

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

Enhancing transparency,
discoverability and supporting the
use of RWD

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Healthcare Data, Data Data Analytics and Methods Task Force

20th Industry Stakeholders platform meeting - operation of EU pharmacovigilance

13 November 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](#)

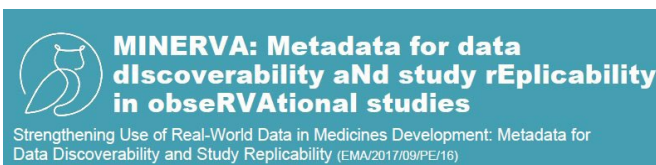
(2024) **Launch of HMA-EMA RWD Catalogue**

(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



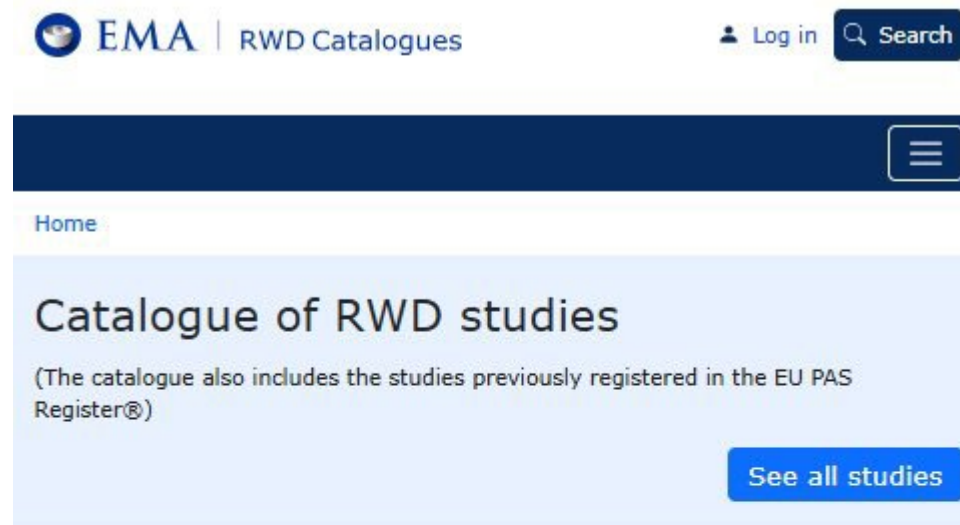
WORKSTREAM OVERVIEW

Data interoperability

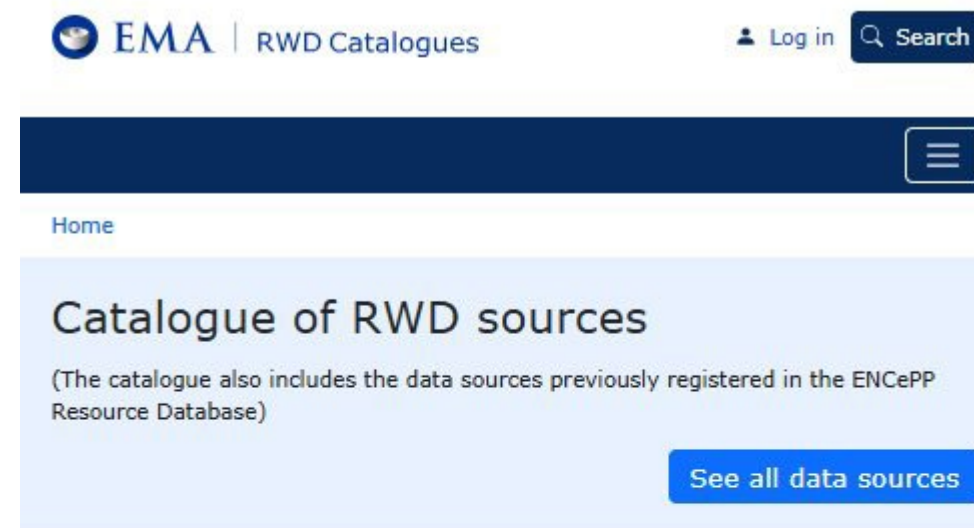
	Q1/Q2 - 2025	Q3/Q4 - 2025	Q1/Q2 - 2026	Q3/Q4 - 2026	Q1/Q2 - 2027	Q3/Q4 - 2027	Q1/Q2 - 2028	Q3/Q4 - 2028
Data asset discovery, cataloguing and metadata management	HMA EMA catalogues of real-world data sources & non-interventional studies							
	Integration of veterinary data sources into the catalogue (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

