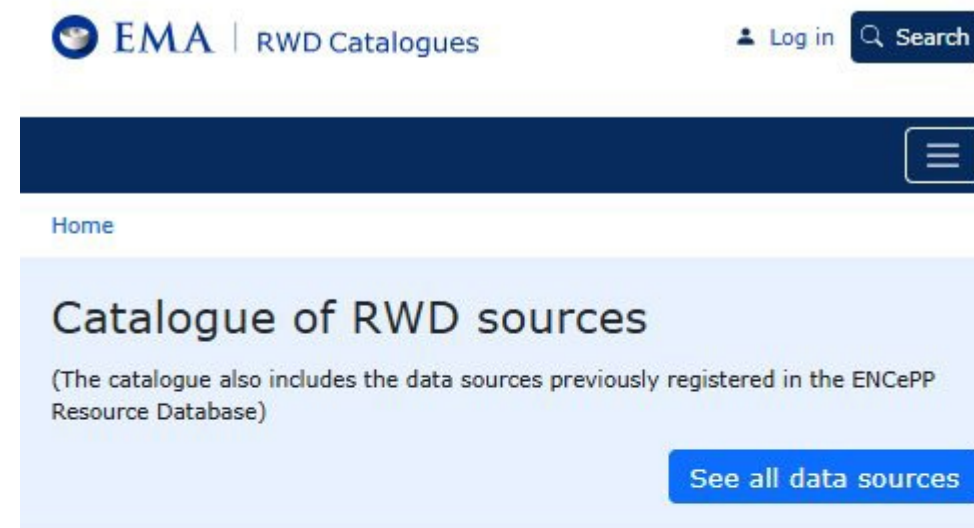
	Q1/Q2 - 2025	Q3/Q4 - 2025	Q1/Q2 - 2026	Q3/Q4 - 2026	Q1/Q2 - 2027	Q3/Q4 - 2027	Q1/Q2 - 2028	Q3/Q4 - 2028
HMA EMA catalogues of real-world data sources & non-interventional studies	Integration of veterinary data sources into the catalogue (v)							
	Engage with stakeholder to populate HMA EMA catalogues (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

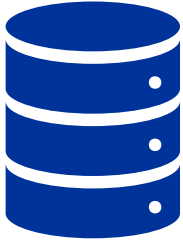
A publicly accessible, centralised resource of metadata on RWD sources and all types of RWD studies to enhance transparency, reproducibility, findability and collaboration in RWD research



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



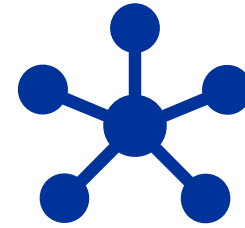
HMA-EMA Catalogues of RWD sources and studies



