EMA
EUROPEAN MEDICINES AGENCY

From Data to Decision in the EU

DARWIN EU and its network

Presented by Patrice Verpillat – March 2026

Séminaire BNDMR

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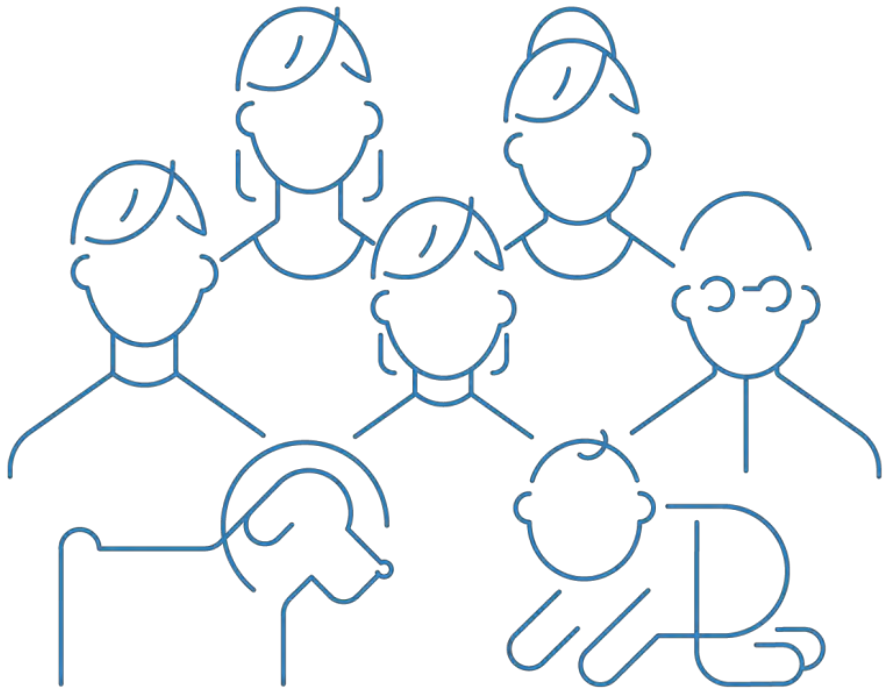
EMA in the EU

Who do we work for?



zdrowie zdravie
zdravlje Gesundheit
salud υγεία saúde
tervist veselība
salute здраве sanħa
terveys sundhed
health hälsa sláinte
egészség’
zdravje zdraví
gezondheid
sveikata
santé sănătate