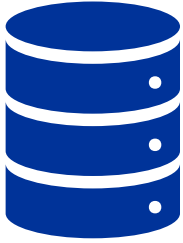
A publicly accessible, centralised resource of metadata on RWD sources and all types of RWD studies to enhance transparency, reproducibility, findability and collaboration in RWD research



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



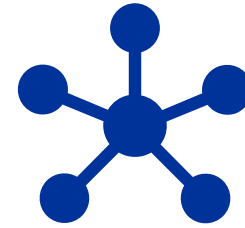
HMA-EMA Catalogues of RWD sources and studies



Standardised metadata
structure



Enhanced search
functionalities



Linkage between data
sources and study records



Open access



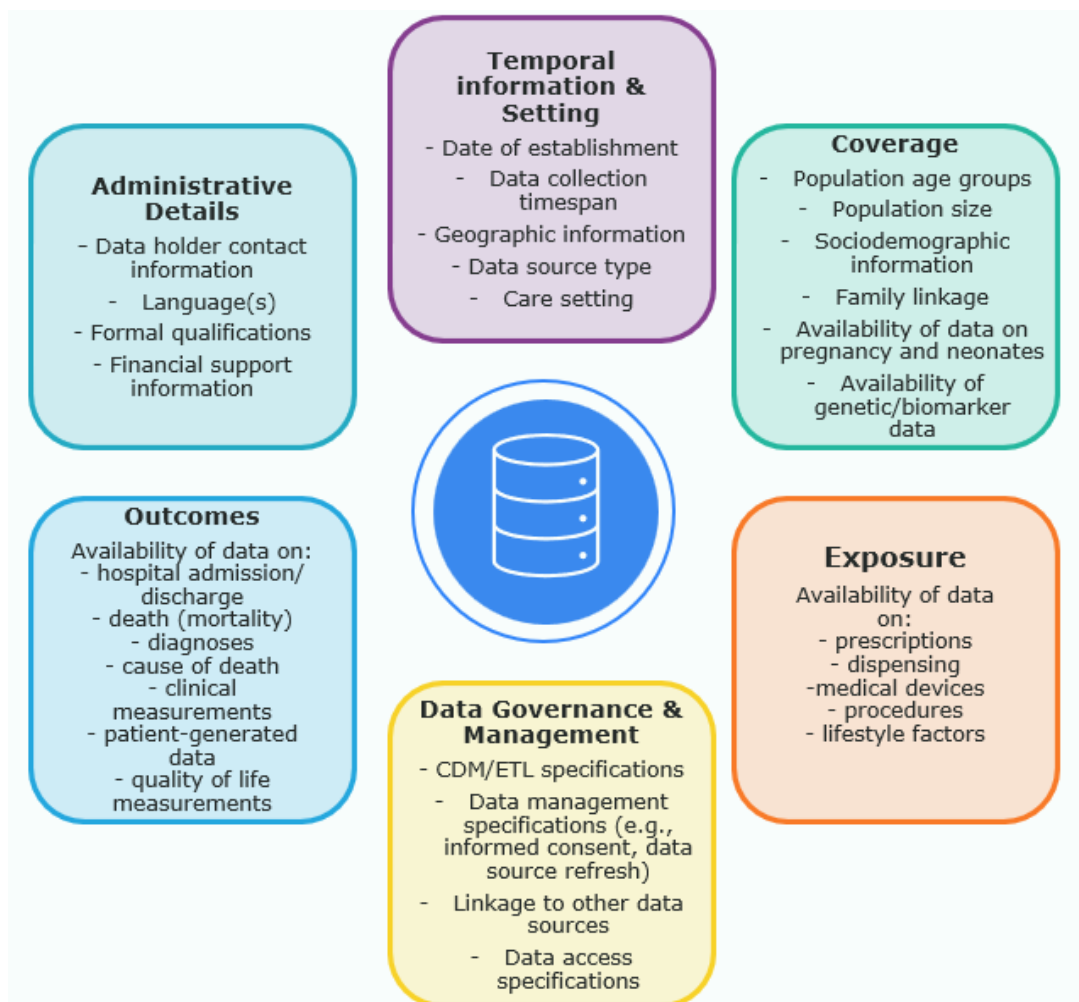
Study documents
accessible