Standardised metadata
structure



Enhanced search
functionalities



Linkage between data
sources and study records



Open access



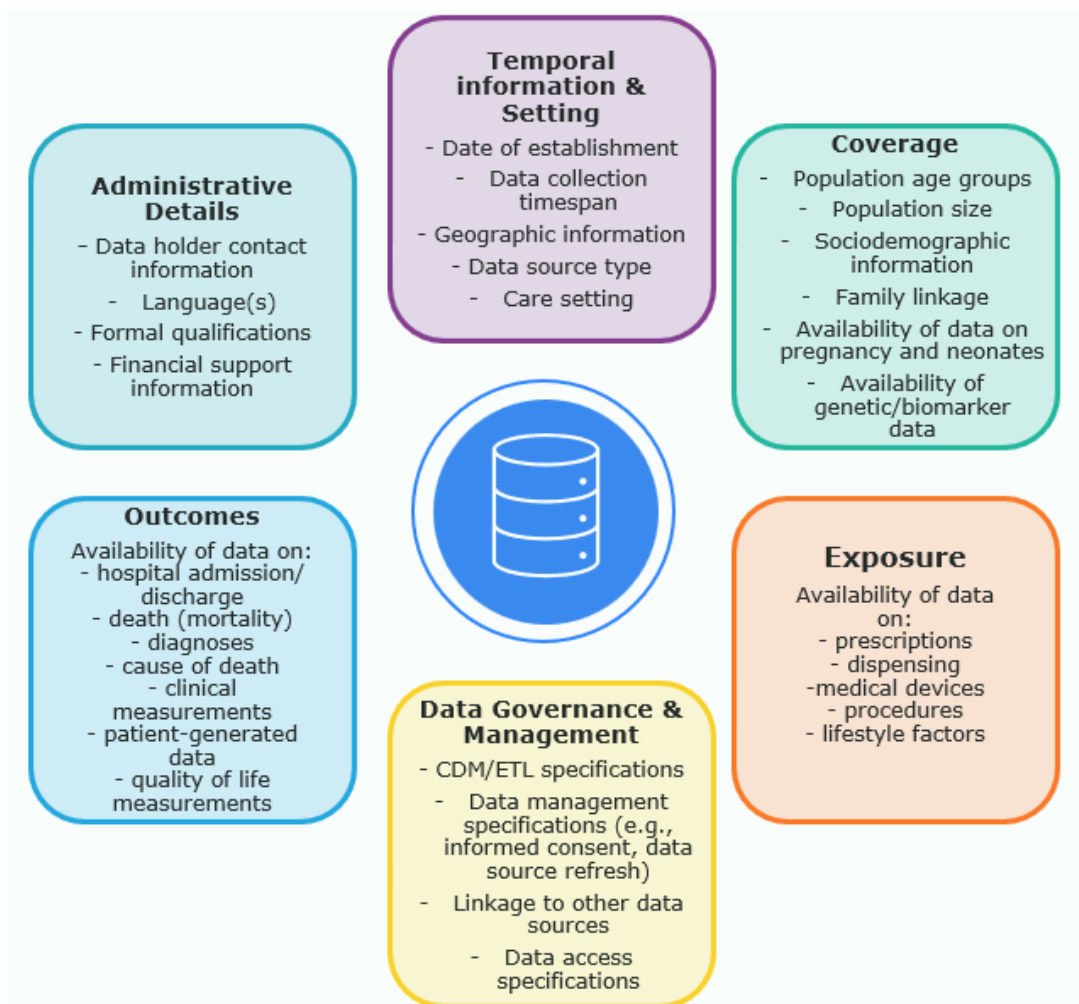
Study documents
accessible



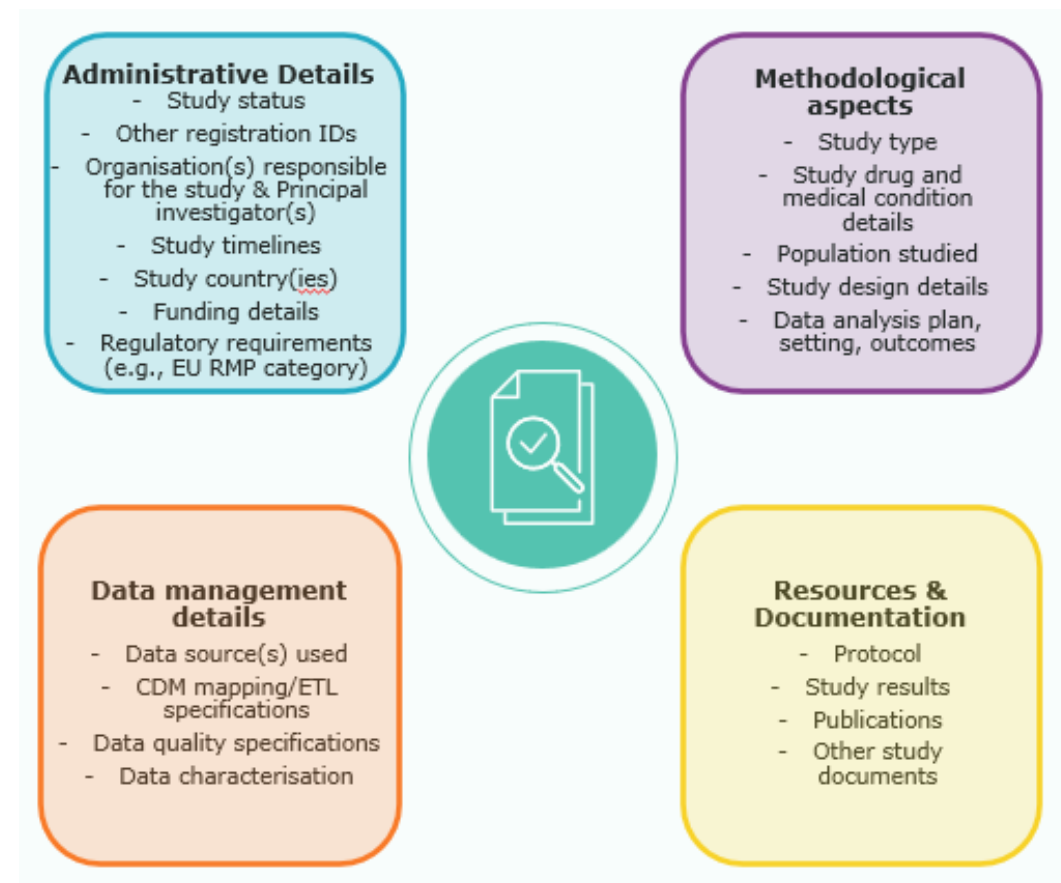
Steady increase of
