Coordination Centre

DARWIN EU®: a transformation in the use of real-world health data for regulatory purpose in the EU

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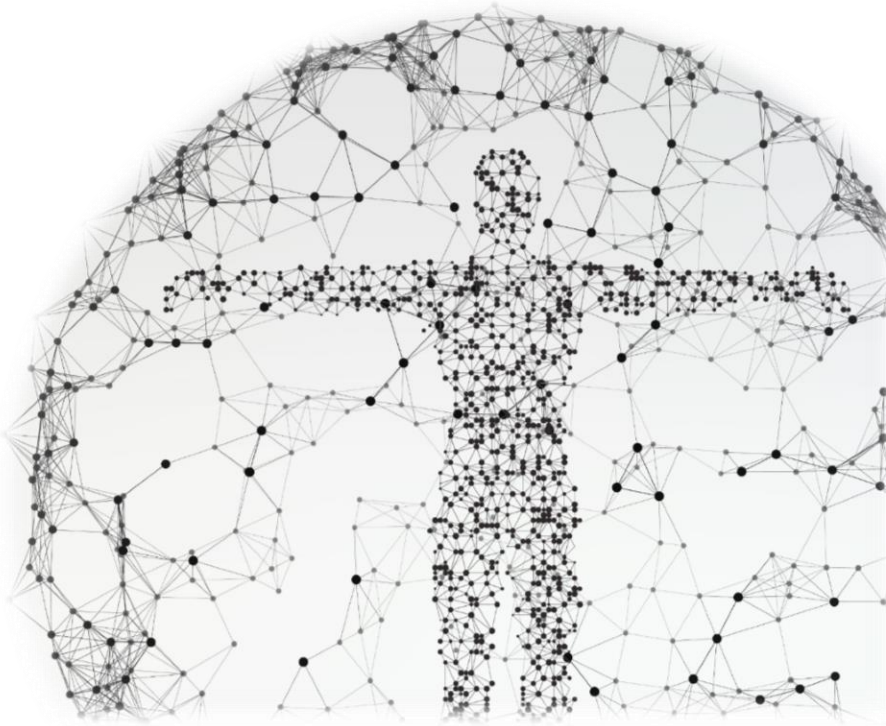
GetReal Symposium



Disclosure

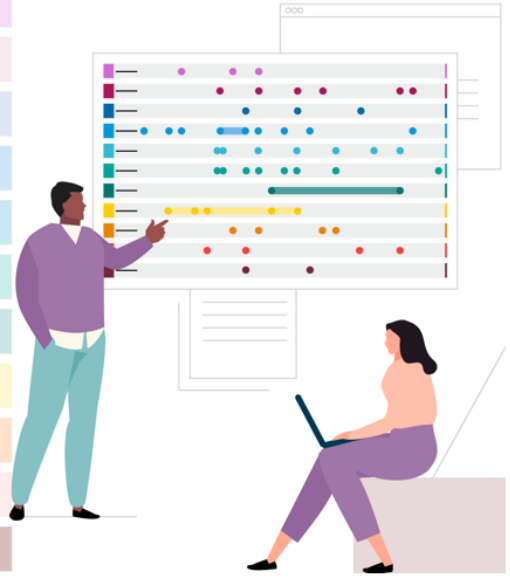
This presentation represents the views of the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the European Medicines Agency or the European Medicines Regulatory Network.

Coordination Centre

Data Analysis and Real World Interrogation Network (DARWIN EU®):

A paradigm shift for the use of real-world health data for regulatory purpose in the EU

- 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



Big Data Task Force 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:

