

EUROPEAN  
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# Real-World-Evidence for Regulatory Decision-making **DARWIN EU®**

## Promises, Limitations and Challenges

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European Regulatory perspectives

ISPOR 2024

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An agency of the European Union



# Disclaimer

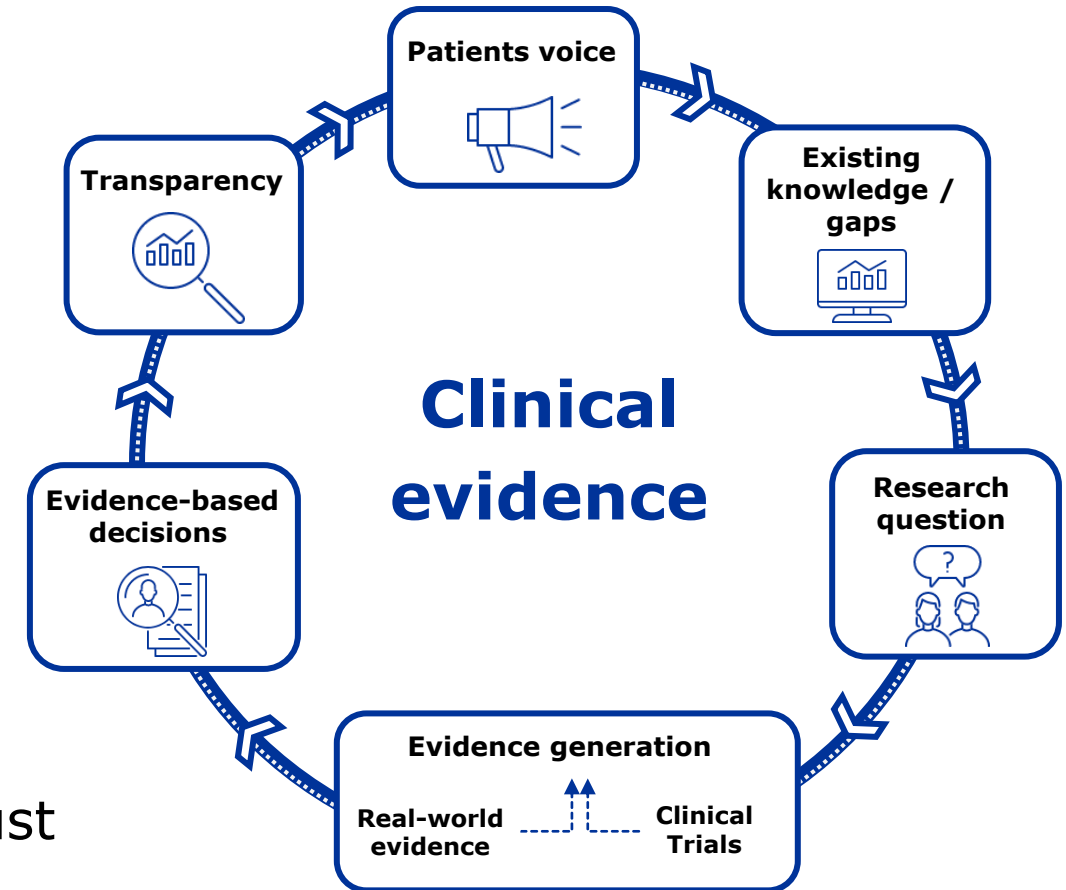
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# EU Regulatory Perspective on “Clinical Evidence”

- Patient voice guides every step of the way
- Evidence generation is planned and guided by **purpose**, data, knowledge and expertise
- Research question drives evidence choice and embraces spectrum of data and methods
- **Clinical trials remain core but are smarter, better and faster**
- **Real world evidence is enabled, and its value is established**
- High transparency level underpins societal trust



## 3 main pathways to use RWD for generating RWE @EMA



### EMA studies using in-house databases

- **Primary and secondary care** health records from **France, Germany and UK**



### Studies procured through EMA FWCs

- Framework contract (FWC) since September 2021: services of **8 research organisations** and academic institutions
- Access to **wide network of data sources**: 59 data sources from 21 EU countries
- Ability to leverage external **scientific expertise**



