DARWIN EU (Data Analytics and Real World Interrogation Network)

PCWP and HCPWP Data workshop 23 September 2020

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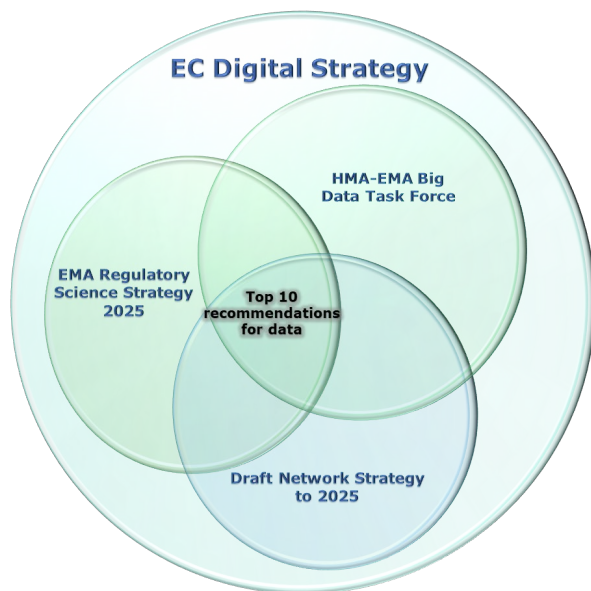Co-chair HMA-EMA Big Data Steering Group

Content

DARWIN EU:

- Mandate
- What it is
  - The importance of a name!
- Benefits
- How it can work
- Interface with the European Health Data Space
- Funding and milestones

Conclusion

# Mandate: EMA and Network strategies both include DARWIN

Big Data Task Force – Priority number 1:

Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data **A**nalysis **R**eal **W**orld **I**nterrogation **N**etwork (DARWIN)**)**

Making best use of big data for public health: publication of the Big Data Steering Group workplan for 2020-21

What DARWIN is – type of data

Real-World Data (RWD): routinely collected data relating to patient health status or the delivery of health care from a variety of sources other than traditional clinical trials