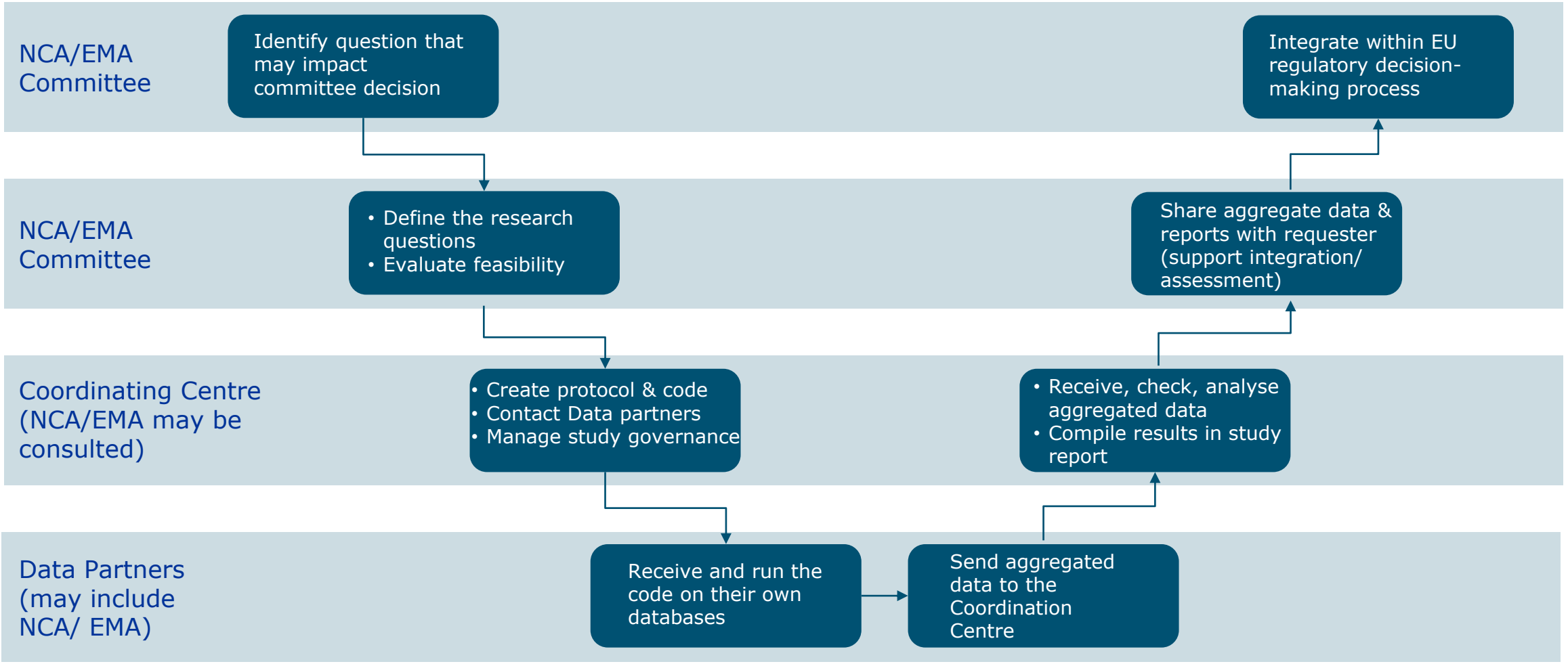
1) To establish and maintain a continually enlarging network of accessible observational data sources
2) To execute all steps of high quality non-interventional studies with the network
3) To make the study results available to the EU Regulatory network to support decision-making

Budget and expected 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/Options	Phase I	Phase II	Phase III	Option 1	Option2
Estimated budget (in million EURO)	**4M**	**8M**	**8M**	**16M**	**16M**
Routine repeated Analysis	At least 1 study	At least 6 studies	At least 30 studies	At least 60 studies	At least 60 studies
Off-the-shelf Study	At least 2 studies	At least 6 studies	At least 30 studies	At least 60 studies	At least 60 studies
Complex Study	1	4	At least 12 studies	At least 24 studies	At least 24 studies
Very complex Study	0	0	0	At least 1 study	At least 1 study

What is the DARWIN EU® process for conducting studies?



Setting up the DARWIN EU® Coordination Centre

DARWIN EU® Coordination Centre

Executive Director
Prof. Peter Rijnbeek
Head of the Department of Medical Informatics
Erasmus MC