### DARWIN EU®

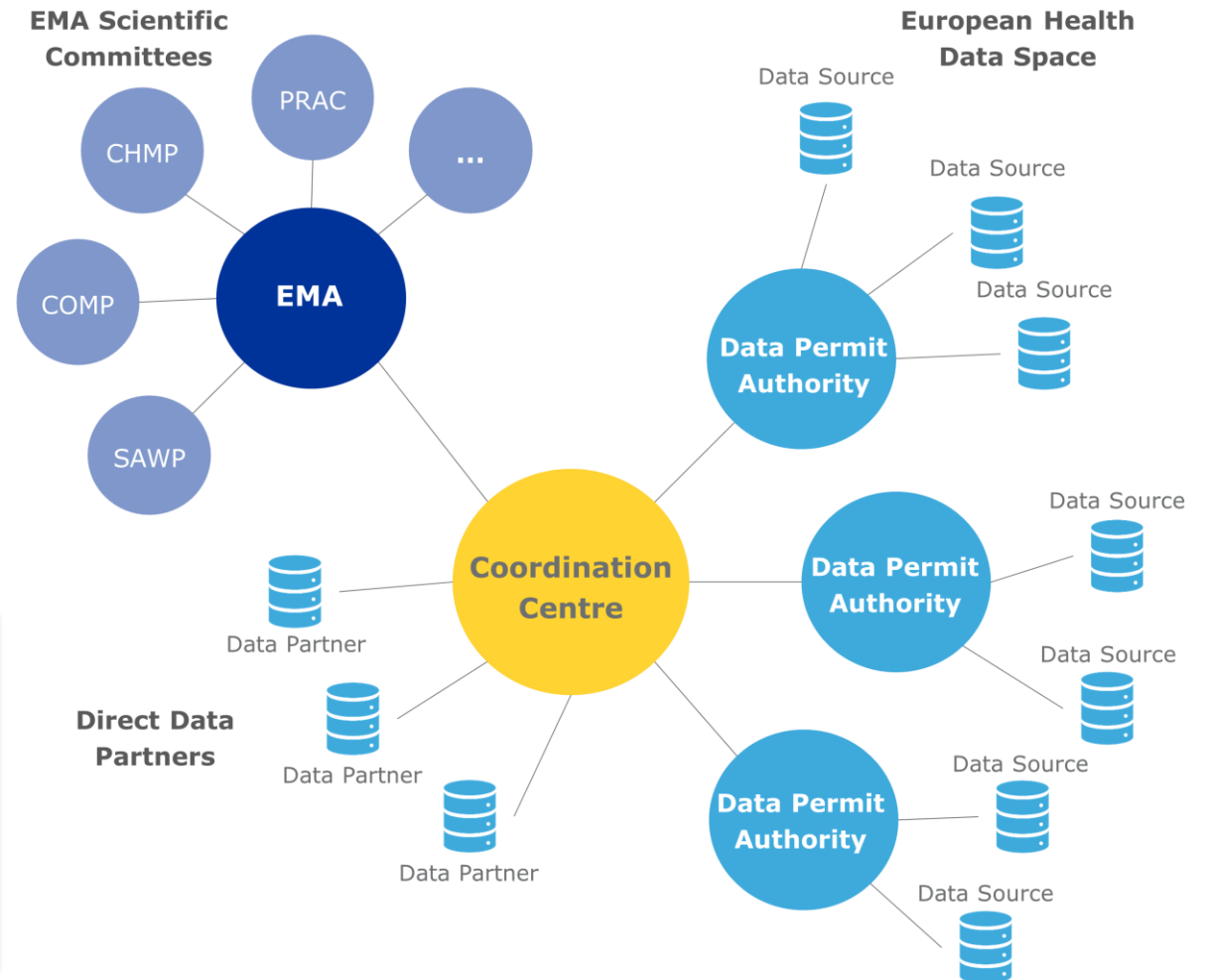
- Coordination Centre launched February 2022
- Onboarded **20 data partners** during the first 2 years
- **20+ studies** finalised
- Additional 10 data partners are foreseen to **be added each year** for 2024 and 2025