Real-World Evidence (RWE): information derived from analysis of real-world data

3
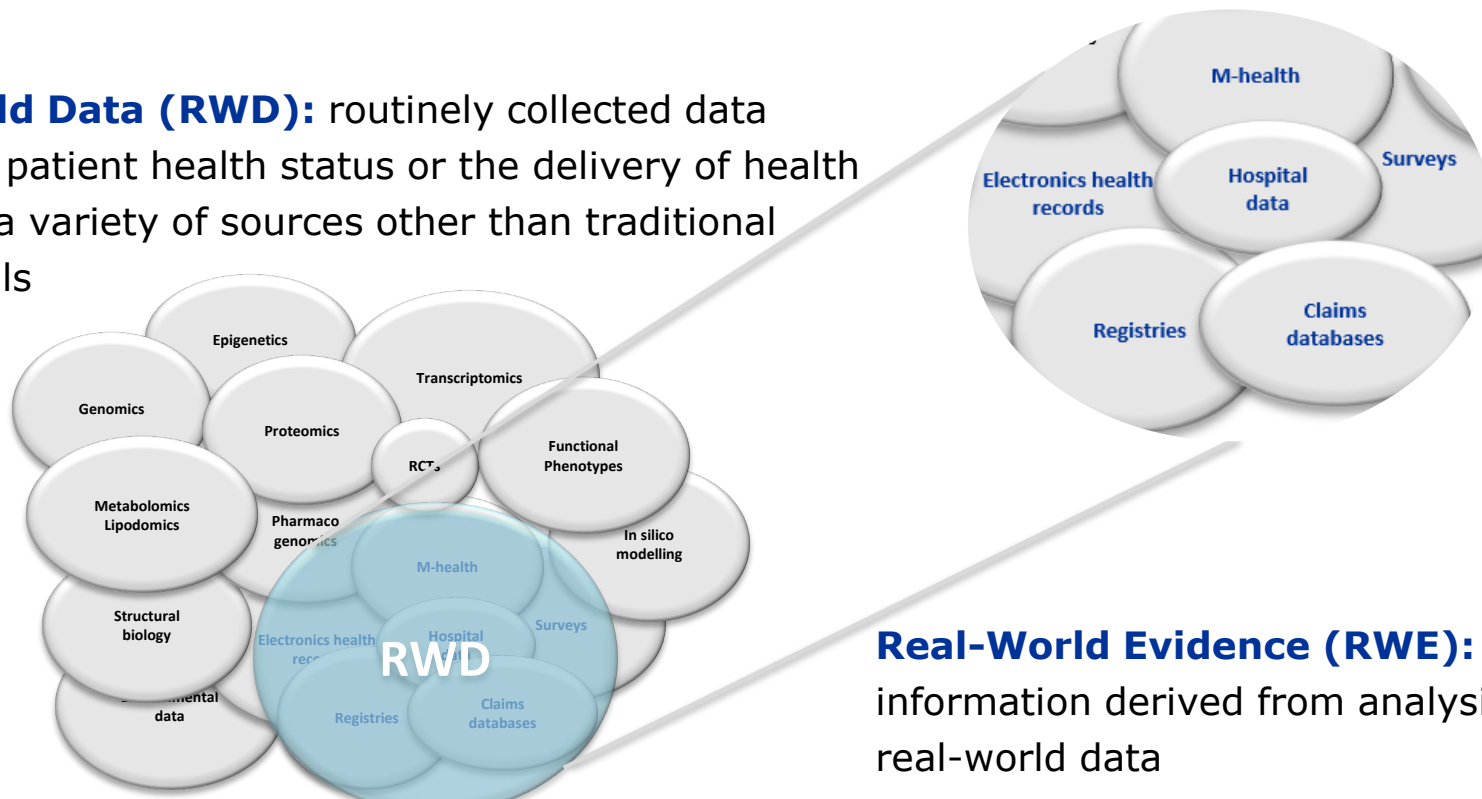
DARWIN is a network

Main characteristics

- Distributed network for fast access and analysis
- Federated data access
  - Data stays local
  - Queried remotely
  - Includes use of a common data model for fast analysis
- Third party coordination centre
- Data exchanged within the network is anonymous
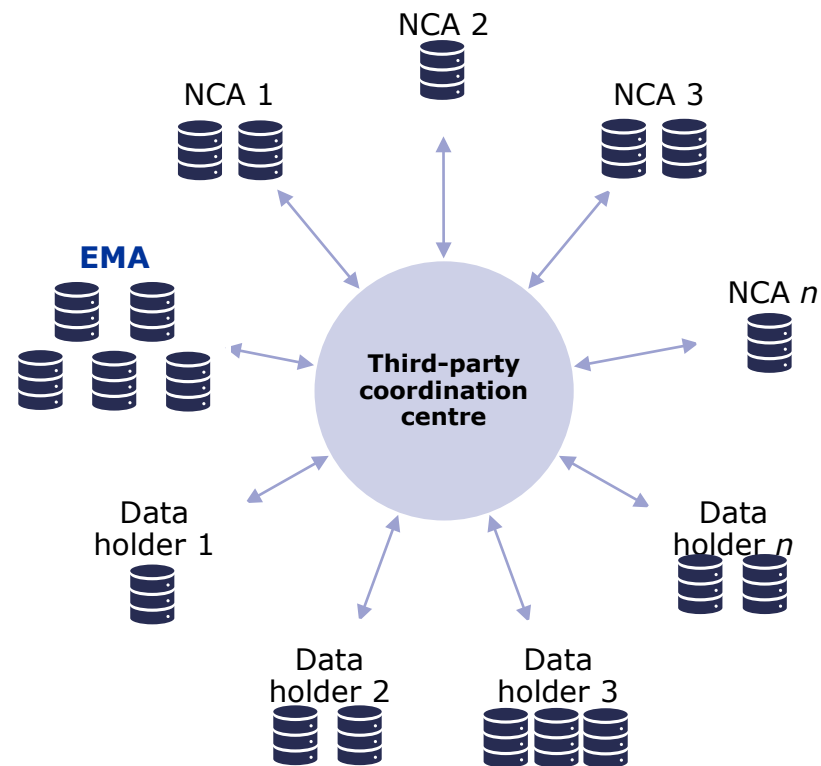
What's in a name?: DARWIN **EU**

- DARWIN is a common name used for many projects including in the field of healthcare data

- Application made for a figurative trademark (drawing + words) with a distinctive logo **'DARWIN EU'**

DARWIN EU: Benefits

- Principal benefits relate to the national and EU regulation of medicines:

  - Drug development – disease epidemiology, unmet need, historical controls, planning

  - Authorisation – contribution to BR, controls, extrapolation to general & special populations

  - On market – benefit risk monitoring, extension of indication

- Additional benefits will come as EU partners participate and access the platform

  - European Commission – delivers on European Health Data Space

  - Healthcare professionals - to support health policy and delivery of healthcare systems