number of records

Data collected

Data source record

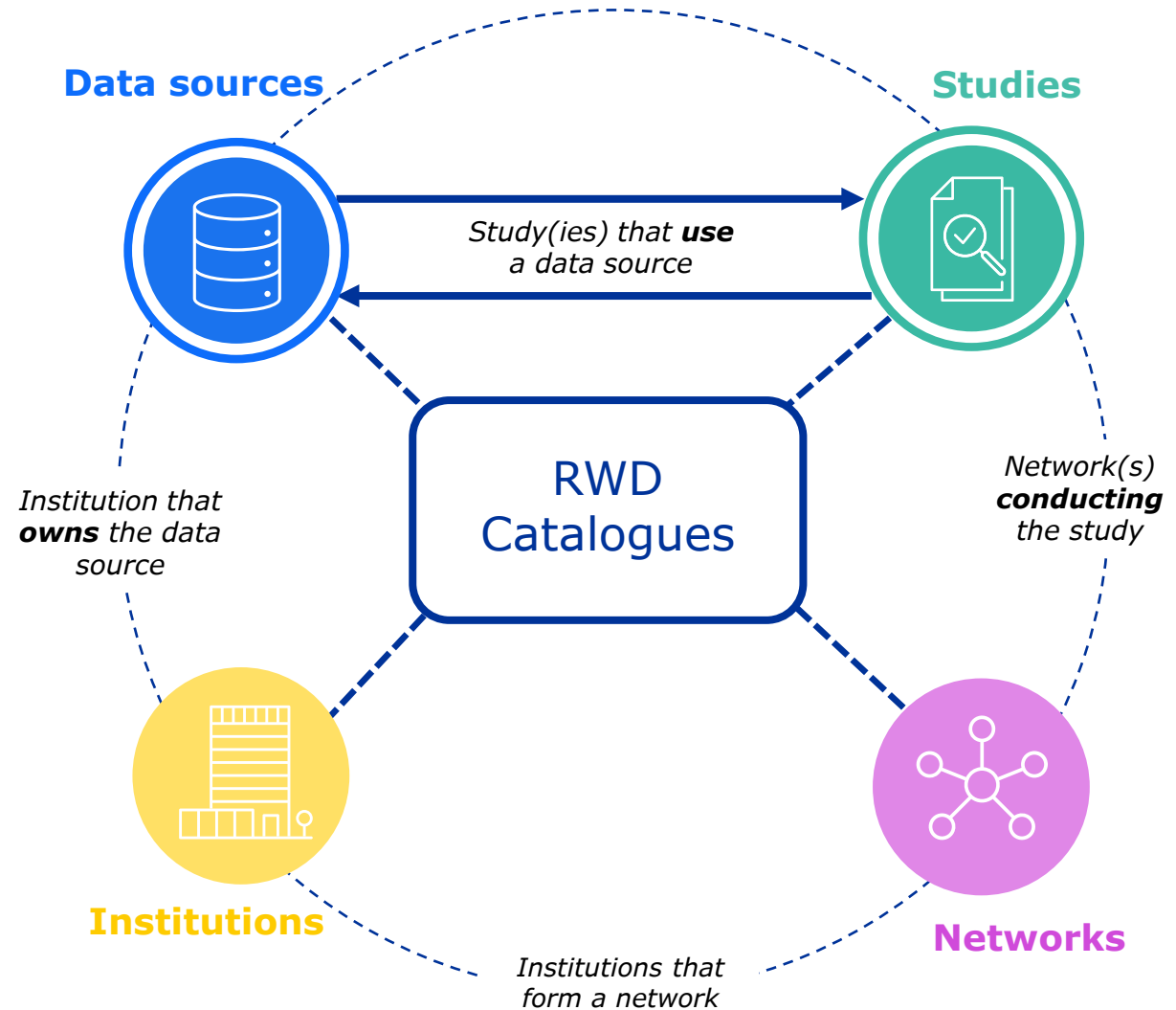


Study record



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

sified as internal/staff & contractors by the European Medicines Agency

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