# Data Analysis and Real-World Interrogation Network **DARWIN EU®**

Federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating **valid and reliable evidence from real-world healthcare data**

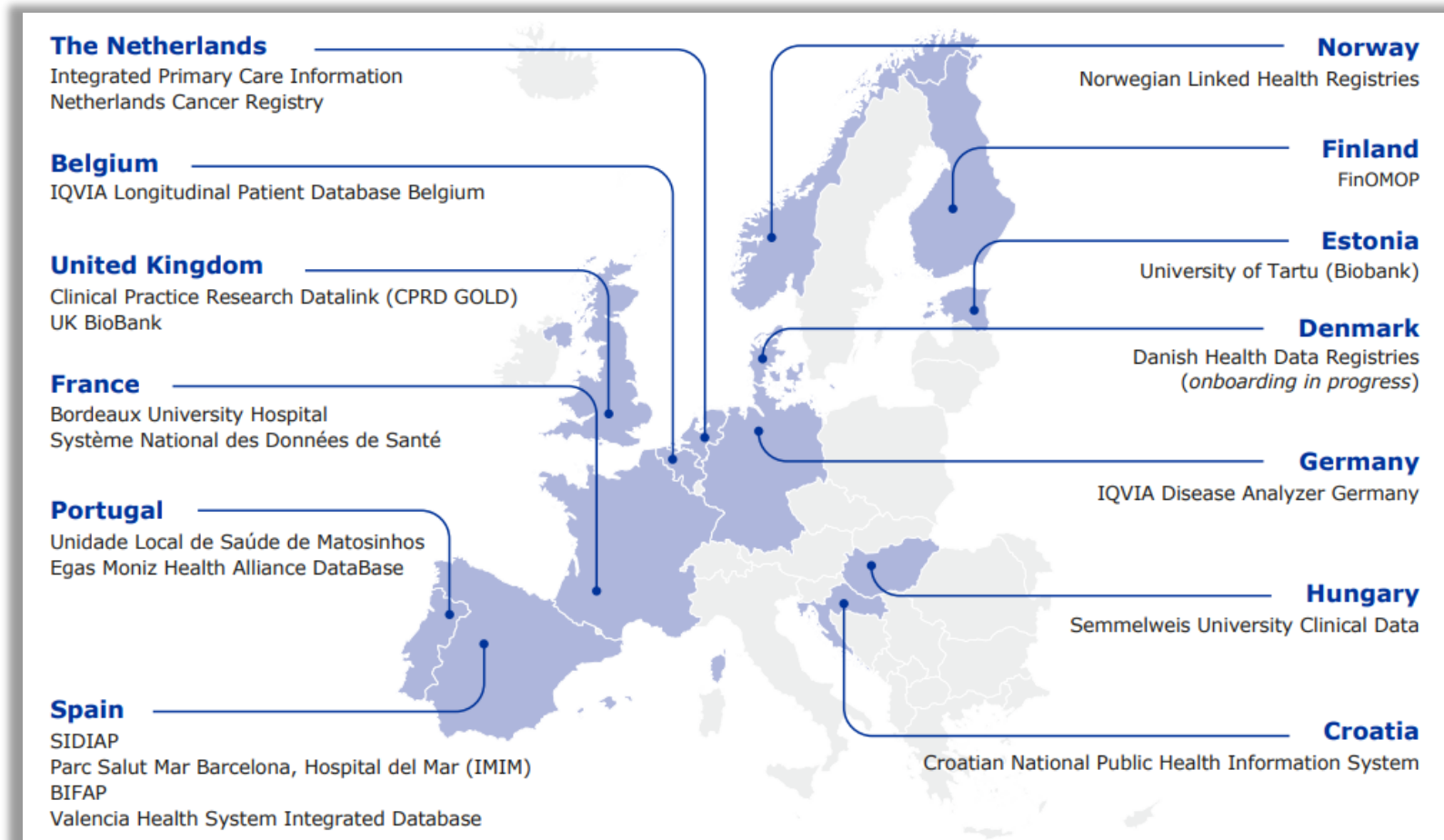
## FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of Common Data Model** (OMOP) to perform studies in a timely manner and increase consistency of results