Deputy Director
Prof. Daniel Prieto Alhambra
Erasmus MC, Oxford University

Deputy Director
Associate Prof. Katia Verhamme
Erasmus MC

Contractor

Erasmus MC
Universitair Medisch Centrum Rotterdam

Sub-contractors

University of Oxford

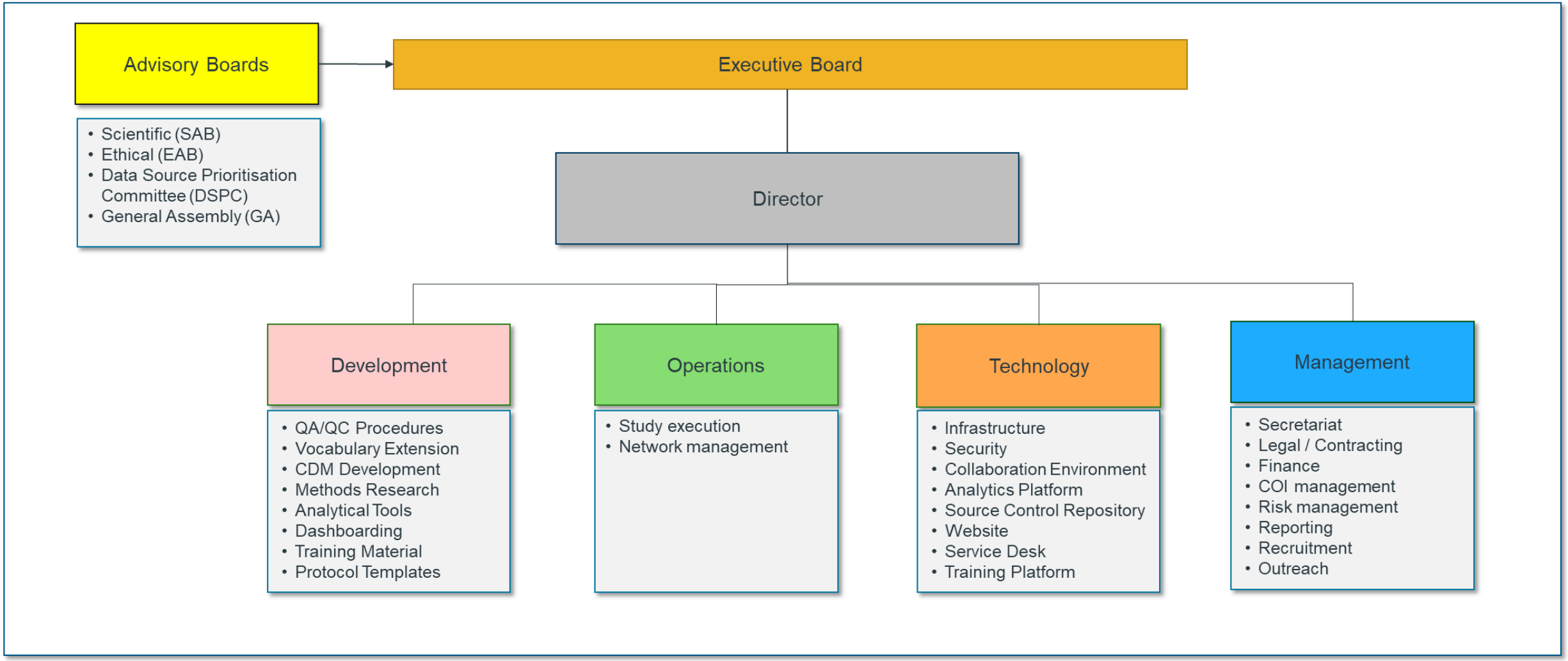
SYNAPSE
RESEARCH MANAGEMENT PARTNERS

IQVIA

The Hyve

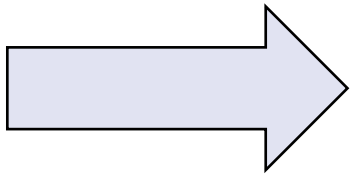
ODYSSEUS
DATA SERVICES INC

Establishment and Evolution of the Coordination Centre



DARWIN EU® Implementing a paradigm shift

- 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
- A long-term investment needed to significantly scale up the number of studies on more databases and improve public health.



Not possible by simply scaling up the traditional approaches.