27 member states

23.9 % of global sales of medicines

24 official languages

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What we do

Protect human and animal health

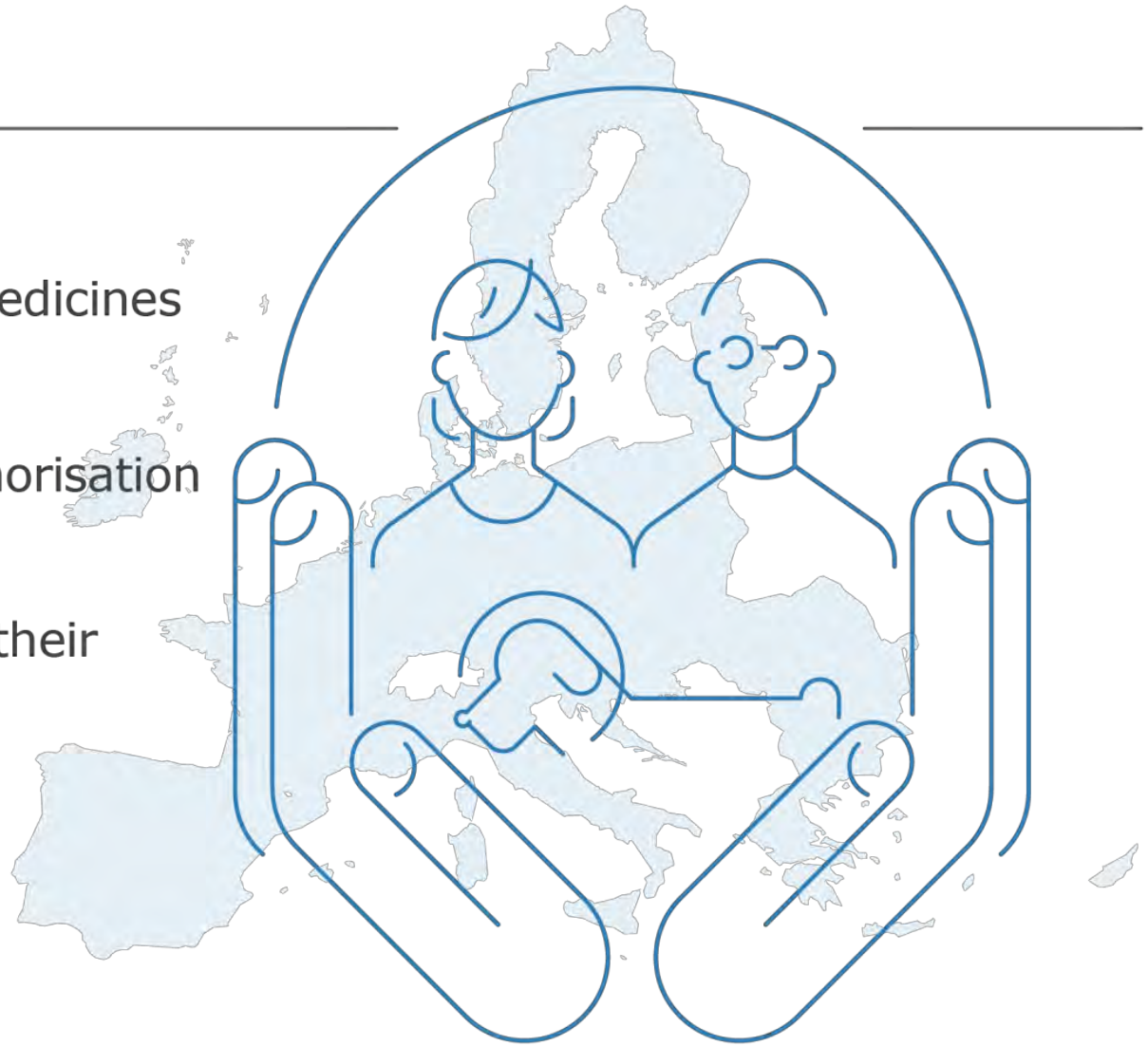
Facilitate development and access to medicines

Evaluate applications for marketing authorisation

Monitor the safety of medicines across their life cycle

ABC
XΨΩ

Provide reliable information on human and veterinary medicines to patients and healthcare professionals