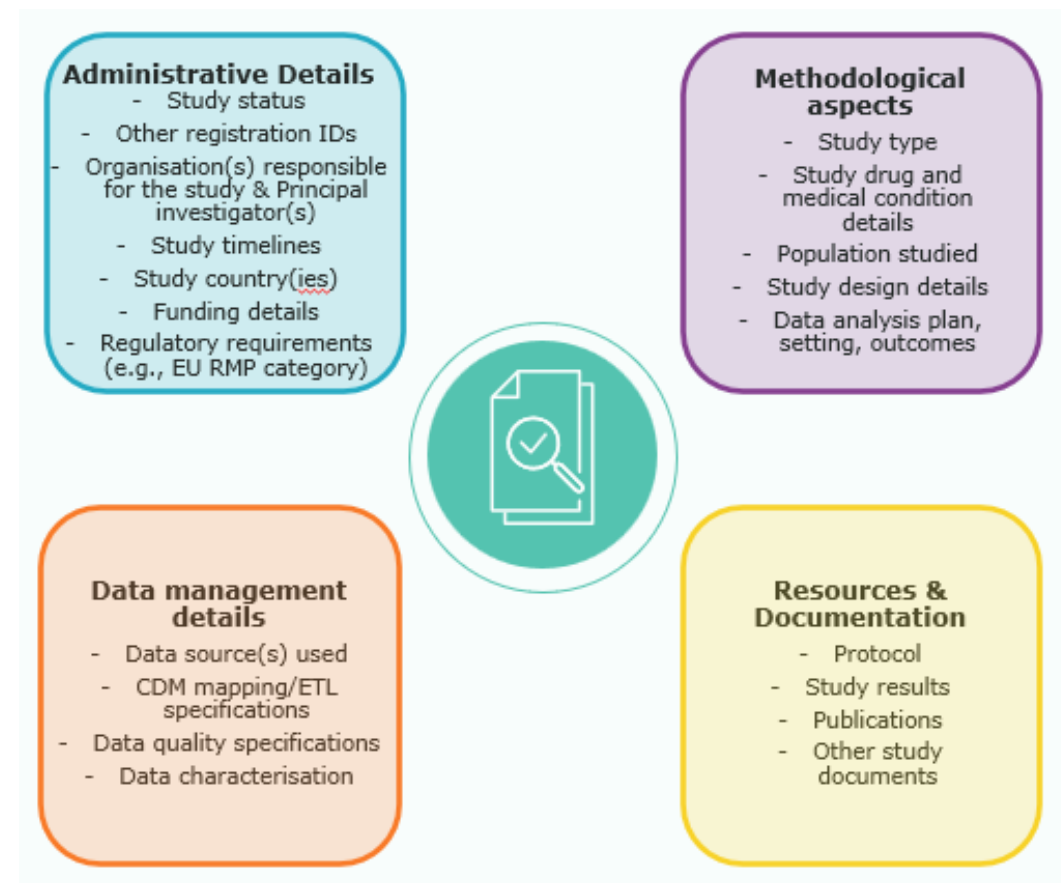
Steady increase of
number of records

Data collected

Data source record

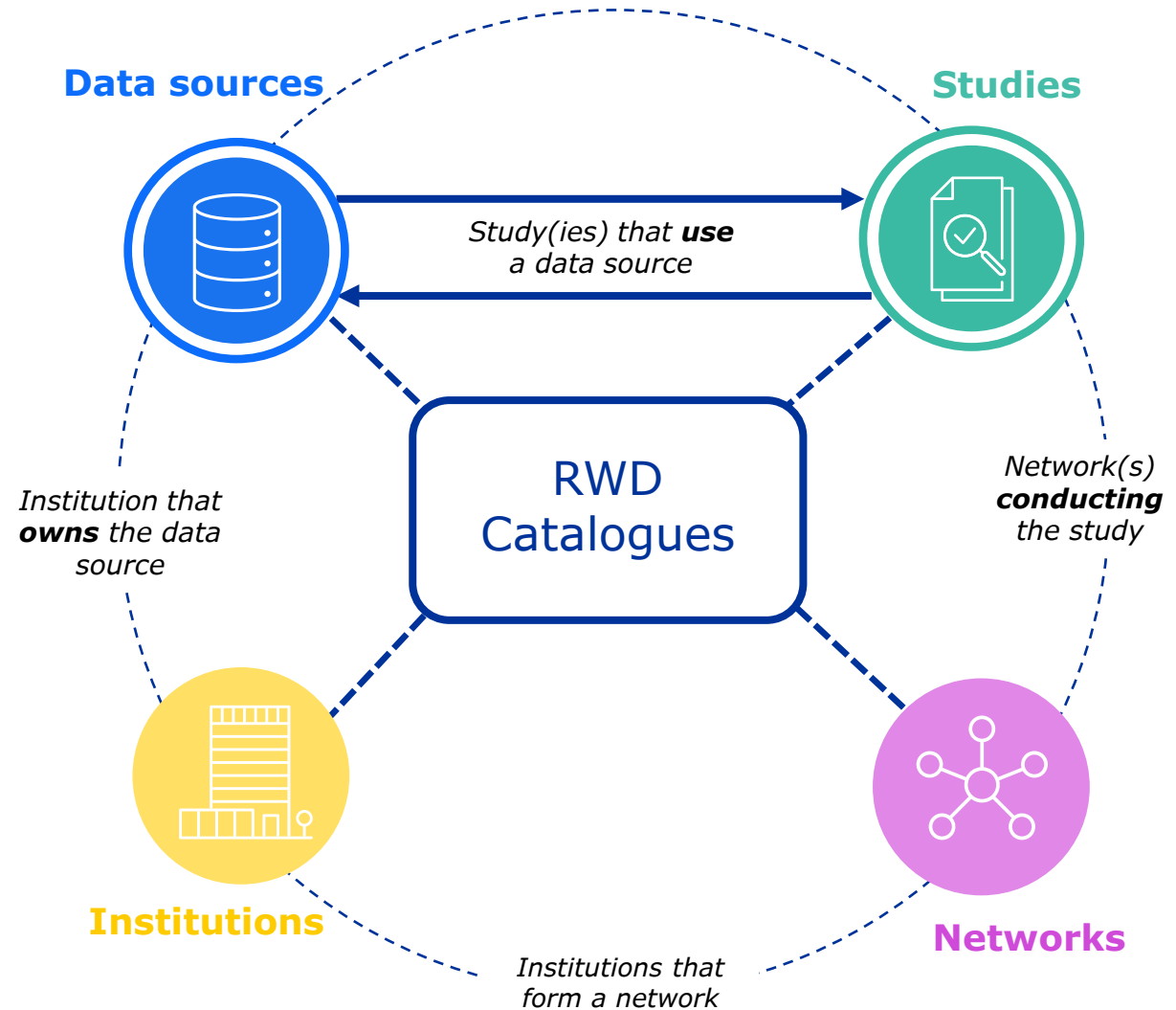


Study record



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

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?