Changing the Paradigm

Research Memory

Interoperability

Community

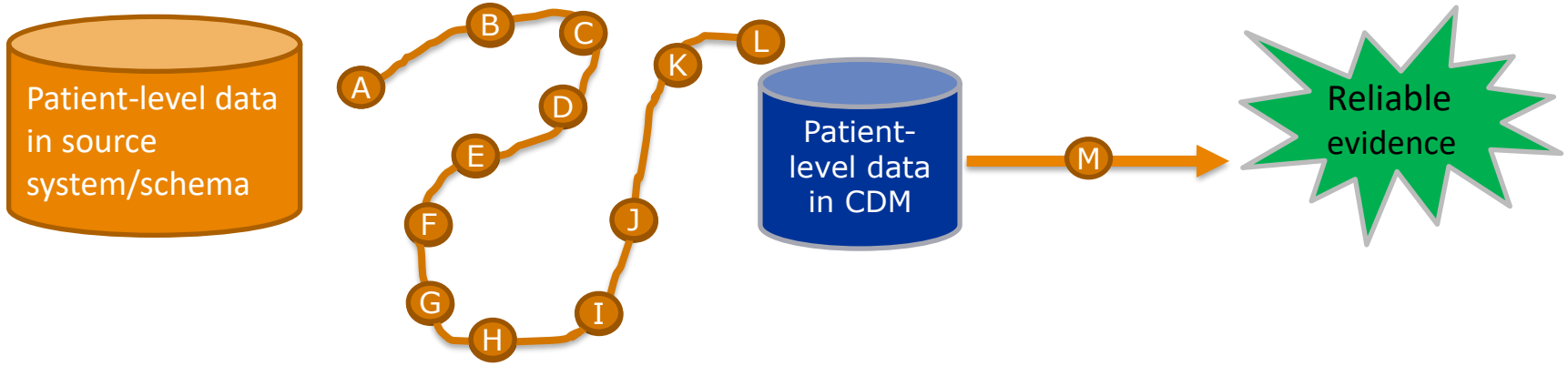
Common Analytics

Improving interoperability of data

- Increasing productivity to an industrial level requires the automation of the analytical processes, which in turn cannot be done without a rigorous standard representation of the data.
- Full interoperability of the data is needed with respect to structure (syntactic interoperability) and coding systems (semantic interoperability) by using a Common Data Model (CDM)

Generating Reliable Evidence using a Common Data Model

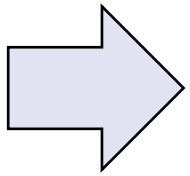
We need to make studies repeatable, reproducible, replicable, generalisable, and robust



A Common Data Model will enable standardised analytics to generate reliable evidence.

Standardising the analytics

- A catalogue of open source standardised analytics is needed to support ”all” regulatory decision-making on the utilisation, safety and effectiveness of medicinal products



Will require alignment on the priority and choice of the analytical methods, and the standardised output!

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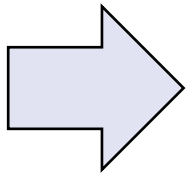

Will require alignment on the priority and choice of the analytical methods, and the standardised output!

- Development will be driven by initial studies taking different complexity levels into account.

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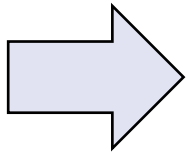

Catalogue of Standard Analyses

Operating a high-quality Data Network

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

First 10 Data Partners are onboarded

- Open Call for Expression of Interest

- All data sources will go through a quality control process approved by EMA

Research Memory

Implementation roadmap

Phase I - 2022

- Start running pilot studies to support EMA committees – **first benefits delivered**
  - Coordination Centre set-up
  - Data Protection Impact Assessment
  - Start recruiting and onboarding data partners
  - Pilot with the EHDS model and existing Data Permit Authorities
- Consultation of stakeholders

Phase II - 2023

- Support the majority of Committees in their decision-making with reliable RWE by 2023

Phase III - 2024

Up scale delivery and capacity to routinely support the scientific evaluation work of EMA's scientific committees and NCAs by delivering studies and maintaining data sources.

Operation - 2025/2026

- DARWIN EU® to be fully operational and yearly evolves to meet the needs from the EU Regulatory Network
- **Integration with the EHDS**

More Information

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

For questions to the Coordination Centre, please contact: enquiries@darwin-eu.org

For regular updates on DARWIN EU® Subscribe to the Big Data Highlights newsletter by sending an email to: bigdata@ema.europa.eu

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HMA Heads of Medicines Agencies

EMA EUROPEAN MEDICINES AGENCY

BIG DATA

HIGHLIGHTS

Quarterly update on implementation activities of the HMA-EMA Big Data Steering Group workplan

Editorial

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INSIDE THIS ISSUE

Welcome to the first edition of the newsletter on Big Data which reports on the implementation of the HMA-EMA Big Data Steering Group workplan 2021-2023 and the data and digital pillar of the Network Strategy 2025.

The BDSG was established in May 2020 with the mandate to take forward and advise on implementation of the priority recommendations set out in the Big Data Task Force final report (phase two). The vision, set out by the Big Data Taskforce that guides delivery of the workplan is that:

> *by delivering a regulatory system able to integrate Big Data into its assessment and decision making, we can support the development of innovative treatments more quickly and optimise the safe and effective use of medicines.*
>
> **Big Data Task Force Final Report, Dec 2019**

Already in 2021, we have seen an impressive array of activities and outputs that support transformation to data-driven medicines regulation. These include the finalisation of the network's data standardisation strategy and a series of technical workshops covering standardisation, real-world data, artificial intelligence, veterinary data and real-world evidence. More details on the 2021 deliverables are included later in this newsletter.

Moving forward, we are excited to be able to share with you more regular updates on big data and the implementation of the BDSG workplan via this newsletter. We look forward to collaborating and leveraging the work of stakeholders to increase the utility of big data in medicines regulation.

The Big Data Steering Group welcomes your feedback and questions you may have by email at bigdata@ema.europa.eu .

We hope you find the Big Data Highlights informative!