# Data Partners

Access to data from ~130 million patients in 2024



# How RWE can support regulatory decision-making?

1

## Understand the clinical context

Disease epidemiology

Clinical management

Drug utilisation

2

## Support the planning and validity

Design and feasibility of studies

Representativeness and validity of completed studies

3

## Investigate associations and impact

(Comparative)  
Effectiveness and safety studies

Impact of regulatory actions

# Reports on RWE experience



Published  
in June  
2023

Period  
covered:  
**Sep 2021  
to Feb  
2023**



Published  
in July  
2024

Period  
covered:  
**Feb 2023  
to Feb  
2024**



# Focus on 2<sup>nd</sup> report

# 60

## NEW research topics (Feb '23 – Feb '24)

# +18

Prior research topics

# 38

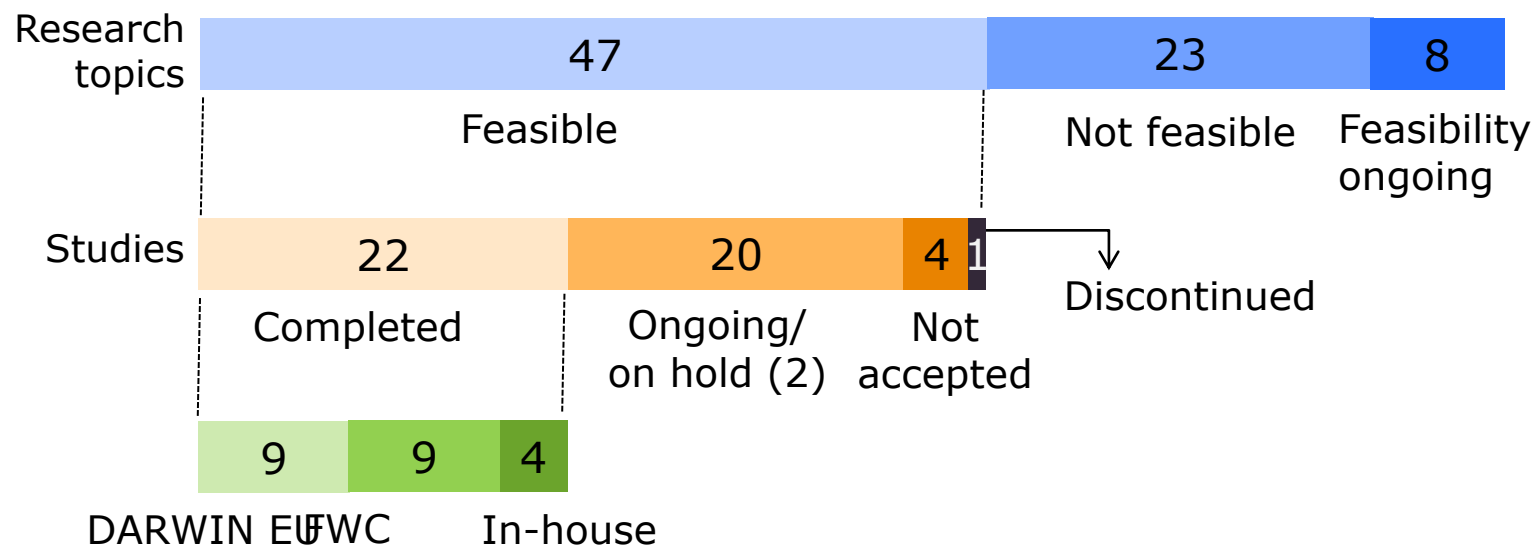
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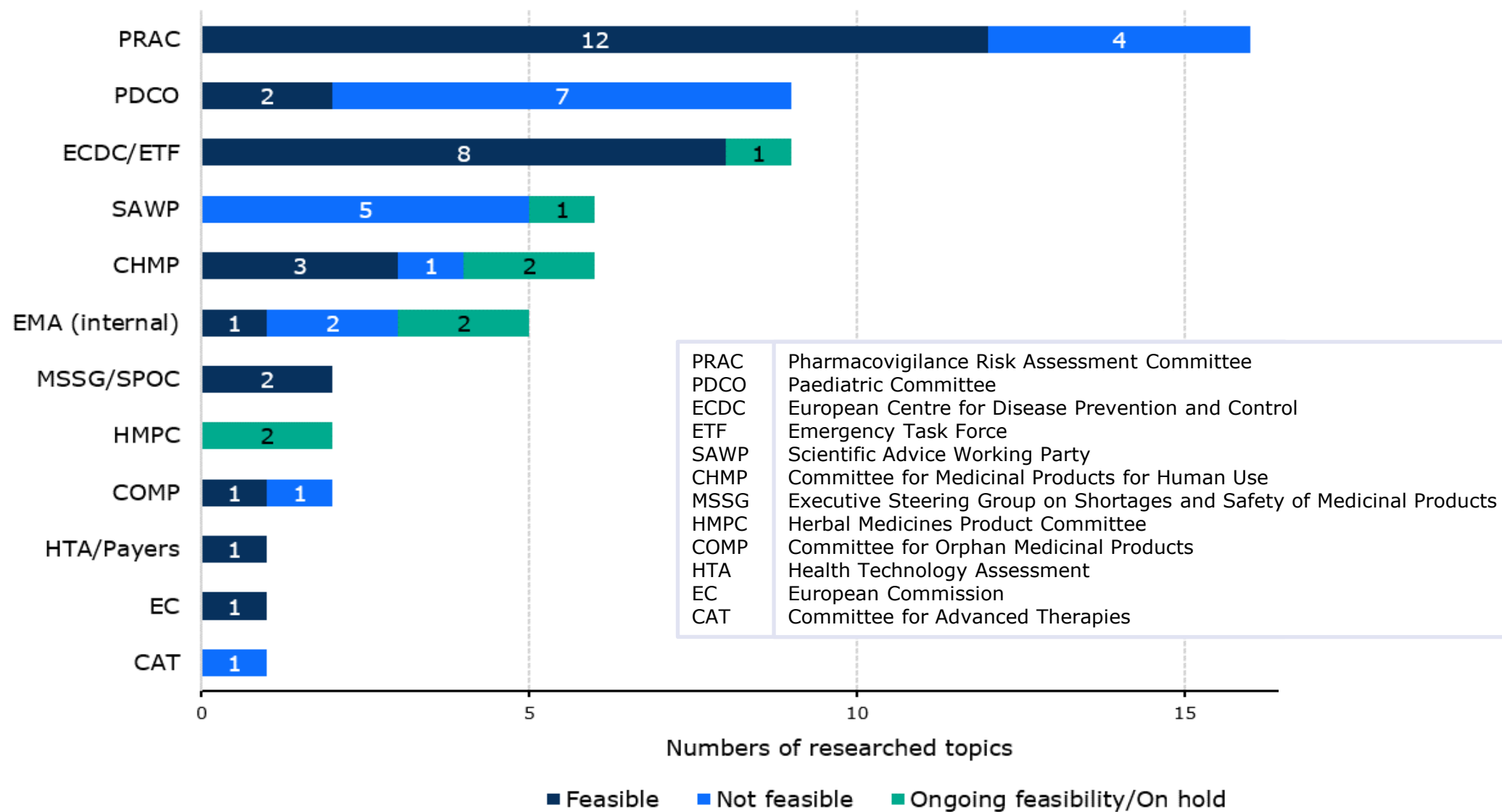
In-house