  - HTA bodies and payers to support better quality decisions on cost-effectiveness

  - EU patients - faster access to innovative medicines and safe and effective use

# Regulatory use cases are numerous
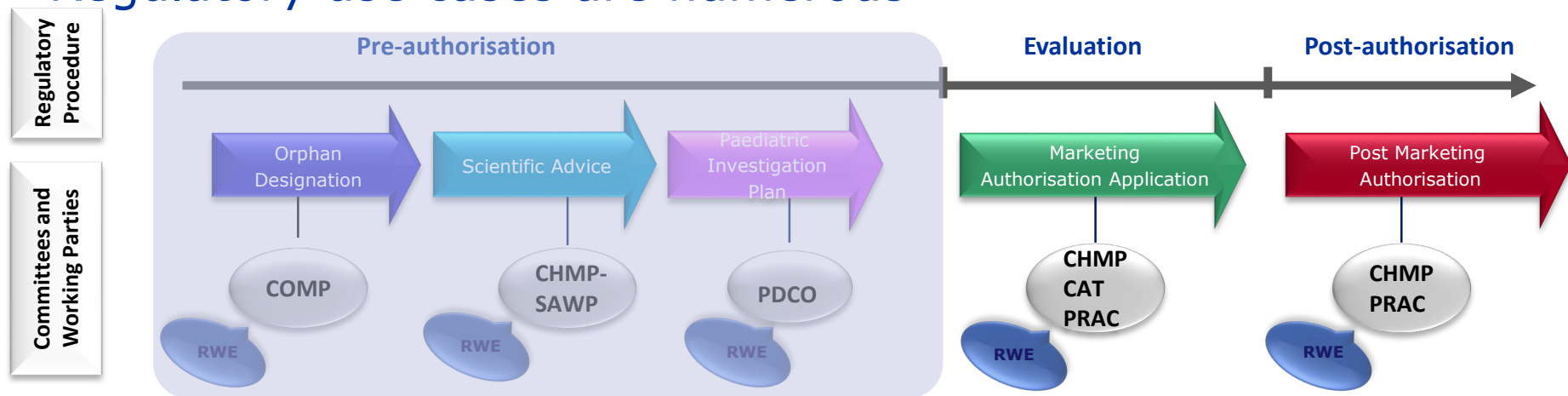
- COMP – Use RWE to check prevalence of diseases to support orphan designation
- SAWP – Advising companies on use of RWE in product development based on feasibility and relevance of studies
- PDCO – Use of RWE to identify needs in children to support waivers and deferrals

Regulatory use cases are numerous
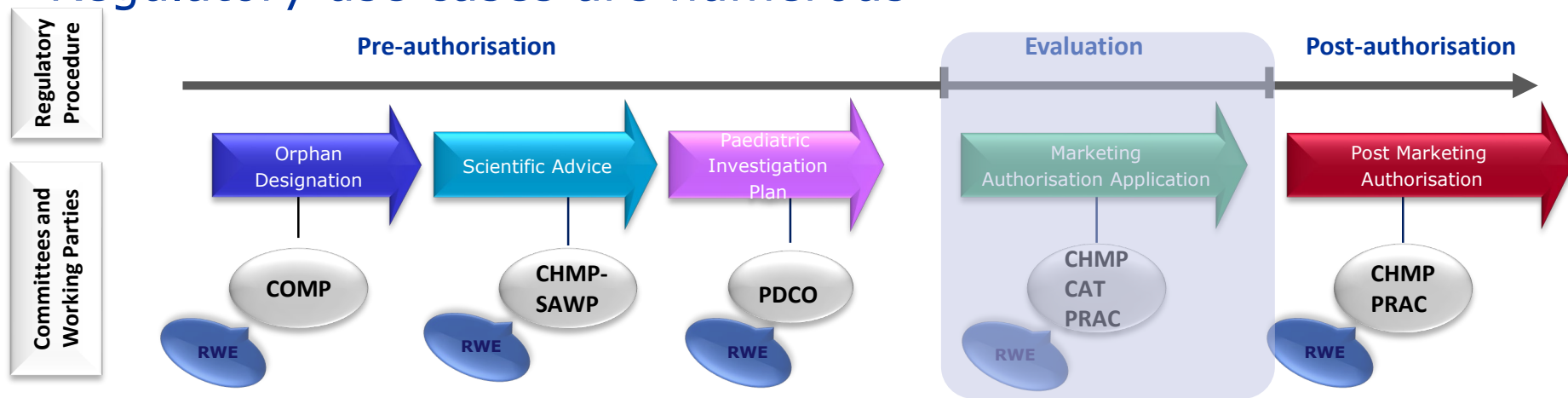
- CHMP and CAT – External controls and RWE to supplement, validate and contextualise clinical trial results
  - E.g. representativeness of patients and the standard of care,…
- CHMP and PRAC – Use of RWE to inform decision-making on Risk Management Plan

