Coordination Centre

DARWIN EU®

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OHDSI Sweden Symposium – 04/11/2025

Disclaimer

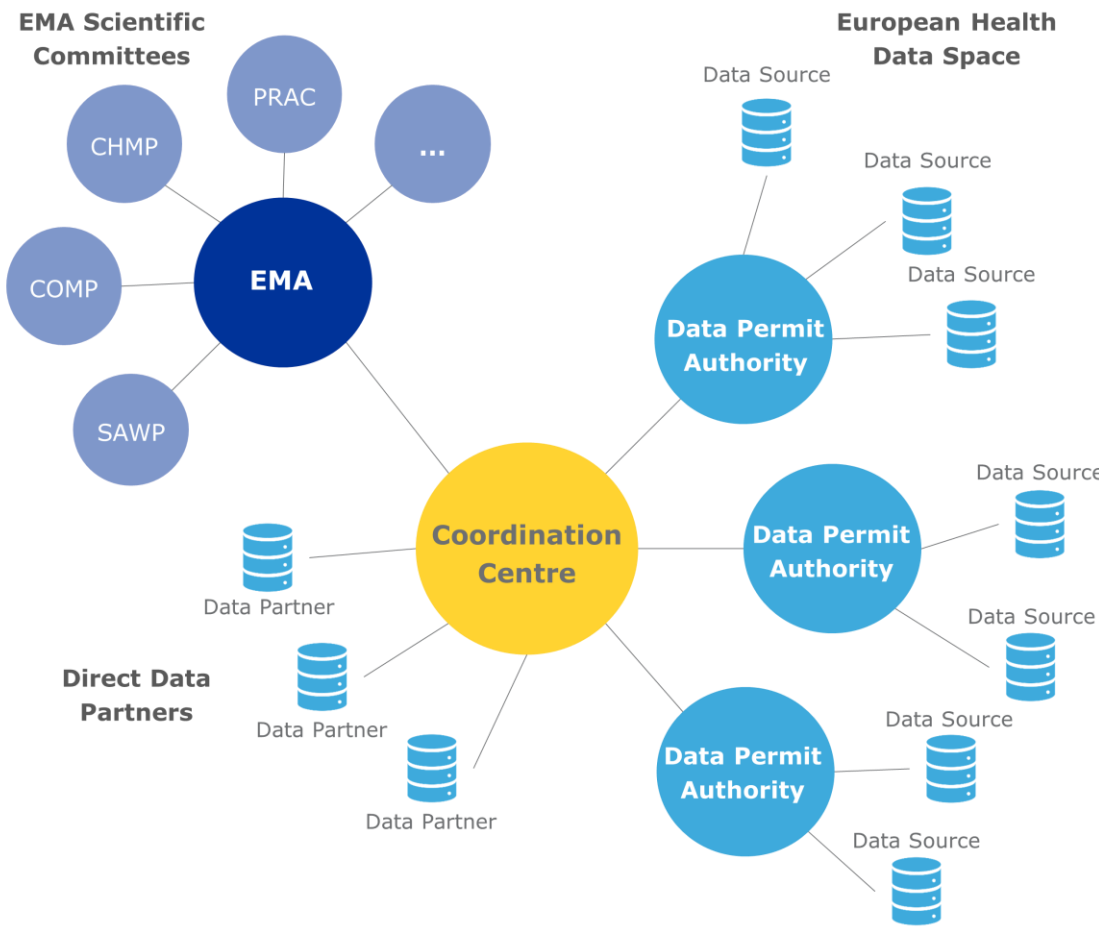
This presentation represents the views of the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the European Medicines Agency or the European Medicines Regulatory Network.