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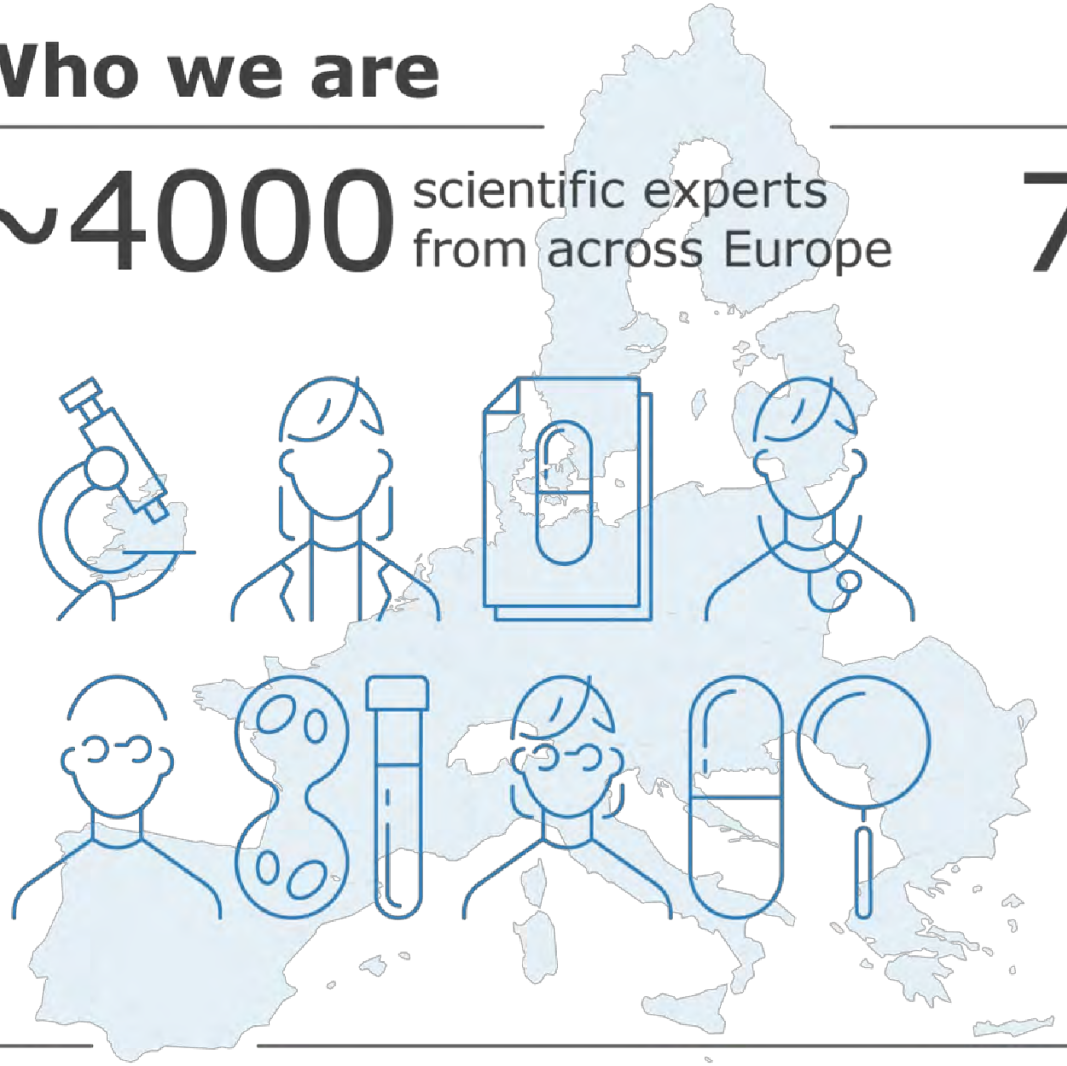
Who we are