Where are we now?



263

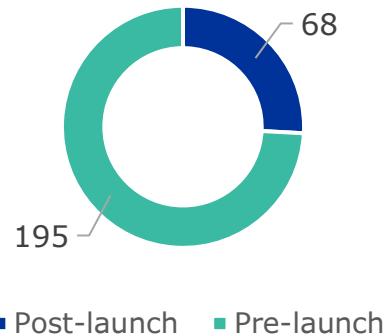
Data sources



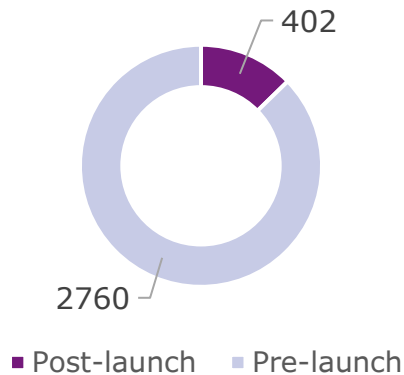
3162

Studies

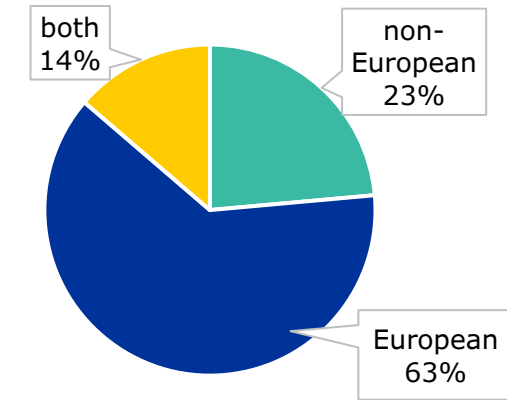
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since launch



