Coordination Centre

Scaling-up Real-World Evidence Generation for Regulators in Europe: DARWIN EU

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Disclaimer

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DARWIN EU

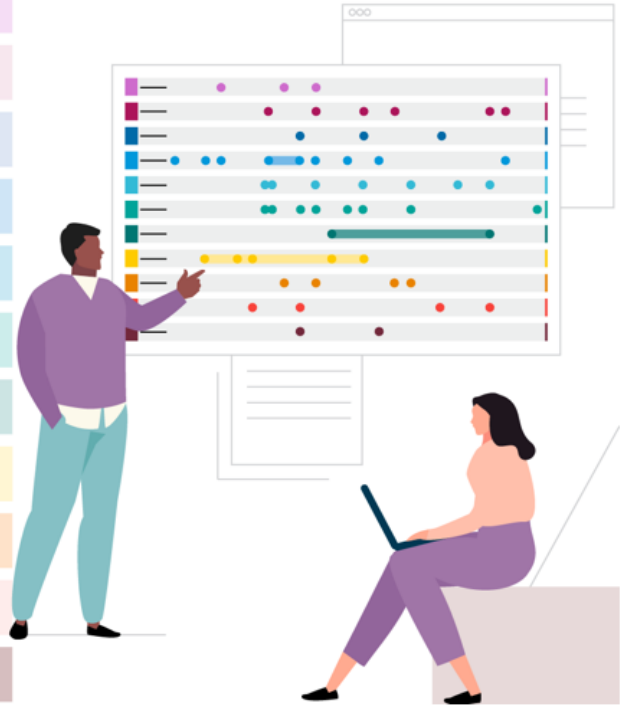
EUROPEAN MEDICINES AGENCY

By 2025 the use of Real-World Evidence will have been enabled and the value will have been established across the spectrum of regulatory use cases

- European Medicines Regulatory Network (EMRN) strategy to 2025 -

Big Data Task Force recommendations (source EMA Website)

- DARWIN EU
- Data quality & representativeness
- Data discoverability
- EU Network skills
- EU Network processes
- Network capability to analyse
- Delivery of expert advice
- Governance framework
- International initiatives
- Stakeholder engagement
- Veterinary recommendations



DARWIN EU® Vision

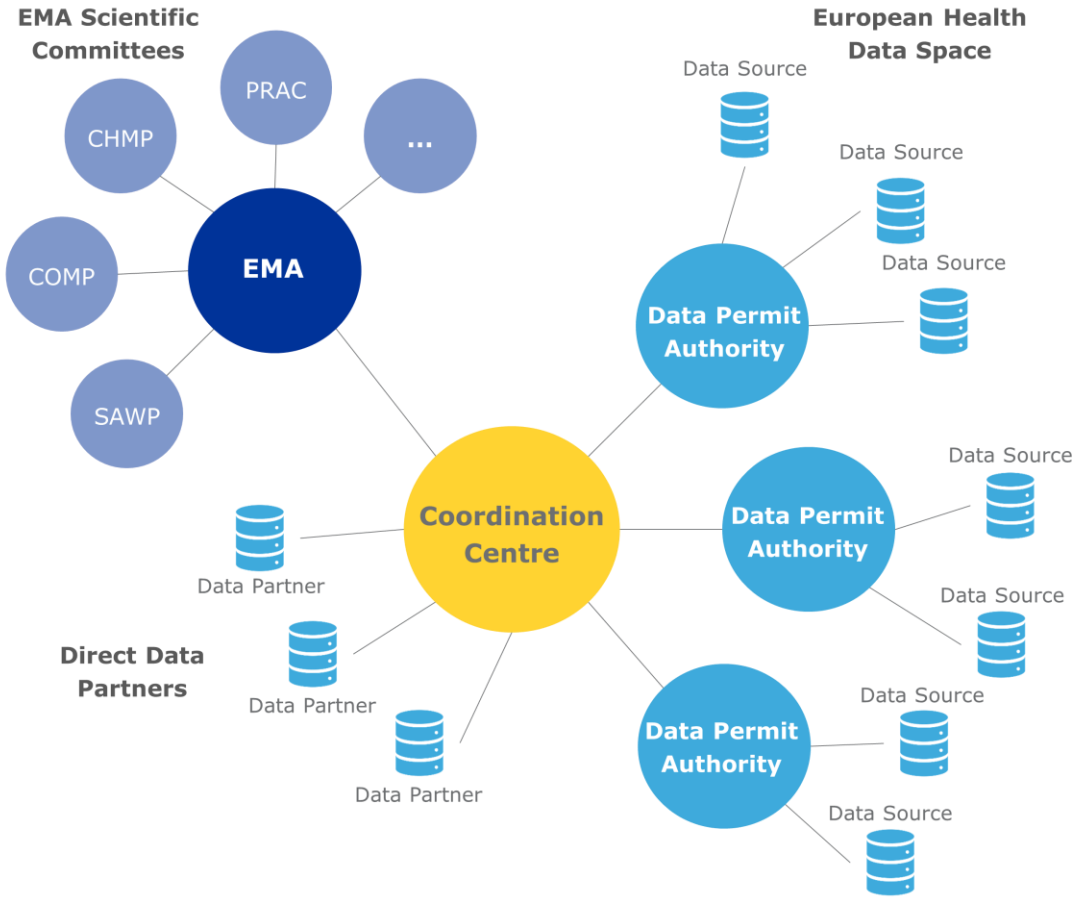
To establish and maintain a framework supporting better decisionmaking throughout the lifecycle of medicinal products with timely, valid and reliable evidence from real world healthcare.