~4000 scientific experts from across Europe



7 Scientific Committees

1 Management Board

CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC

27 Member States' representatives

4 Civil society representatives

2 European Commission representatives

2 European Parliament representatives

1995 EMA established

~900 staff members

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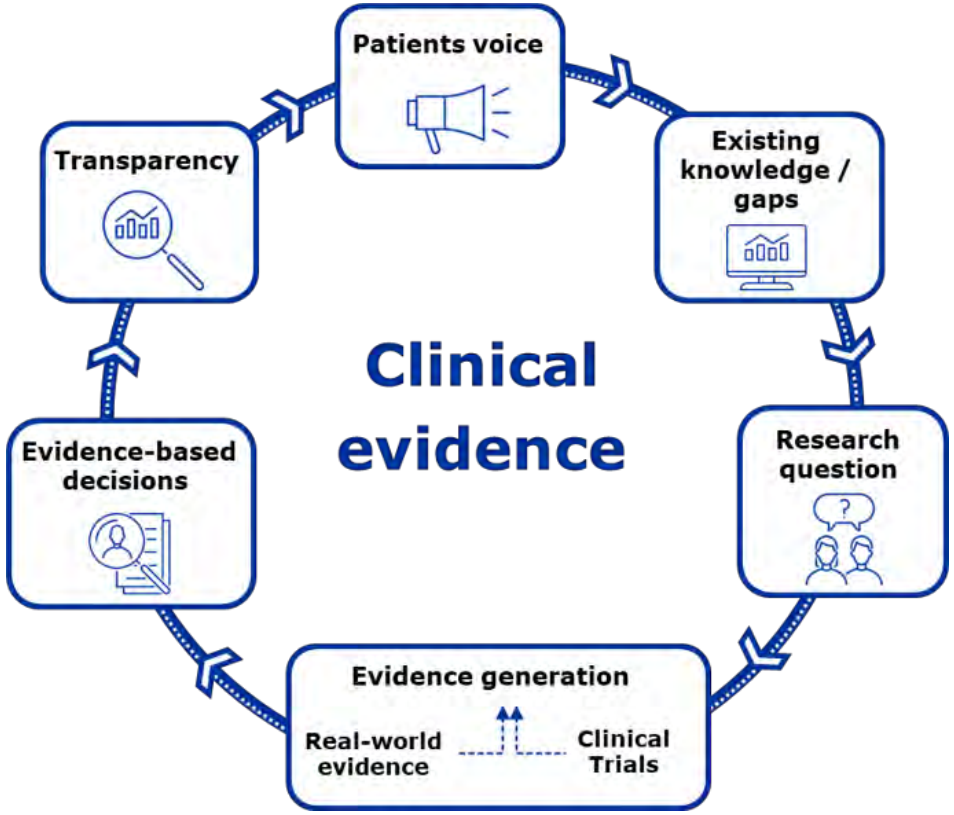
Generating clinical evidence
Shared vision towards 2030



- **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 should be **better, faster** and **optimised**
- Real world evidence is **enabled**, and its value is **established**
- High **transparency** level underpins societal trust

Clinical Evidence 2030. Arlett P, Umuhire D, Verpillat P, Foggi P, Wändel Liminga U, Sepodes B, Lunzer M, Aylward B, Vamvakas S, Roes K, Pétavy F, Thirstrup S, Lamas M, Cooke E, Broich K. *Clin Pharmacol Ther*. 2025 Feb 14. doi: 10.1002/cpt.3596.