# 6

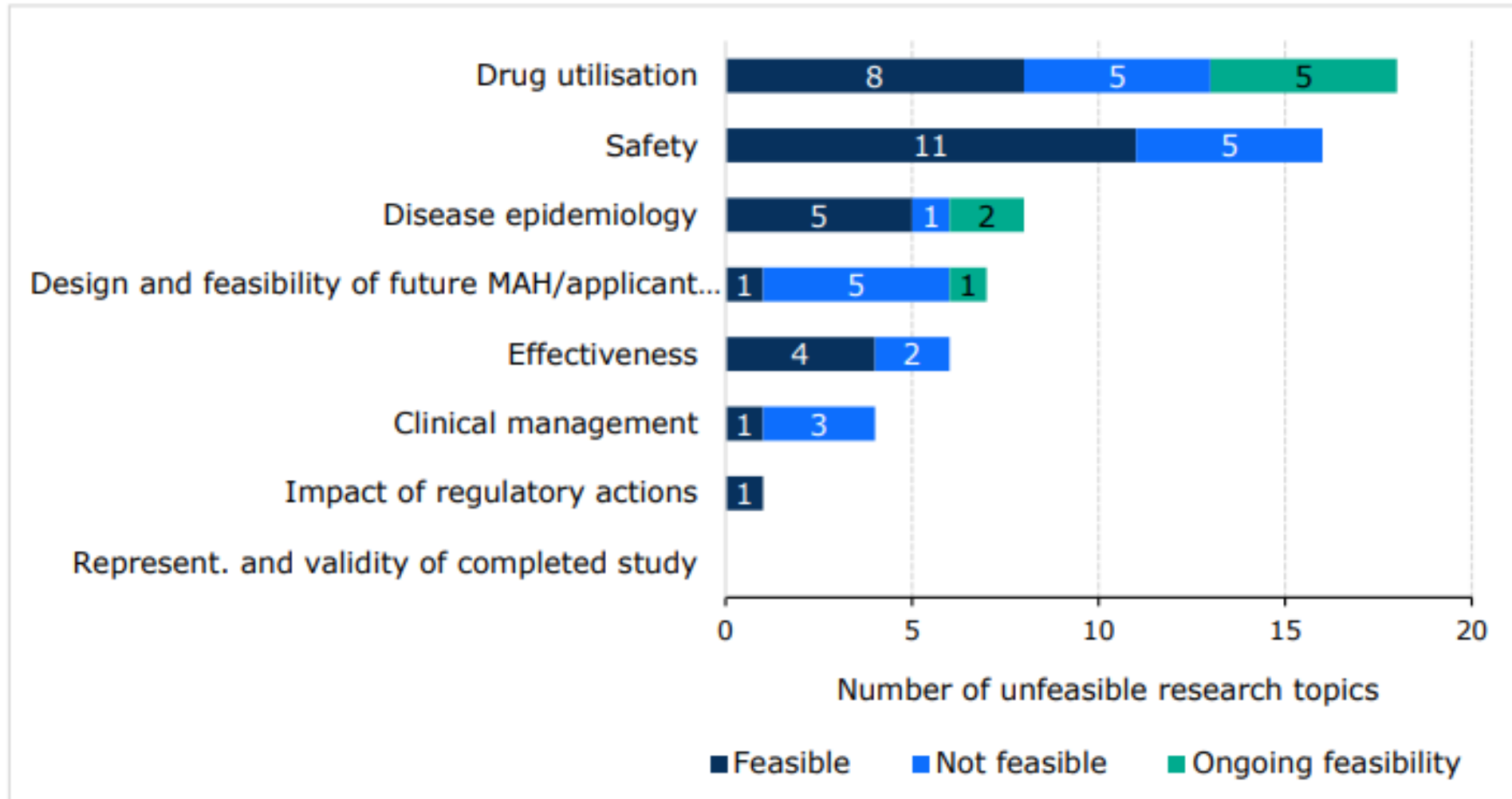
FWC



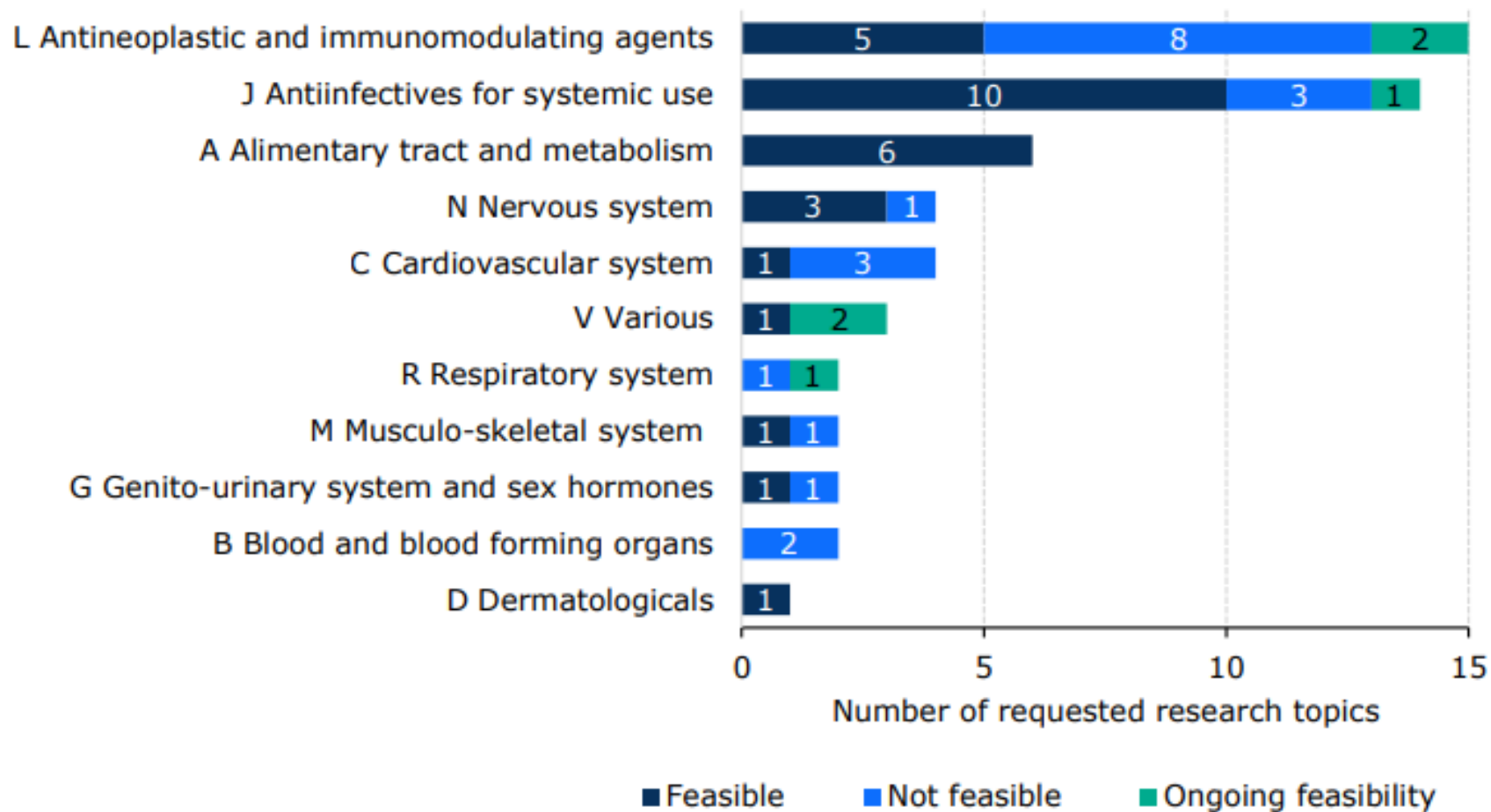
# Study topics by 'requester' from Feb '23 to Feb '24



# Type of research topic by use case and feasibility status



# Research topics by Anatomical Therapeutic Chemical (ATC) classification



# Recommendations for enabling the use of RWE



## Access to data sources

Wider access to more diverse and complementary data sources.



## Collaboration

Close collaboration with decision-makers and other stakeholders.



## Accelerate

Strategies to further accelerate RWE generation.