267

Data sources

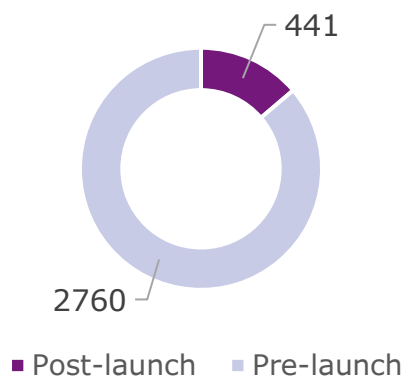
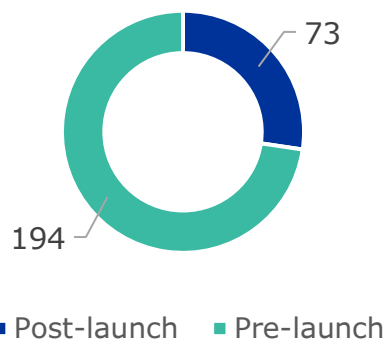


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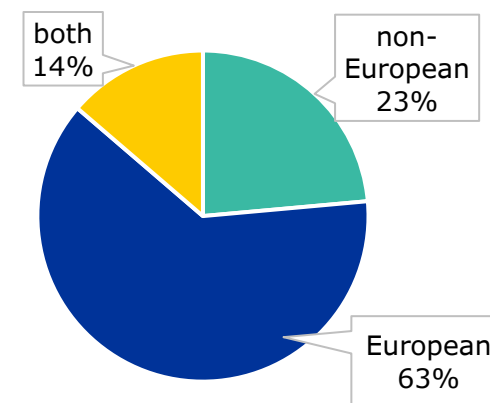
Studies