DARWIN EU® - Data Analysis and Real World Interrogation Network

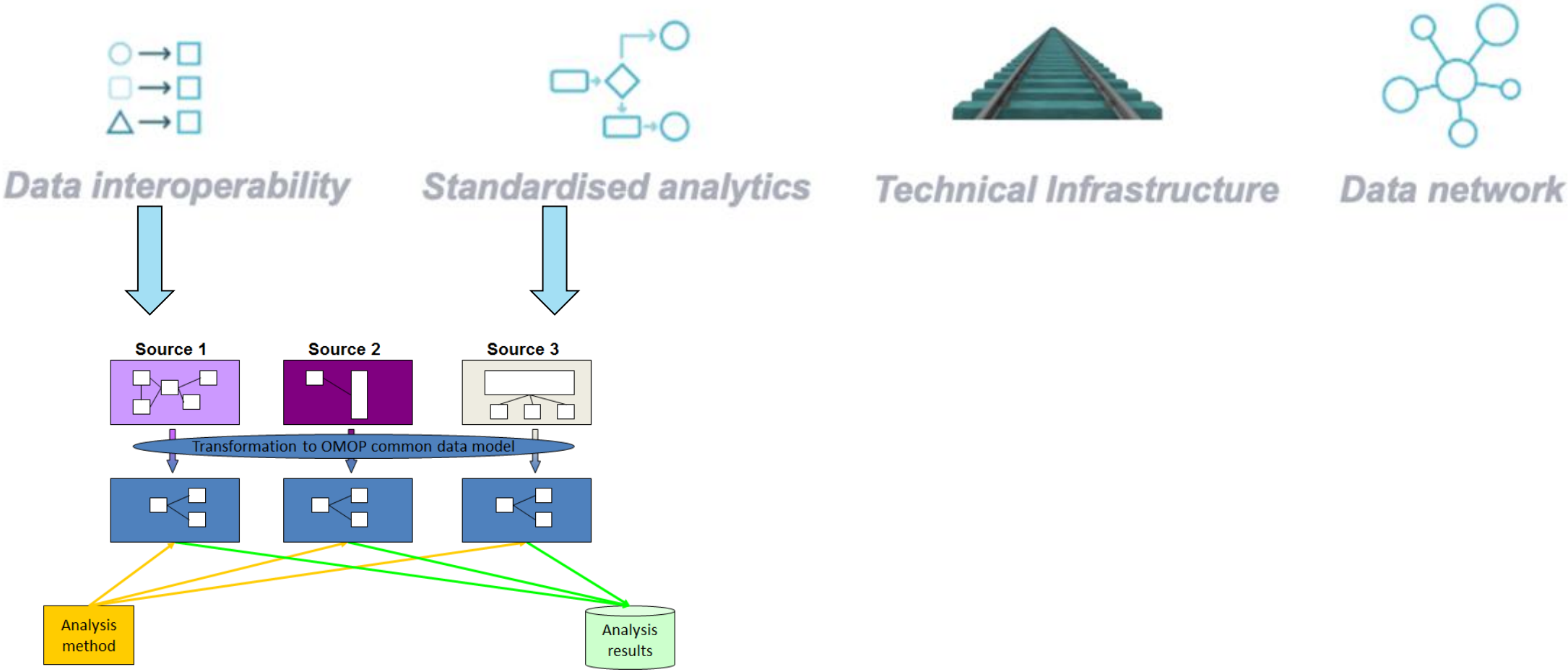
To **establish** and **maintain** a framework supporting better decisionmaking throughout the lifecycle of medicinal products with **timely, valid and reliable evidence** from real world healthcare.

Objectives:

1) To establish and maintain a continually enlarging network of accessible observational data sources
2) To execute all steps of high quality non-interventional studies with the network
3) To make the study results available to the EU Regulatory network to support decision-making