## Capacity and capability

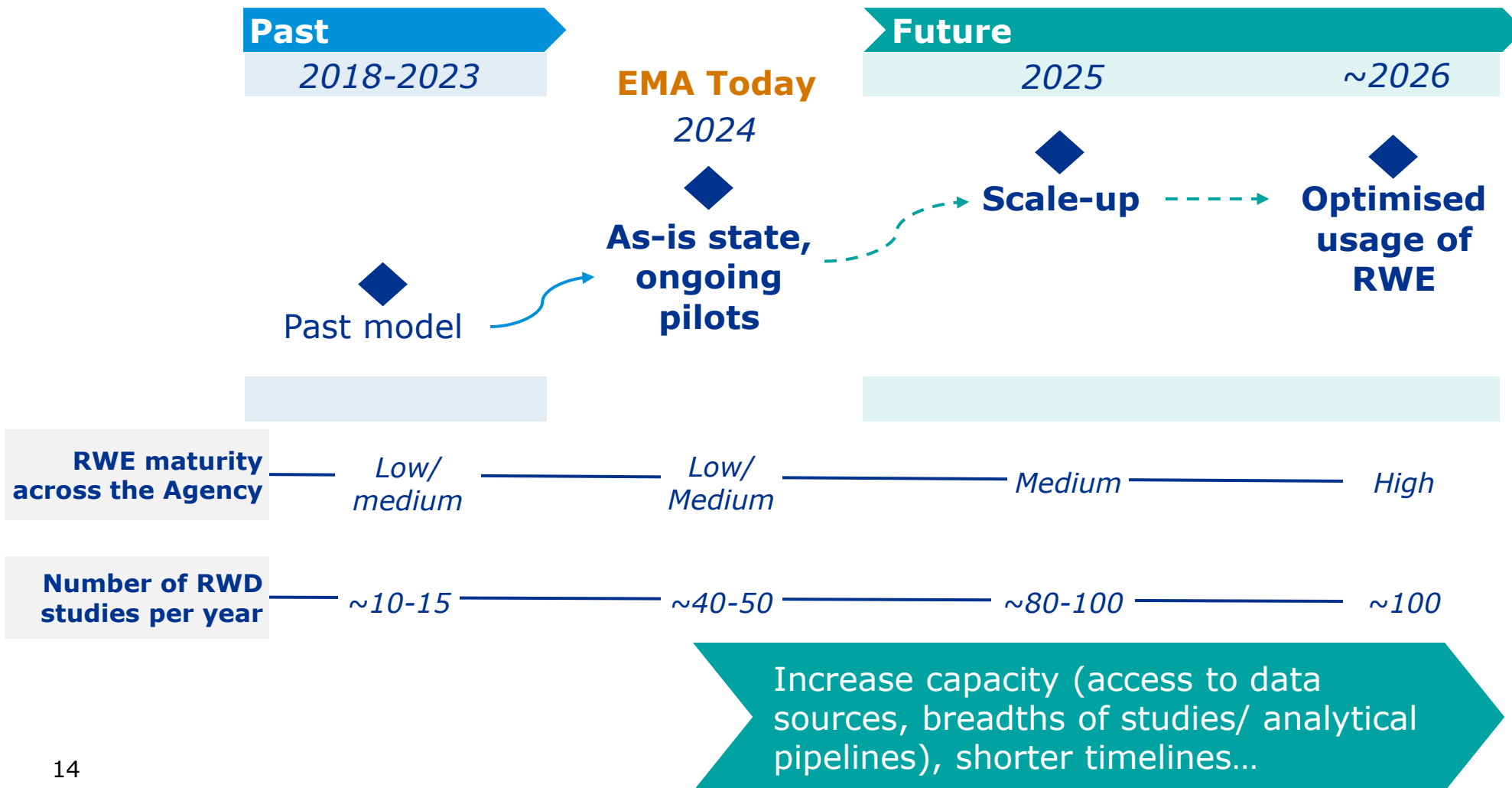
Develop educational and knowledge management sharing tools.



## Regulatory context

Anticipate RWE needs of decision-makers by identifying research questions earlier.

# In summary...



**Our vision**  
**By 2025 enable use & establish value of RWE**



# Thank you!

## Further information

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