↑ **+38%**
since launch

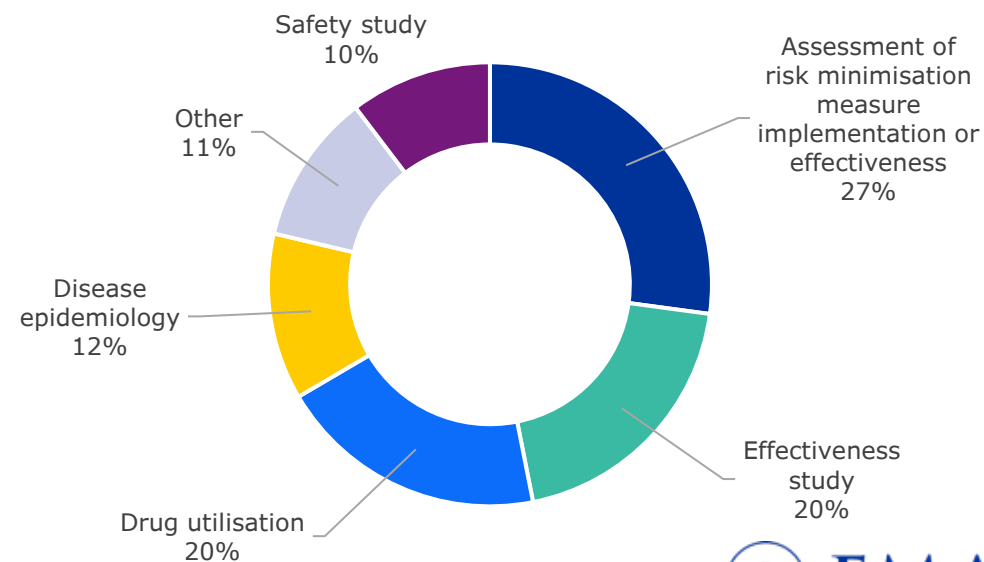
↑ **+16%**
since launch



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

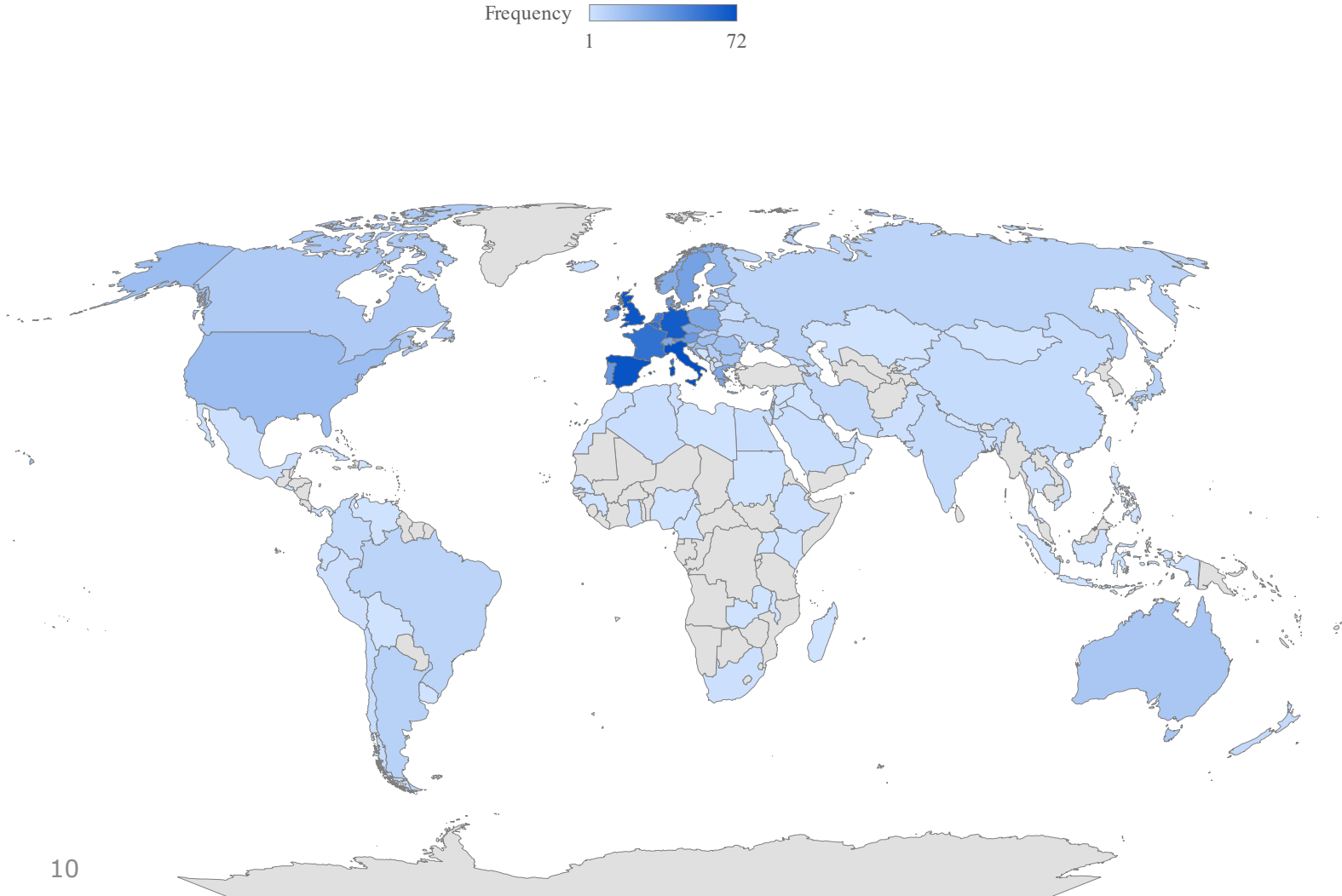


Distribution of Study Scope

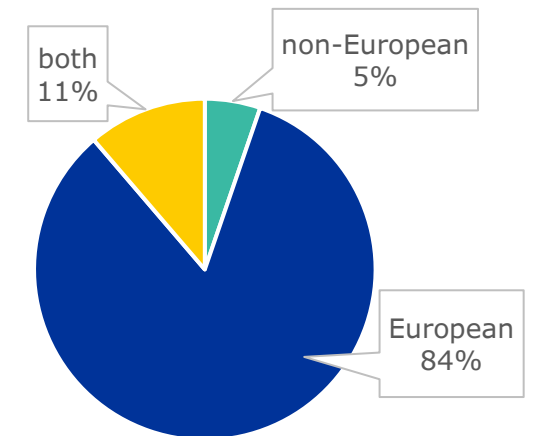


Where are we now?

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

Identify suitable data sources for study planning

Compare multiple data sources

Analysis of a data source used in a study

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](#)

EU guidance supporting the use of RWD and RWE – how it links to the RWD catalogues

Guidance	Main focus	How it connects to the RWD Catalogues
<u>Reflection Paper on the use of RWD in Non-Interventional Studies</u>	Discusses methodological aspects of non-interventional studies (NIS) using RWD to generate RWE for regulatory purposes. Emphasises data quality, transparency and reproducibility.	The RWD studies catalogue provides the transparency platform to register studies, share protocols and results, and link supporting analytical materials.
<u>Data quality framework for EU medicines regulation (EMRN DQF)</u> & <u>Data Quality Framework for EU medicines regulation application to real-world data (Draft) (RW-DQF)</u>	EMRN DQF sets out general considerations on data quality that are relevant for regulatory decision making and defines the key data quality dimensions . RW-DQF builds on the EMRN DQF setting out the specificities of RWD. Provides metrics and checklists to assess fitness-for-purpose.	The RWD sources catalogue captures these dimensions through structured metadata fields, making data quality attributes visible and comparable across sources. The RWD sources catalogue is proposed to support the provision of information on data quality of the existing data sources
The HMA-EMA Catalogues provide the operational platform to apply some of the principles and methods outlined in the guidance documents.		

How the RWD data sources catalogue captures information relevant to data quality

Data Quality Dimensions

How much data is there?
Extensiveness

Reliability
Is data correct?
Is it representing what is meant to represent?

Coherence
Can data be analysed as a whole?

Relevance
Is this the kind of data I need?

Timeliness
Is data available at the right time?

DQ

• Metadata on systems and processes

The Catalogues include structured metadata describing how data are generated and managed e.g.:

- data sources governance details
- data collection and recording processes
- mapping to a common data model
- vocabularies used



These elements support the assessment or understanding of **reliability, extensiveness, coherence, and timeliness** of each data source.

• Metadata on dataset content

The Catalogues capture information on:

- Setting
- Population
- Exposures
- Outcomes
- Time elements
- Also, link to studies performed using the data sources



These elements support the assessment of the **relevance** of a data source to answer a specific research question.