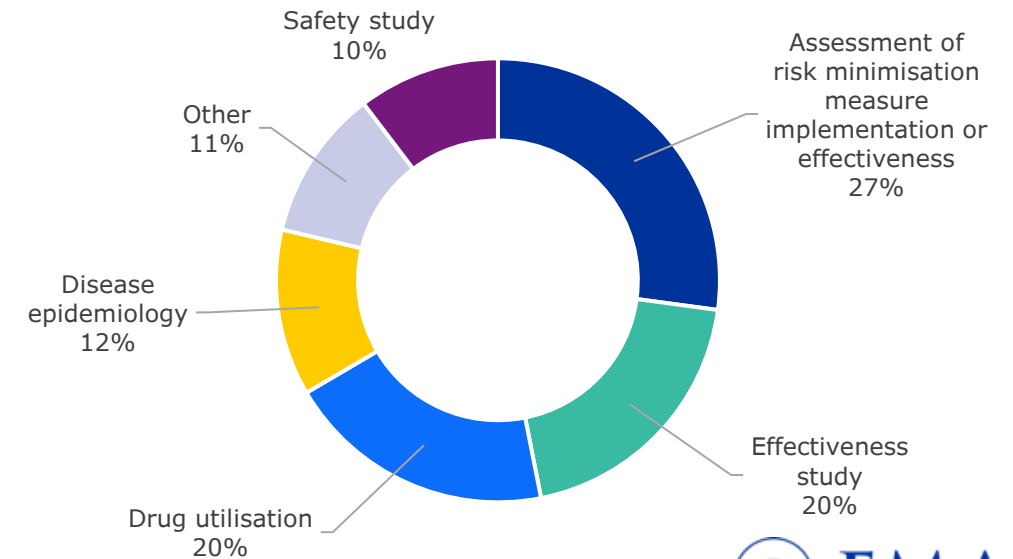
↑ **+15%**
since launch



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

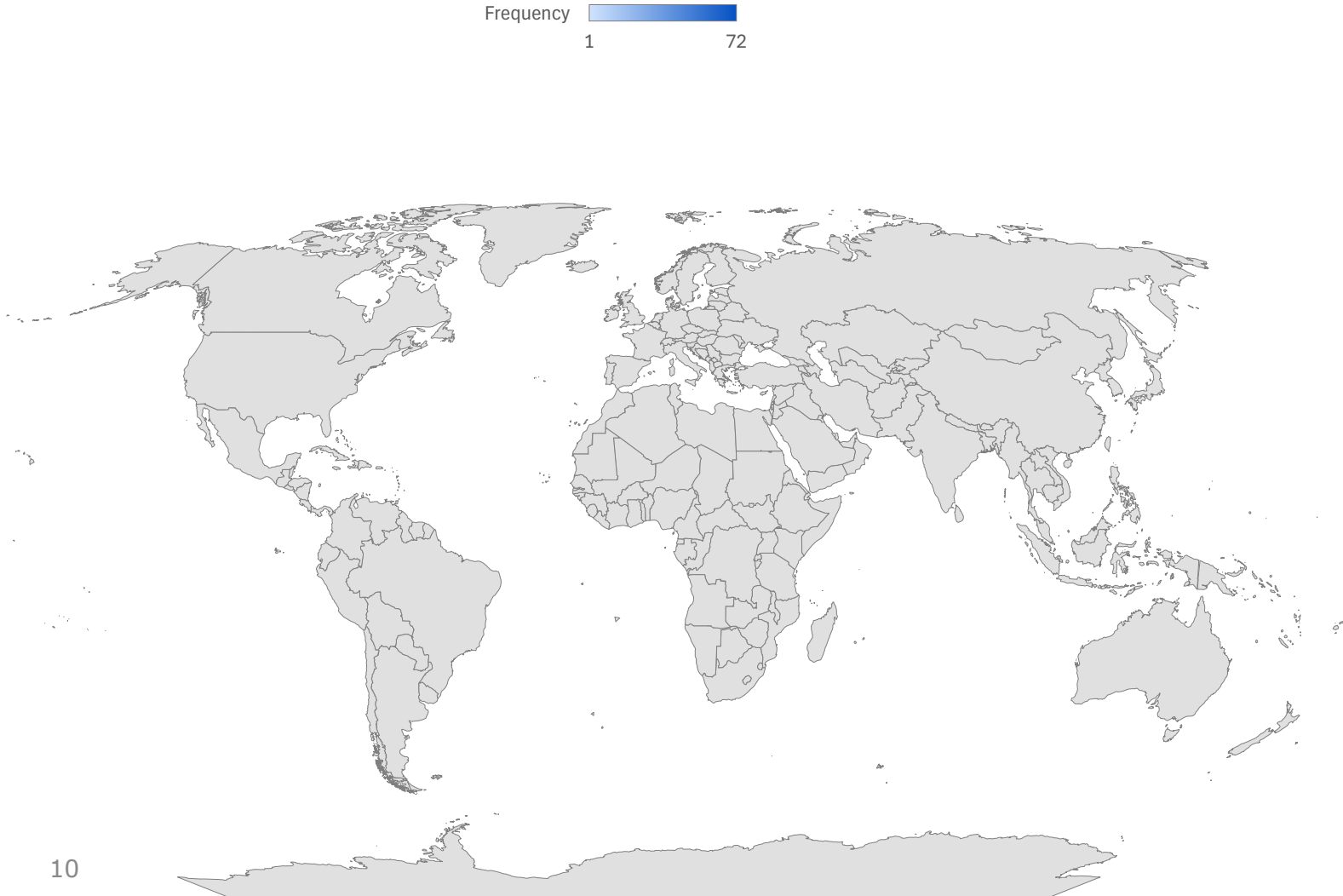


Distribution of Study Scope

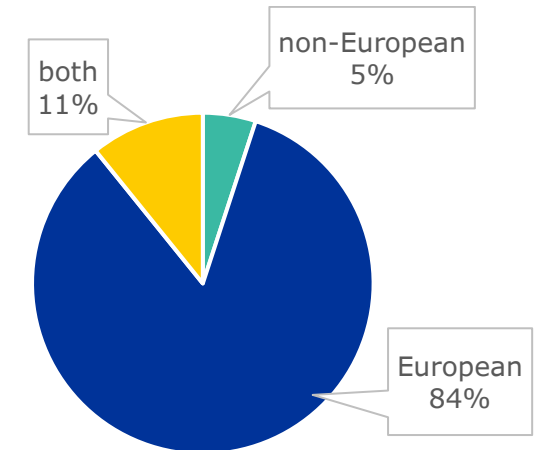


Where are we now?

Geographical distribution of data sources registered in the RWD Catalogues



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



Use cases for the industry & Resources

Compare multiple data sources

Identify suitable data sources for study planning

Assess a study protocol and suitability of the proposed data source