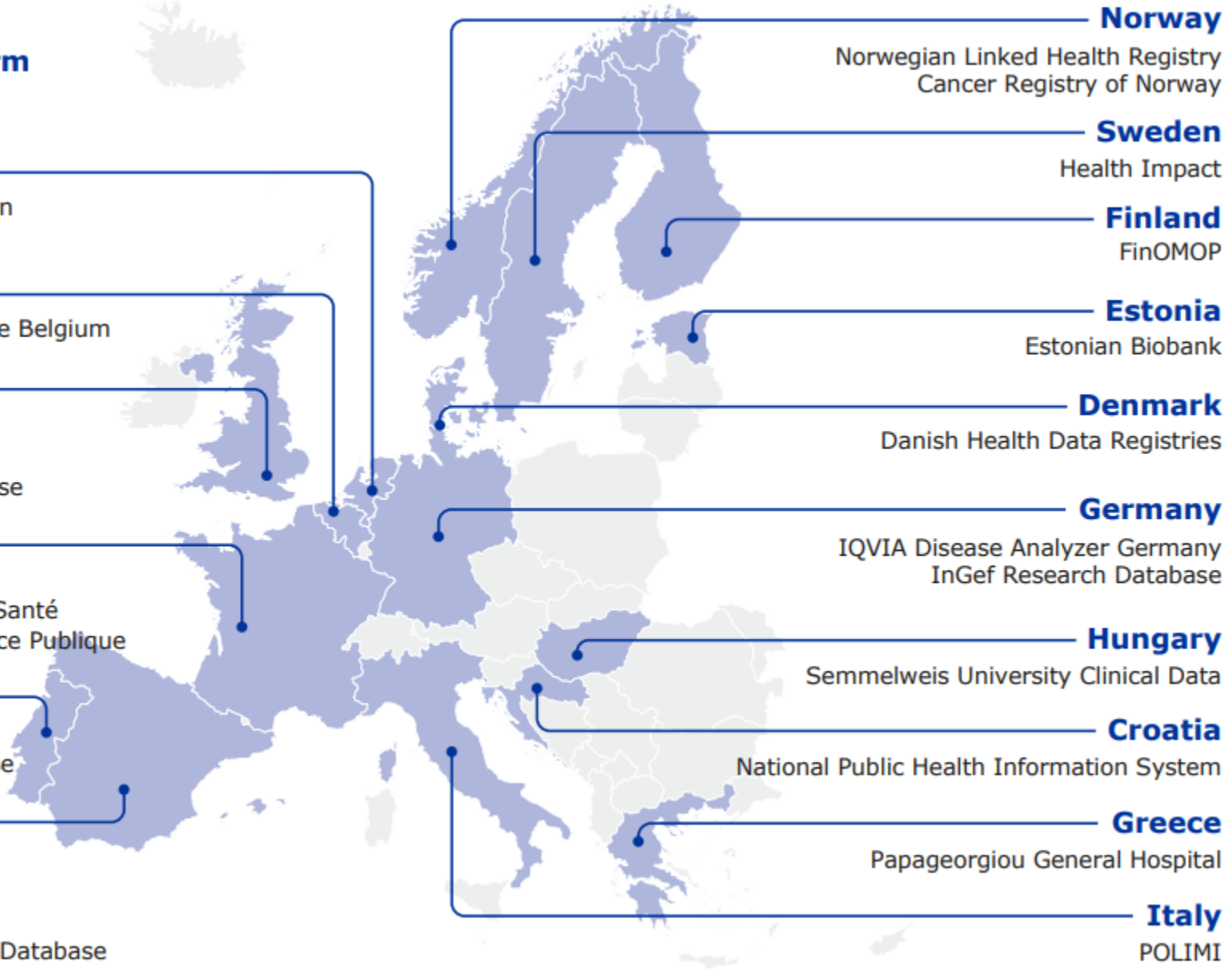


What is needed to facilitate observational studies at scale?



Co-creating this paradigm shift with EMA and the Data Partners
is a great journey to be involved in.