Regulatory use cases are numerous
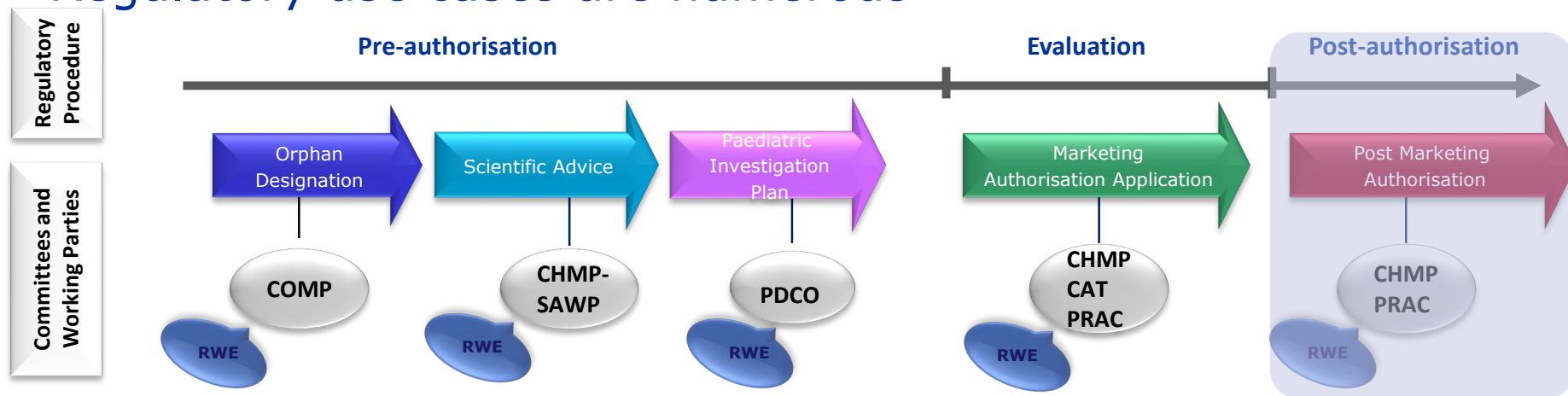
- CHMP and PRAC

 - Assessing benefit and risks on the market when imposing studies on specific companies is not appropriate (established substances, non-product specific issues)

  - Safety and effectiveness in special populations and off label use

  - Characterisation of safety profile and monitor effectiveness of risk minimisation measures

  - Support estimates of medicines demand to identify possible shortages

COVID-19 and RWE: better preparedness for future health crises

The informed response to the pandemic brought an unprecedent interest and scrutiny in RWE

- Need to focus on strengthening all steps from data collection to assessment of evidence