Use standardised information (metadata) to streamline the preparation of study documents

- [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](#)

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

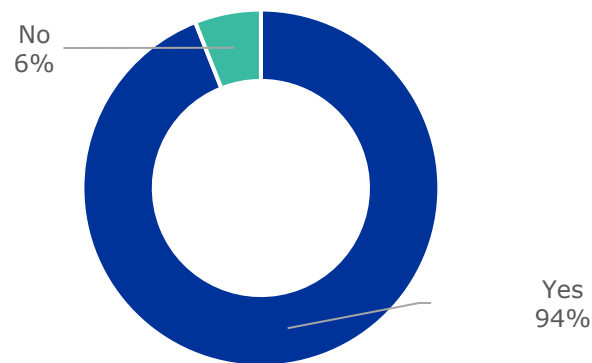


TEHDAS2 Joint Action

- 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

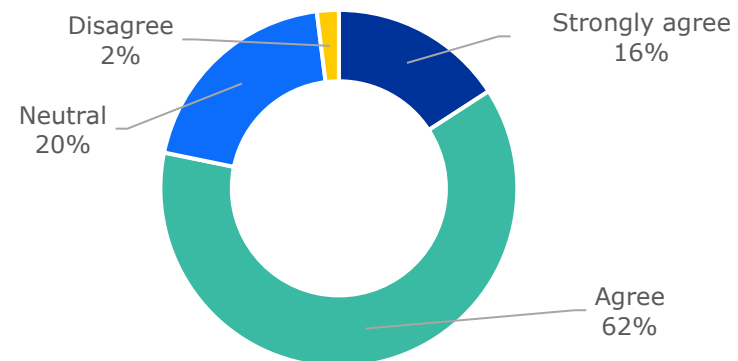
Results from 2024 industry survey on awareness, use cases, and areas for improvement

Awareness of the HMA-EMA RWD Catalogues



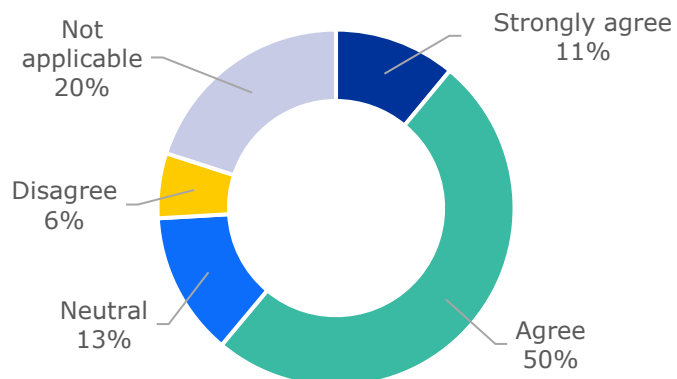
Survey Q: I am aware of the HMA-EMA Catalogues of RWD sources and studies