DARWIN EU Network of Data Partners



International data platform
HARMONY Big Data Platform

The Netherlands
Integrated Primary Care Information
Netherlands Cancer Registry

Belgium
IQVIA Longitudinal Patient Database Belgium

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

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

Portugal
ULSM-RT
Egas Moniz Health Alliance DataBase

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

Norway
Norwegian Linked Health Registry
Cancer Registry of Norway

Sweden
Health Impact

Finland
FinOMOP

Estonia
Estonian Biobank

Denmark
Danish Health Data Registries

Germany
IQVIA Disease Analyzer Germany
InGef Research Database

Hungary
Semmelweis University Clinical Data

Croatia
National Public Health Information System

Greece
Papageorgiou General Hospital

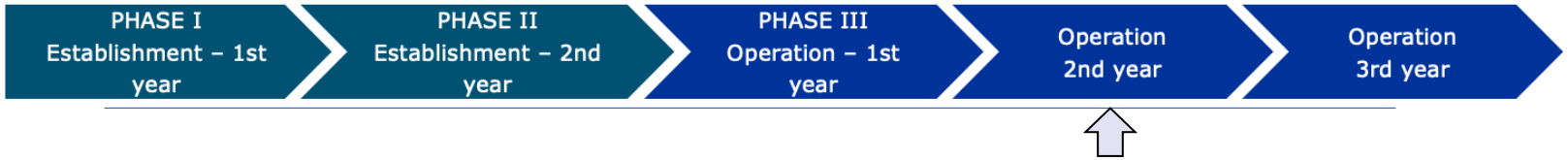
Italy
POLIMI

30 Data Partners as of Feb 2025 (~ +10 by end of Feb 2026) in **16 European countries**

From ~26 to ~180 million active patients

EMA

Establishment and Evolution of the Coordination Centre



Development

- QA/QC Procedures
- Vocabulary Extension
- CDM Development
- Methods Research
- Analytical Tools
- Dashboarding
- Training Material
- Protocol Templates

Operations

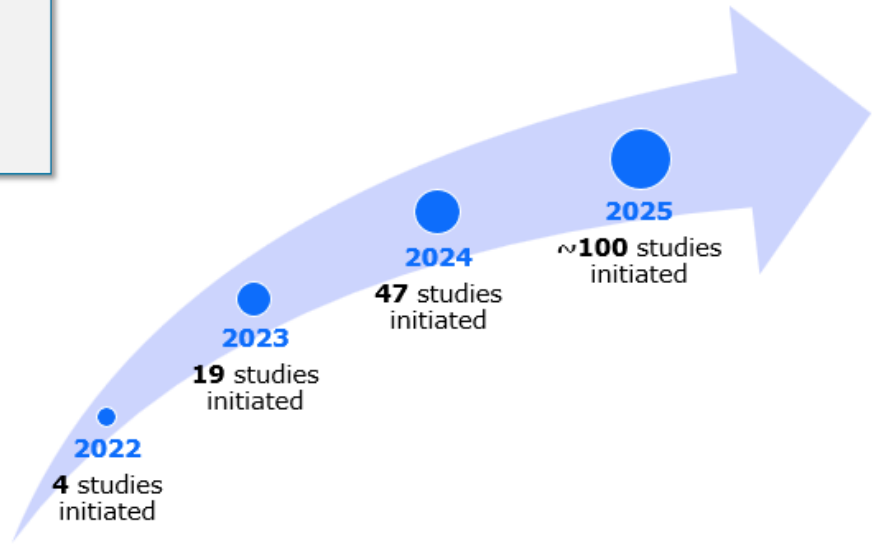
- Study execution
- Network management

Technology

- Infrastructure
- Security
- Collaboration Environment
- Analytics Platform
- Source Control Repository
- Website
- Service Desk
- Training Platform

Management

- Secretariat
- Legal / Contracting
- Finance
- COI management
- Risk management
- Reporting
- Recruitment
- Outreach



What analyses and studies is DARWIN EU® delivering?

Category of observational analyses and studies	Description
Off-the-shelf studies	Studies for which a generic protocol is adapted to a research question
Complex Studies	Studies requiring development or customisation of specific study designs, protocols, phenotypes, or Statistical Analysis Plans (SAPs)
Routine repeated analyses	Routine analyses based on Off-The-Shelf or Complex Studies (see above), repeated periodically with a pre-specified regularity (e.g. yearly)
Very Complex Studies	Studies which would require complex and/or novel methodological work

Number of studies

PHASE I Establishment – 1st year → PHASE II Establishment – 2nd year → PHASE III Operation – 1st year → Operation 2nd year → Operation 3rd year

	Year 1	Year 2	Year 3	Year 4	Year 5
Phases	Phase I	Phase II	Phase III	Option 1	Option 2
Routine Repeated analysis	-	-	4	35-50	35-50
Off the shelf studies	3	14	23	35-50	35-50
Complex Studies	1	4	10	15-20	15-20
Very Complex Studies	0	0	0	1	1

https://darwin-eu.org/index.php/studies

Standardising the analytics

- A catalogue of open source standardised analytics was created to support regulatory decision-making on the utilisation, safety and effectiveness of medicinal products

Requires alignment on the priority and choice of the analytical methods, and the standardised output.