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

Federated Network of Data

DARWIN EU® is a federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**



What type of analyses and studies will DARWIN EU® deliver?

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 cannot rely only on electronic health care databases, or which would require complex and/or novel methodological work

DARWIN EU® establishment and operational phases

		Phase I	Phase II	Phase III	Option I	Option II
Studies	**Off the shelf**	2	6	30	60	60
	Routine repeated	1	6	30	60	60
	Complex study	1	4	12	24	24
	Very complex	0	0	0	1	1
Data Partners (total)		10	20	30	40	40

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A highly needed paradigm shift for the fast delivery of reliable evidence for regulatory decision-making on the utilisation, safety and effectiveness of medicinal products throughout their lifecycle.

Not possible by simply scaling up the traditional approaches.

DARWIN EU® Coordination Centre

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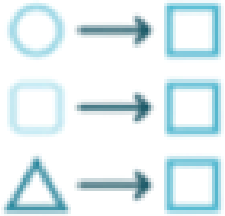
SYNAPSE
RESEARCH MANAGEMENT PARTNERS

IQVIA

The Hyve

ODYSSEUS
DATA SERVICES INC

Changing the Paradigm



Interoperability

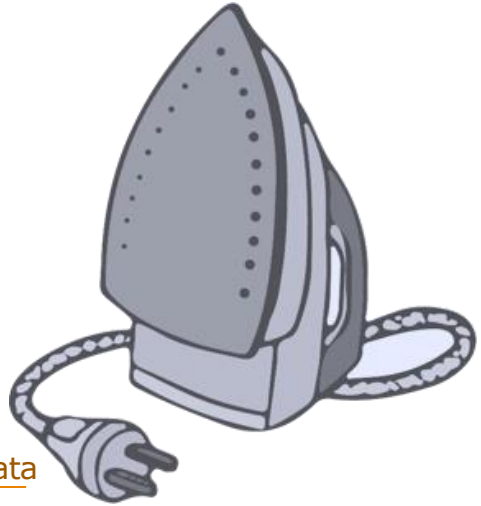
Common Analytics

Data

Requirements to Scale up Real World Evidence Generation

Improving Interoperability

Analytical method



Link to data

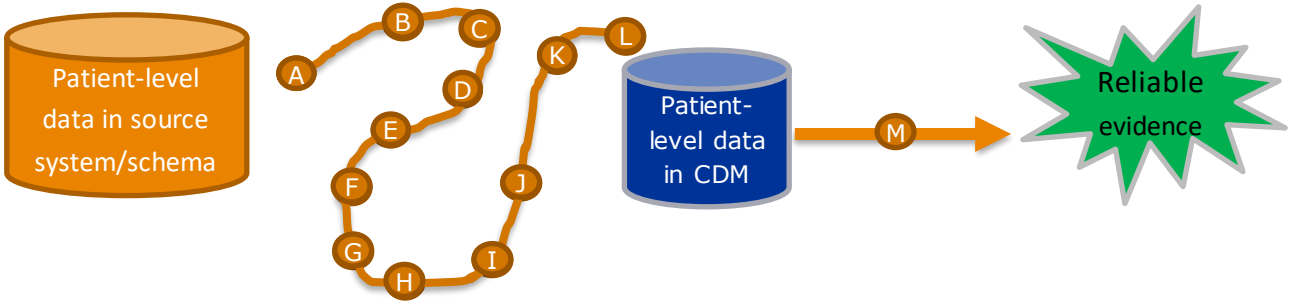
The structure…

The language…

110V, 120V, 127V, 220V, 230V, 204V, …

Generating Reliable Evidence using the OMOP Common Data Model

We need to make studies repeatable, reproducible, replicable, generalisable, and robust



A Common Data Model enables standardised analytics to generate reliable evidence.

www.ohdsi.org

Standardising the analytics

A catalogue of open source standardised analytics is developed to support ”all” 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!