- Need for timely answers
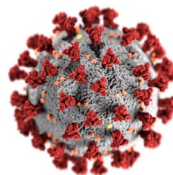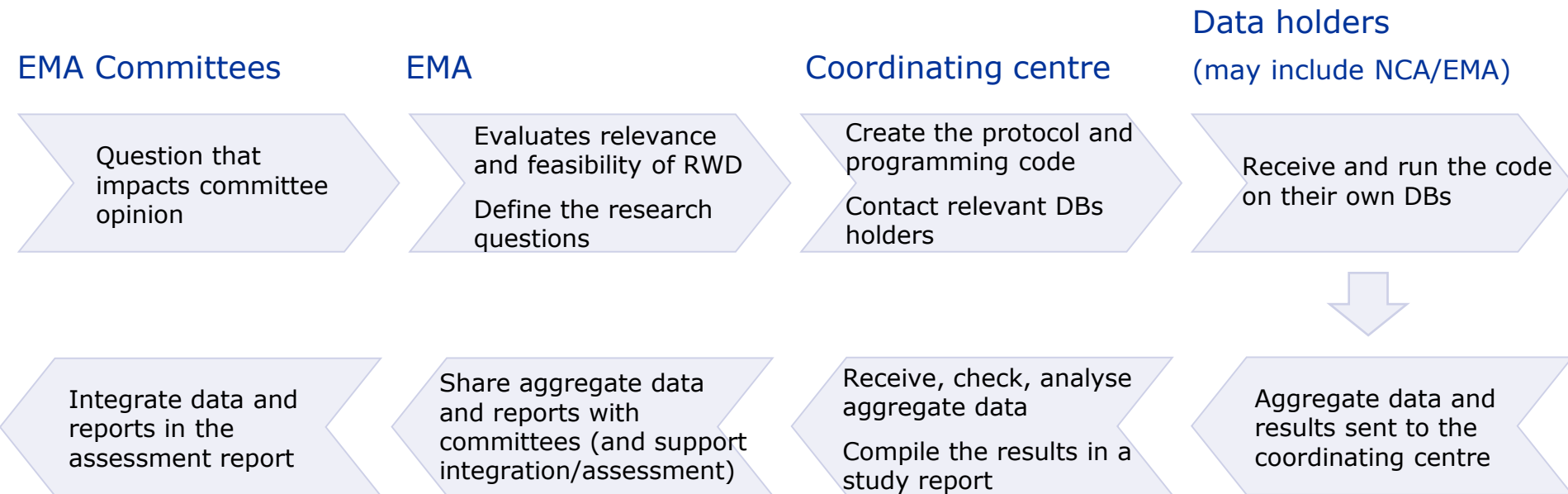
DARWIN EU will support future crisis responses with an operational infrastructure for conducting rapid studies

- EU wide network of data sources identified and characterised

- Quality framework and continuous quality monitoring

- Governance: prespecified agreements, processes and methods

- Availability of analytical tools with routine analyses already pre-specified

How the DARWIN network might operate: EMA committee initiates an analysis

EMA Committees

Question that impacts committee opinion

Integrate data and reports in the assessment report

EMA

Evaluates relevance and feasibility of RWD

Define the research questions

Share aggregate data and reports with committees (and support integration/assessment)

Coordinating centre

Create the protocol and programming code

Contact relevant DBs holders

Receive, check, analyse aggregate data

Compile the results in a study report

Data holders
(may include NCA/EMA)

Receive and run the code on their own DBs

Aggregate data and results sent to the coordinating centre

EC digital strategy and the European Health Data Space (EHDS)

European Commission

THE EUROPEAN DATA STRATEGY

SHAPING EUROPE'S DIGITAL FUTURE

EHDS promotes health data exchange and supports research and innovation on new preventive treatments, medicines, medical devices

- Access of citizens to health data and portability of data

- Access of regulators to health data for policy making and regulatory purposes

- Study on regulatory gaps in cross border digital healthcare (eHealth, AI in health)

- Joint Action to provide rules, governance structures, guidelines, data quality framework, infrastructure