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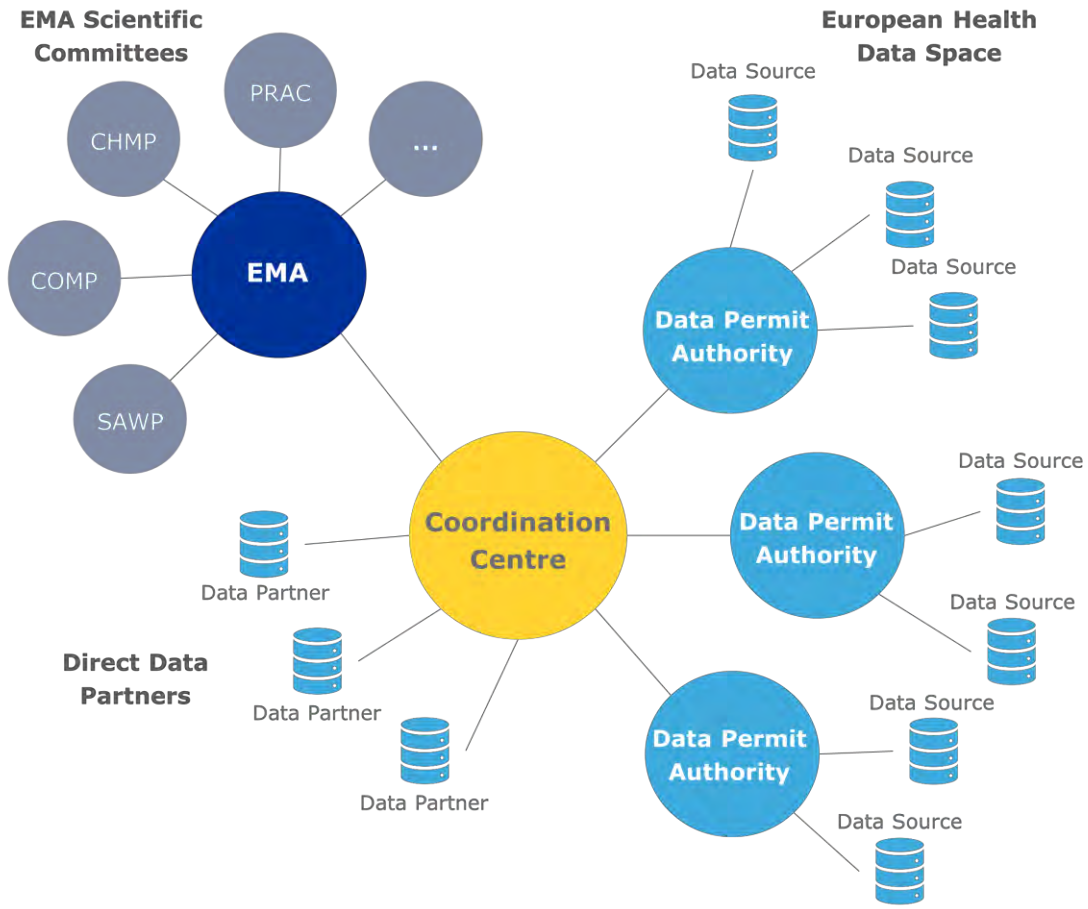
DARWIN EU®
Data Analysis and Real-World Interrogation Network

Federated **network** of **data**, **expertise** and **services** set up in *February 2022* to better support 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



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Three main areas where RWD analyses support decision-making

1

Understand the clinical context

- Disease epidemiology
- Clinical management
- Drug utilisation

2

Support the planning and validity

- Design and feasibility of planned studies
- Representativeness and validity of completed studies

3

Investigate associations and impact

- (Comparative) Effectiveness and safety studies
- Impact of regulatory actions

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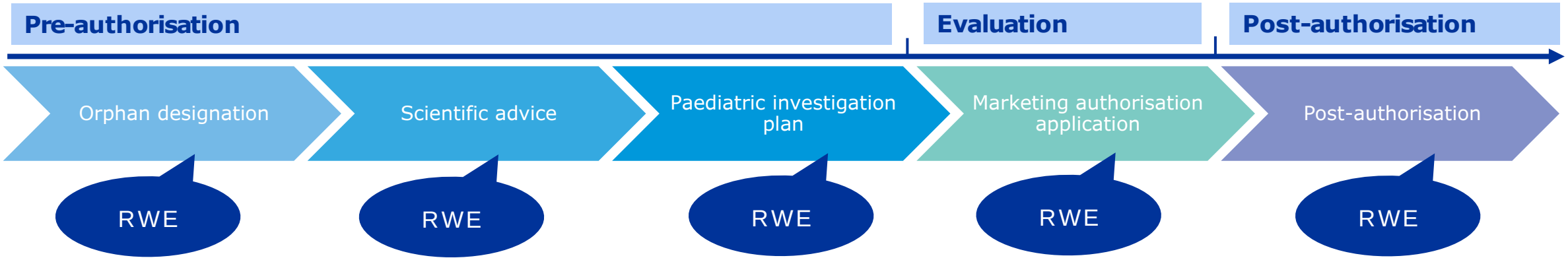
RWE use across the medicinal product lifecycle



- Generate prevalence data to support orphan designation

- Advise companies on use of RWE in product development based on feasibility and relevance of studies