For more information see:
https://darwin-eu.org/index.php/methods/standardised-analytics

Operating a high-quality Data Network

- Selection of data partners
  1) Prioritisation of already converted data sources
  2) Potentially mapping highly valued data sources

- All data sources go through an onboarding process approved by EMA including quality control steps

See https://darwin-eu.org/index.php/data/how-to-join-the-network for more information.

Data Partners – Phase I

UK

1. Clinical Practice Research Datalink (CPRD GOLD)

Belgium

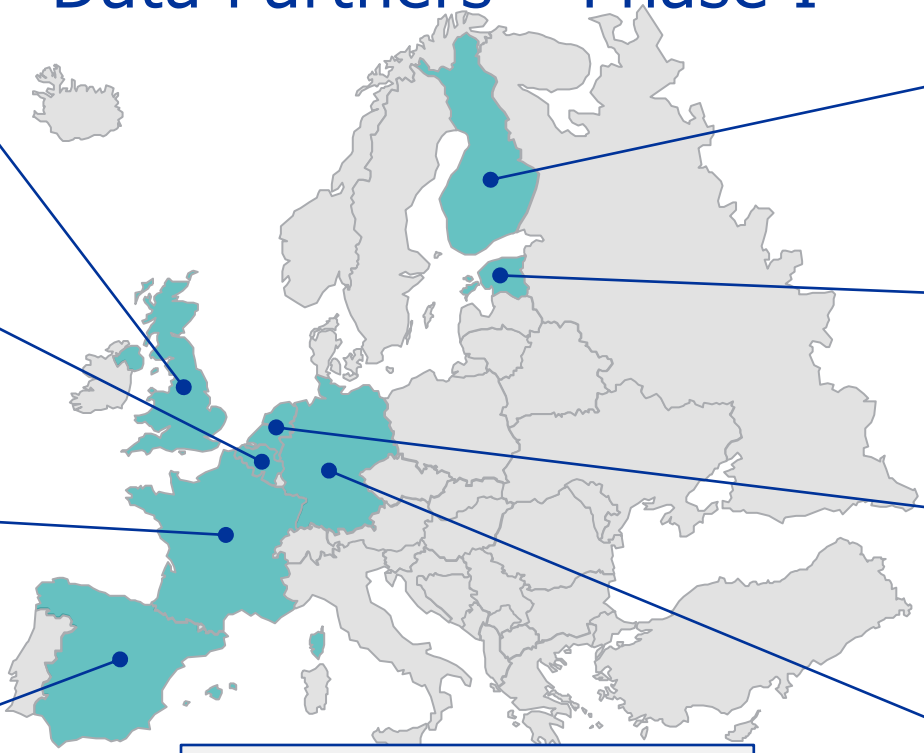
2. IQVIA Belgium Longitudinal Patient Data

France

3. Bordeaux University Hospital

Spain

4. IDIAPJGol
5. Parc Salut Mar Barcelona, Hospital del Mar (IMIM)



~26 million active patients

Finland

6. Auria Clinical Informatics at Hospital District of Southwest Finland (HDSF)

Estonia

7. University of Tartu (Biobank)

Netherlands

8. Integrated Primary Care Information
9. Netherlands Comprehensive Cancer Organisation

Germany

10. IQVIA Germany Disease Analyser

Currently **onboarding Phase II DPs and selecting Phase III data partners** via **open call for expression of interest**

Selection of Ongoing studies

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

Background all-cause **mortality rates in patients with severe asthma aged ≥12 years** old [EUPAS103936]

CHMP
Complex

EHDS coagulopathy of COVID-19

EC/EHDS
Complex

Effectiveness of **COVID-19** vaccines against severe COVID-19 and post-acute outcomes of SARS-CoV-2 infection.

ECDC/VMP
Complex

Drug utilisation study on co-prescribing of **endothelin receptor antagonists** (ERAs) and **phosphodiesterate-5 inhibitors** (PDE-5is) in pulmonary arterial hypertension. [EUPAS106052]

CHMP
OTS

Multiple myeloma: patient characterisation, treatments and survival in the period 2012-2022 [EUPAS105033]

HTA/Payers
OTS

Drug utilisation study of **medicines with prokinetic properties** in children and adults diagnosed with gastroparesis

NCA
OTS

Naloxone use in treatment of opioid overdose. [EUPAS105644]

CHMP
OTS

Drug utilisation study of prescription **opioids**. [EUPAS105641]

PRAC
OTS

OTS = off-the-shelf study

Closing remarks

- RWE use is being enabled and established across regulatory use cases, informing regulatory decision making on medicines across their lifecycle
- Current focus on scale-up: Data Partners, studies, pilot use cases and developing standard analytical pipelines
- Higher study volume meeting the demand and shorter timelines being initiated in Phase III

Data Analysis and Real World Interrogation Network (DARWIN EU) | European Medicines Agency (europa.eu)

Coordination Centre website: www.darwin-eu.org

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