Usefulness of the Catalogues



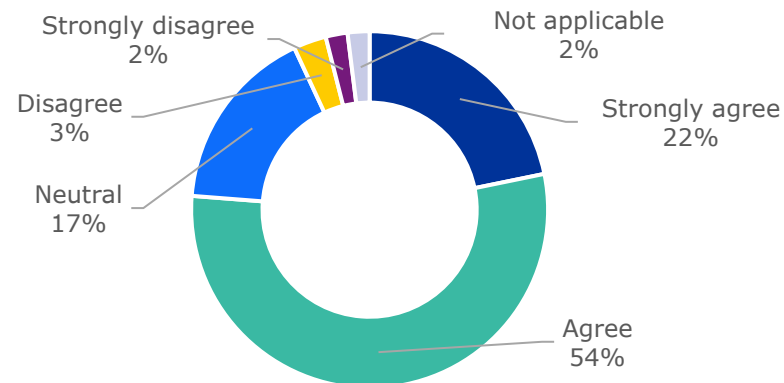
Survey Q: The Catalogues provide information that is useful and relevant to my regulatory/research/business activities

Clarity of information about data sources



Survey Q: Information provided about data sources is clear and detailed

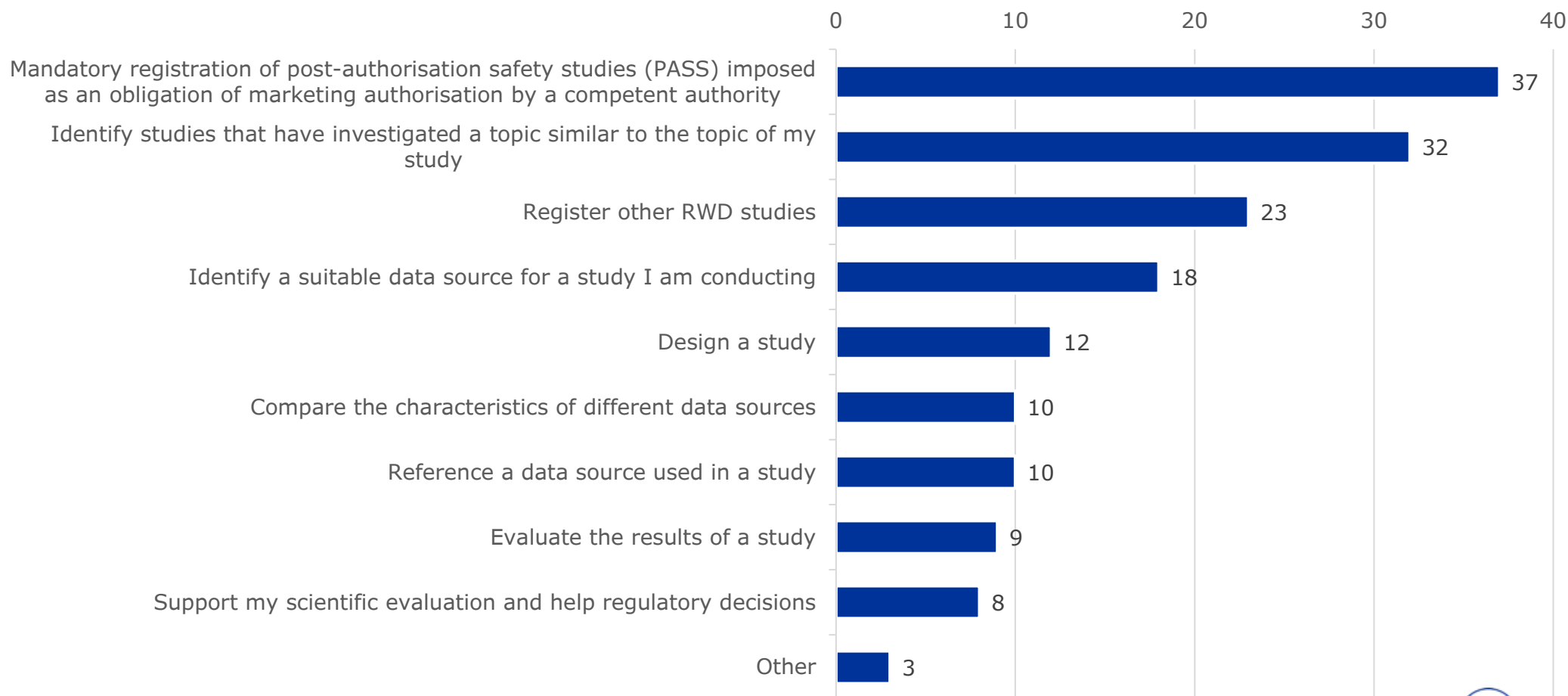
Clarity of information about studies



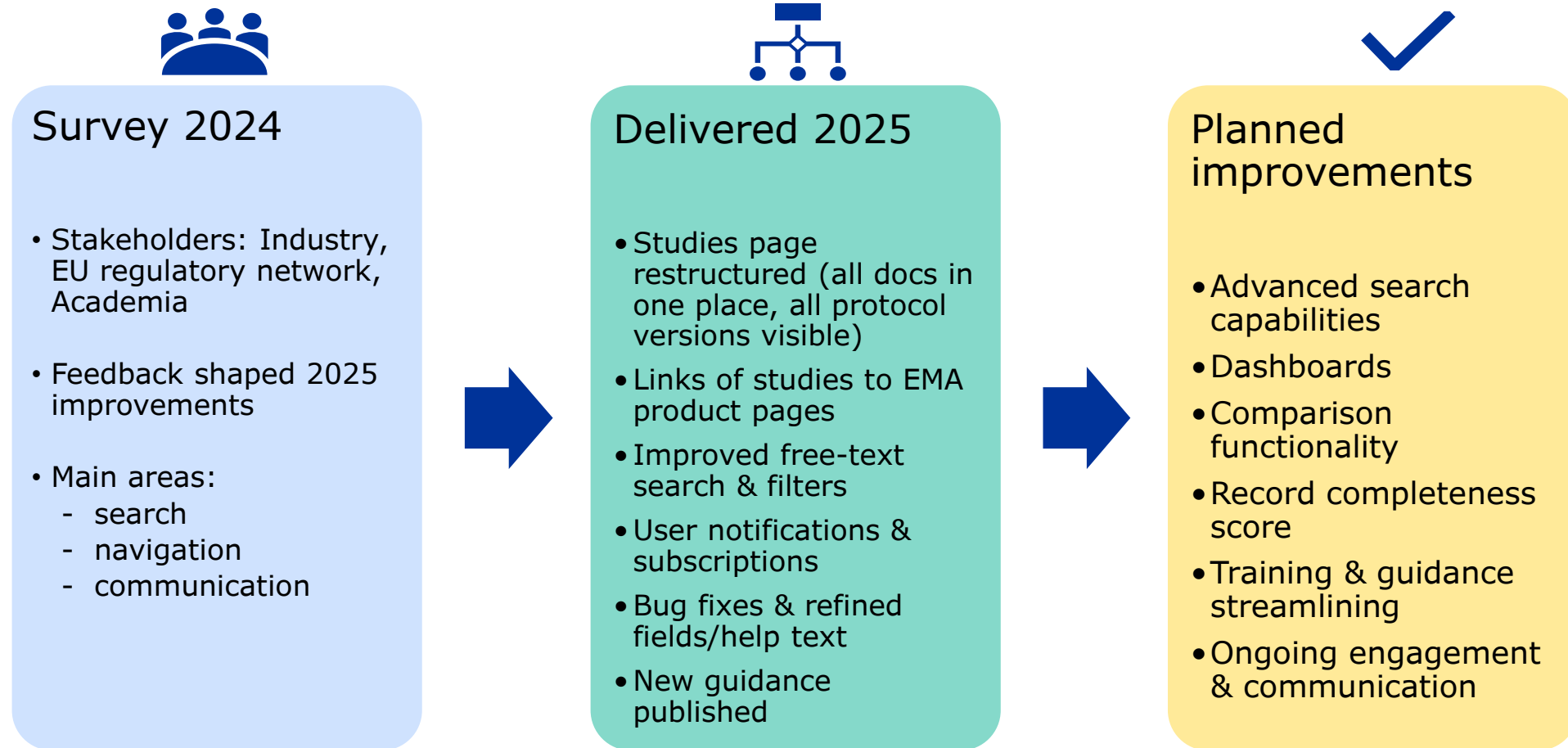
Survey Q: Information provided about studies is clear and detailed

Results from industry survey 2024 on awareness, use cases, and areas for improvement

Uses of the catalogues by industry



Improvements delivered and ahead - guided by user feedback



Call for action



Industry survey on awareness, experience and expectations



Help enhance the RWD Catalogues: Data holders and study investigators are invited to contribute information on data sources and studies to advance transparency and collaboration



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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