- Identify needs in children to support waivers/deferrals (i.e., for diseases that only affect the adult population)
- Establish and regularly update an inventory of paediatric medicine needs

- Supplement, validate and contextualise clinical trial results to inform benefit-risk decision
- Inform decision-making on post-authorisation studies (e.g., feasibility of imposed PASS)
- Select specific patient populations who will respond to a treatment (Personalized medicine e.g., for cancer)

- Monitor performance (Assess benefit and risks in real world) on the market and inform decision-making
- Monitor safety and effectiveness in special populations, off-label use
- Characterise safety profile and monitor the effectiveness of risk minimisation measures
- Assess extension of indication and repurposing of medicines

COMP	CHMP / SAWP / CAT	PDCO	CHMP / CAT / PRAC	CHMP / PRAC / CAT / HMPC / CMDh

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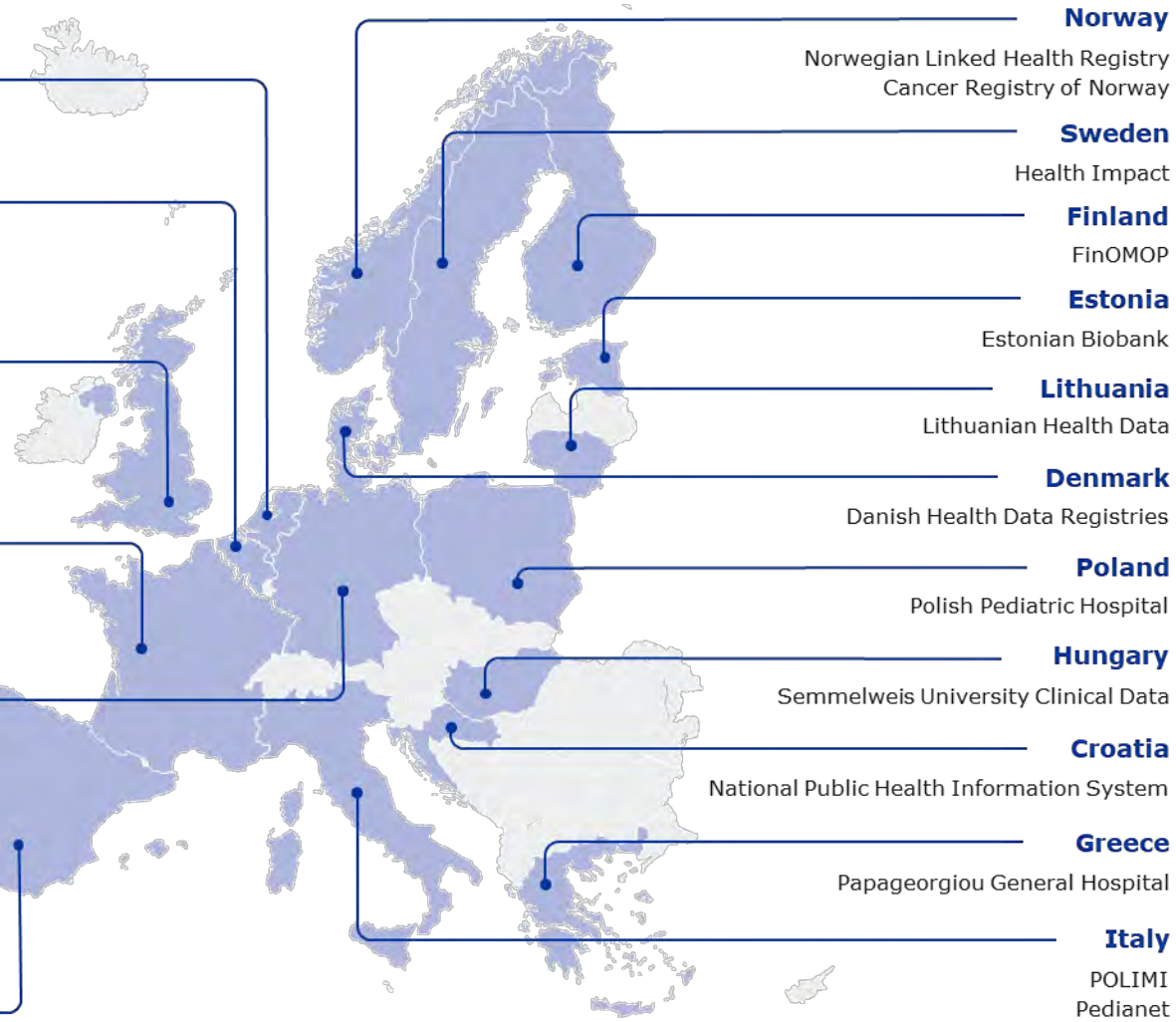
DARWIN EU Network of Data Partners