12

Evolution: from early delivery to fully leverage of the EHDS

DARWIN EU **2023**

- Coalition of existing datasets with medicines regulators

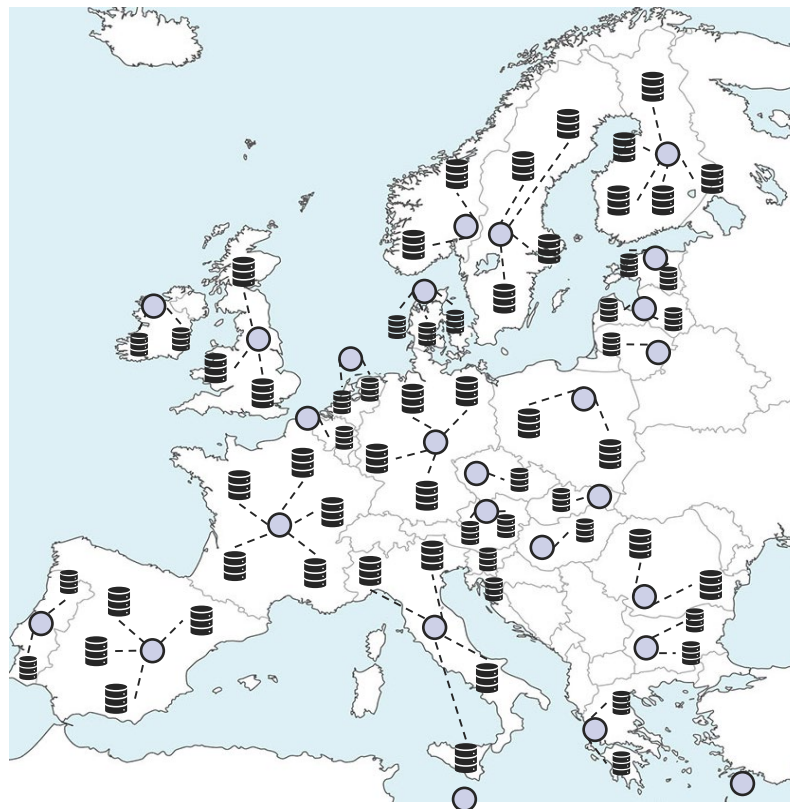- Federated access to data holders
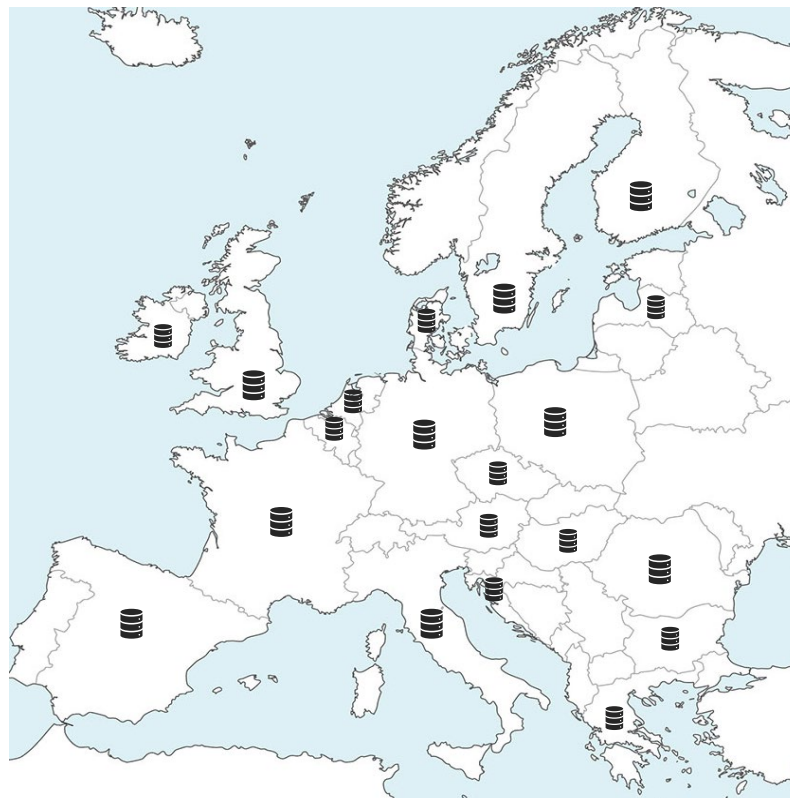
Evolution: from early delivery to fully leverage of the EHDS

DARWIN EU **evolution**

- Node in the EHDS

- Access including Data Permit
  Authorities (DPerA)

DARWIN EU will evolve to
fully embrace the EHDS

How might DARWIN EU be funding

Project (2021-2023) EU Funding	• **Infrastructure and governance**: funding anticipated over 3 years through EU4Health Programme starting 2021
	• **Real world data methodologies +/- capacity building**: anticipated through Horizon Europe starting 2021
Maintenance (2023 onwards) Revised EMA fee regulation	• Cover both maintenance and evolution • Maintain infrastructure and governance • Data maintained at high quality, structured and available for analysis • Funding of routine and bespoke analyses to meet the network needs for RWE

Possible project milestones

	2020		2021				2022				2023	2024
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
Agree business case		◆										
Agree project funding			◆									
Establish project and project board			◆									
Start building IT and governance			◆									
Prepare change management							◆					
Revised fees regulation applied											◆ To be confirmed	
DARWIN EU version 1											◆ To be confirmed	
DARWIN EU version 2												◆ To be confirmed

DARWIN RWE services to support regulatory decisions from 2023

Conclusions

- DARWIN EU is priority recommendation on Big Data – supported by stakeholders for Network Strategy to 2025

- DARWIN EU can deliver for better medicines regulation *and* be early deliverable for European Health Data Space

- DARWIN EU requires EU project funding and maintenance should be based on EMA fees to ensure sustainability long-term

- Building and operating DARWIN EU will require the involvement of EU patient and healthcare professional organisations

  DARWIN EU will strengthen regulatory decisions and benefit public health.

Thank you

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Thanks……in particular

The members of the Big Data Steering Group

Commission colleagues (units B3, B4 and B5)

EMA colleagues, including: Jolanta Palepsaitiene, Gianmario Candore, Francois Domergue, Loris Piccolo