https://www.darwin-eu.org/methods/standardised-analytics

Catalogue of Standard Analyses:
Off-the-shelf studies and examples

Standard Analysis	Regulatory example
Population-level disease epidemiology	• Prevalence of rare disease/s • Background rates of AESI
Patient-level disease epidemiology	• Natural history/prognosis • Current practice/treatment patterns
Population-level DUS	• Incidence and prevalence of use of medicine/s over time
Patient-level DUS	• Describing indication/s for drug/s • Treatment duration, cumulative use

https://www.darwin-eu.org/methods/standardised-analytics

Catalogue of Standard Analyses:
Complex studies and examples

Standard Analysis	Regulatory example
RMM Effectiveness	• Incidence of drug/s use before and after a regulatory action • Medicine/s user/s profile after new indication or contraindication
New user, active comparator, cohort studies	• Post-authorisation safety study • Comparative effectiveness
Self-controlled case series	• Vaccine safety surveillance

https://www.darwin-eu.org/methods/standardised-analytics

HMA
Heads of Medicines Agencies

EMA
EUROPEAN MEDICINES AGENCY

DARWIN EU

Real-world evidence framework to support EU regulatory decision-making

3rd report on the experience gained with regulator-led studies from February 2024 to February 2025

Association between doxycycline use and risk of suicidality and incidence of suicidality in patients with specific chronic skin conditions (PRAC request to support signal assessment)

There were spontaneous reports on a potential association between use of doxycycline and suicide. By means of a self-controlled case series and an active comparator cohort study, the DARWIN EU study aimed to assess the association between use of doxycycline and suicidality events.

The study results provided evidence which did not confirm an association between use of doxycycline and risk of suicide related events in individuals with acne.

In a second, complementary, DARWIN EU disease epidemiology study that evaluated suicidality-related events in patients with acne, psoriasis, and in the general population in UK, the Netherlands, Spain, and Croatia, it was observed that acne patients consistently had a higher incidence of suicidality-related outcomes, particularly among younger females, when compared to the general population. This suggests a potentially strong effect of confounding by indication. Considering these findings, the signal was closed with no product information update warranted.

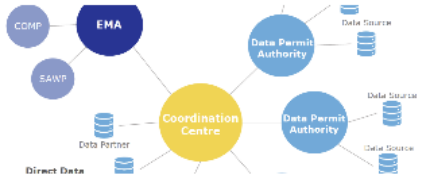
DARWIN EU

The European Medicines Agency (EMA) and the European Medicines Regulatory Network established a coordination centre to provide timely and reliable evidence on the use, safety and effectiveness of medicines for human use, including vaccines, from real world healthcare databases across the European Union (EU). This capability is called the **Data Analysis and Real World Interrogation Network (DARWIN EU®)**.

Expression of Interest Call now open for Data Partners.

More information can be found here.

Latest News



DARWIN EU® Network requirements

Network requirements A strategic priority for DARWIN EU® is to expand the scope of the network for generation of new evidence supporting...

European Health Data Space

European Health Data Space DARWIN EU will connect the European medicines regulatory network to the European Commission's European Health... Read More

catalogues.ema.europa.eu

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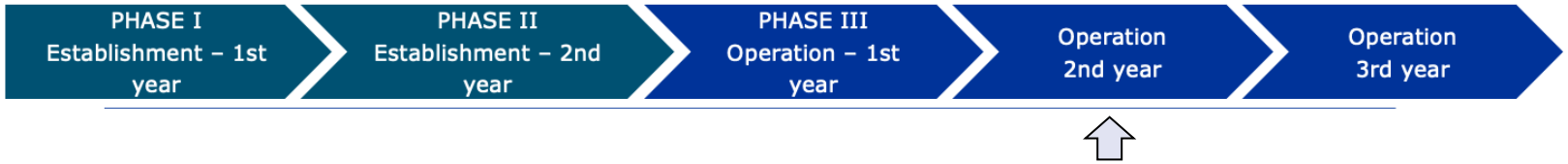
HMA-EMA Catalogues of real-world data sources and studies

The Catalogues for real-world data sources, studies, institutions and networks replace and enhance the previous EU PAS Register® and ENCePP Resource Database.

What is next for DARWIN EU?



- Onboarding of additional data partners
- Continued development of analytical tools
- Continued quality control and improvement of CDMs
- Continued training of data partners, CC, EMA
- Expand information on data sources on the website
- Execution of many studies!!

Thank you!

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