The Netherlands
Integrated Primary Care Information
Netherlands Cancer Registry

Belgium
IQVIA Longitudinal Patient Database Belgium
UZA Antwerpen
Belgian Cancer Registry

United Kingdom
UK BioBank
Clinical Practice Research Datalink GOLD
Clinical Practice Research Datalink AURUM
National Neonatal Research Database

France
Bordeaux University Hospital
Système National des Données de Santé
Health Data Warehouse of Assistance Publique

Germany
IQVIA Disease Analyzer Germany
InGef Research Database
Dresden University Hospital

Portugal
ULSM-RT
Egas Moniz Health Alliance DataBase
IPO Porto

Spain
SIDIAP
BIFAP
IMASIS and IMIM
Valencia Health System Integrated Database
H12O
Health Data Research Platform of the Balearic Islands
Hospital Universitario Virgen Macarena

Norway
Norwegian Linked Health Registry
Cancer Registry of Norway

Sweden
Health Impact

Finland
FinOMOP

Estonia
Estonian Biobank

Lithuania
Lithuanian Health Data

Denmark
Danish Health Data Registries

Poland
Polish Pediatric Hospital

Hungary
Semmelweis University Clinical Data

Croatia
National Public Health Information System

Greece
Papageorgiou General Hospital

Italy
POLIMI
Pedianet

International data platform
HARMONY Big Data Platform

United States of America
IQVIA US Ambulatory EMR, PharMetrics, Oncology

40 Data Partners as of Feb 2026, **18 European countries**

Access to data from ≈250 million patients in Europe

Few examples

Understand the clinical context | Support the planning and validity | Investigate associations and impact

- Respiratory Syncytial Virus (RSV) disease epidemiology (**CHMP** request to support discussion on unmet medical need)
- Juvenile polymyositis (JPM) and dermato-myositis (JDM) and disease natural history in paediatric population (**PDCO** request to better understand the disease context and assess feasibility of a CT)
- Doxycycline and association with risk of suicidality (**PRAC** request to facilitate signal assessment)
- Clozapine and the risk of agranulocytosis (**PRAC** request to assess the need for updated RMM)
- Non-Small Cell Lung Cancer (NSCLC) and immunotherapy treatments (**HTA bodies** request to assess comparative overall survival)