Engagement with European & Global Initiatives



ICH E23 Working Group

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

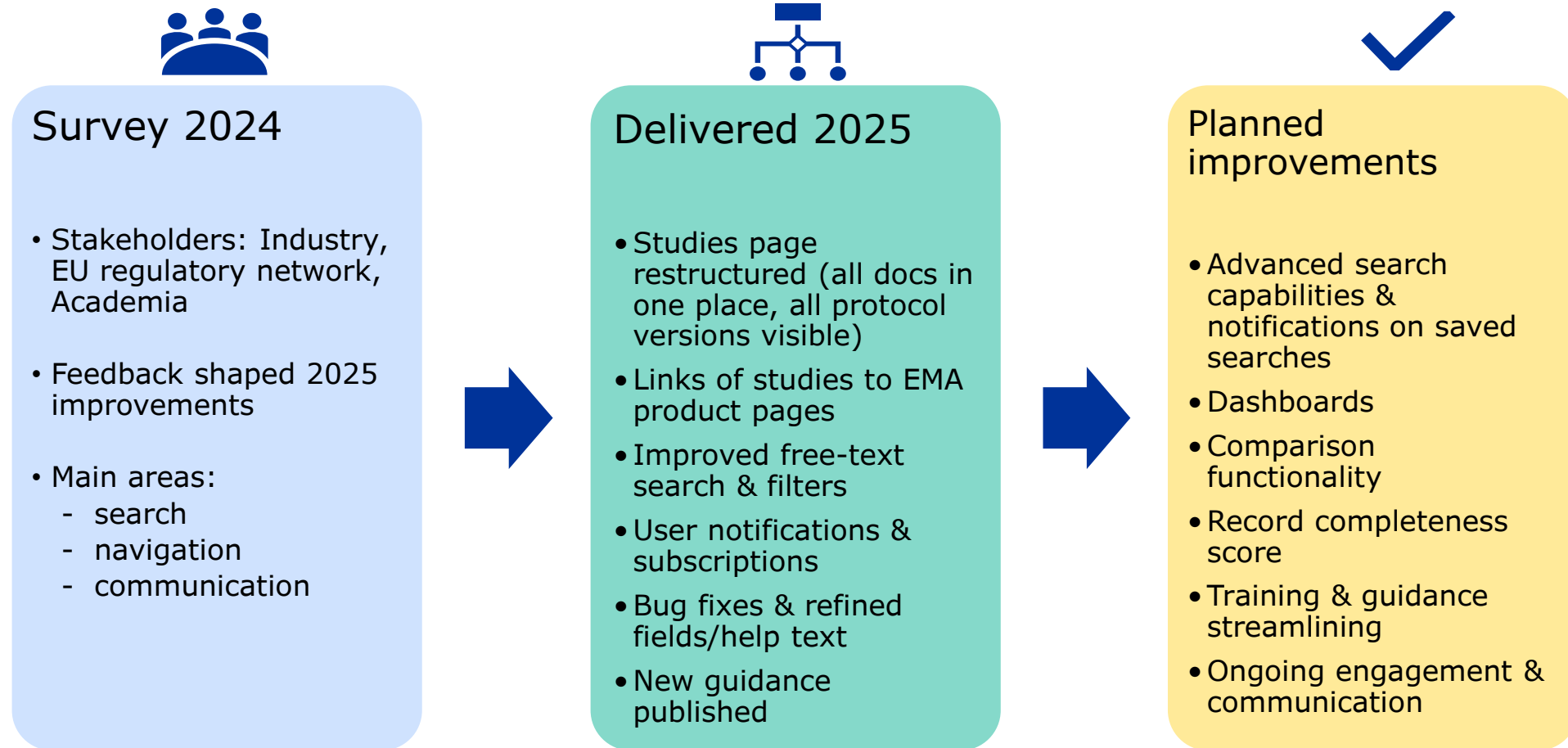
- RWD and RWE terminologies
- List of core metadata
- General principles for assessment of RWD/RWE (focus on effectiveness studies)
- EC, Europe rapporteur of the WG



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

Improvements delivered and ahead - guided by user feedback



Call for action

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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Real-World Data Quality Framework



Metrics with examples

Proposed metrics are supported by many examples and guidance, where applicable on their recommended use



Checklists and visuals

To aid the assessment, checklists of elements to be taken into consideration are proposed



Leveraging HMA-EMA RWD sources Catalogue

The RWD sources catalogue is proposed to support the provision of information on data quality of the existing data sources



Focus on research question

Data quality being defined as 'fit for purpose', there's a focus on addressing data quality in this context