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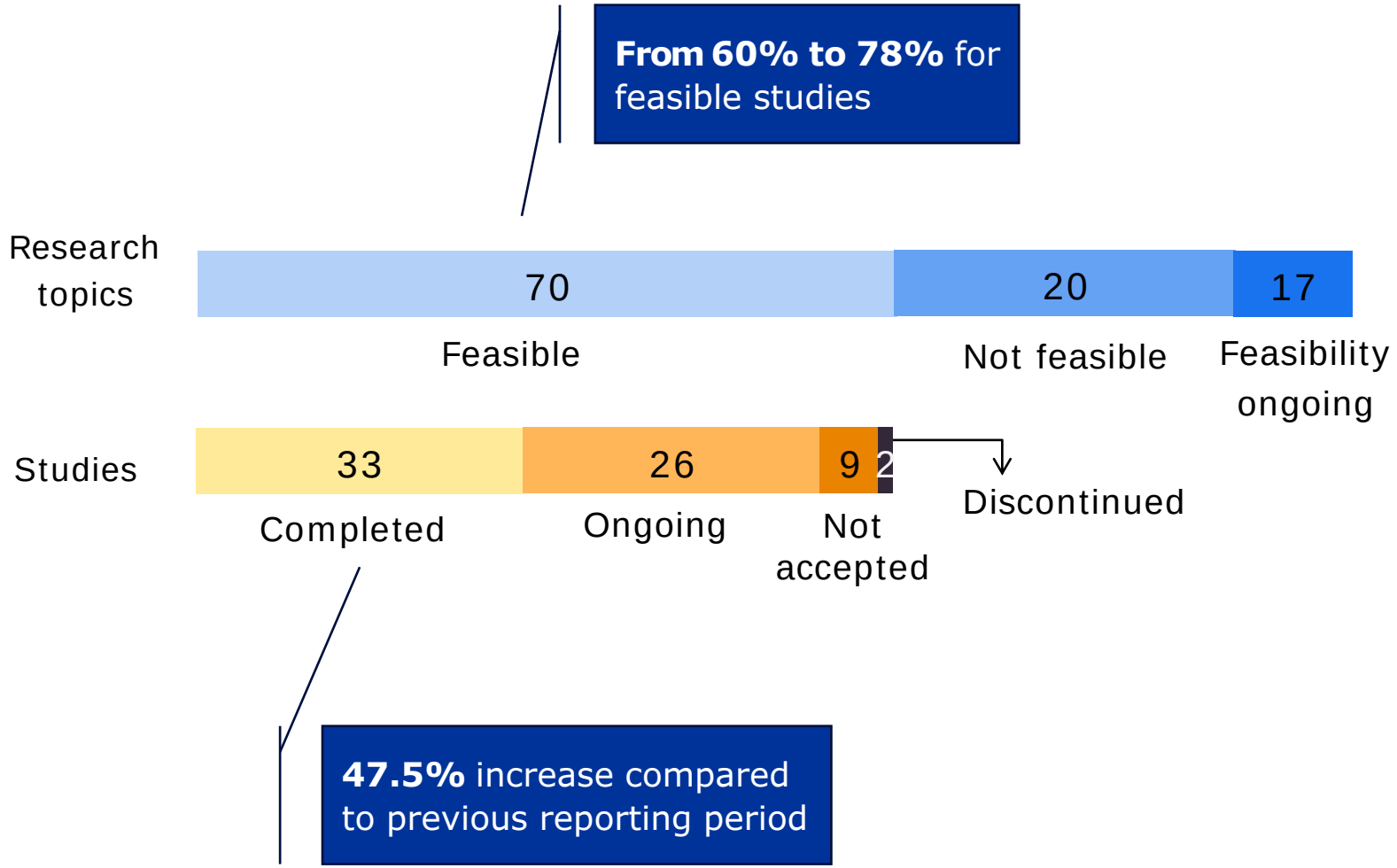
RWE Annual Report

107

Research topics

(Feb '24 – Feb '25)

89	9	9
DARWIN EU	I-H	FWC



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Recommendations

Further actions

- **Continue the growth of DARWIN EU**, focusing on more **specialised data sources** including data in special populations, rare diseases and oncology
- Strengthen the **outreach to data/registry owners** to facilitate access to data for secondary use

Expected features of additional data

- Nationwide coverage preferred (–> Incidence/Prevalence studies)
- Source covering more than a single disease or treatment (->used for several research questions)
- High level of granularity (-> allow to answer diverse set of questions)
- Complement existing data (-> expand the possibilities and minimise the number of non-feasible studies)
- OMOP converted preferred (-> short timelines to reply for some regulatory procedures)

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Thank you

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