Coordination Centre

Introduction of the DARWIN EU® Coordination Centre

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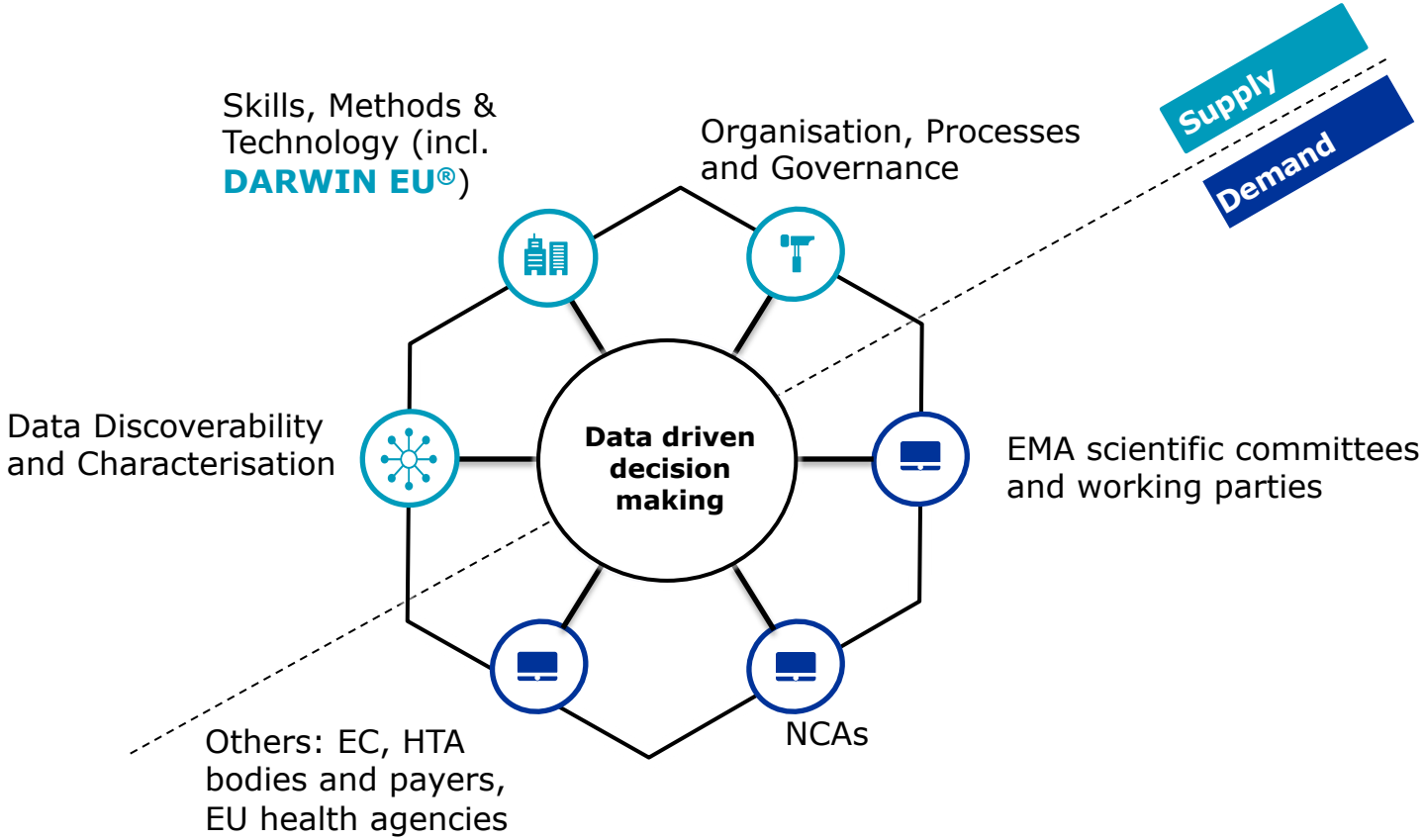
Executive Director

OHDSI Community Meeting Tuesday 2022-05-03

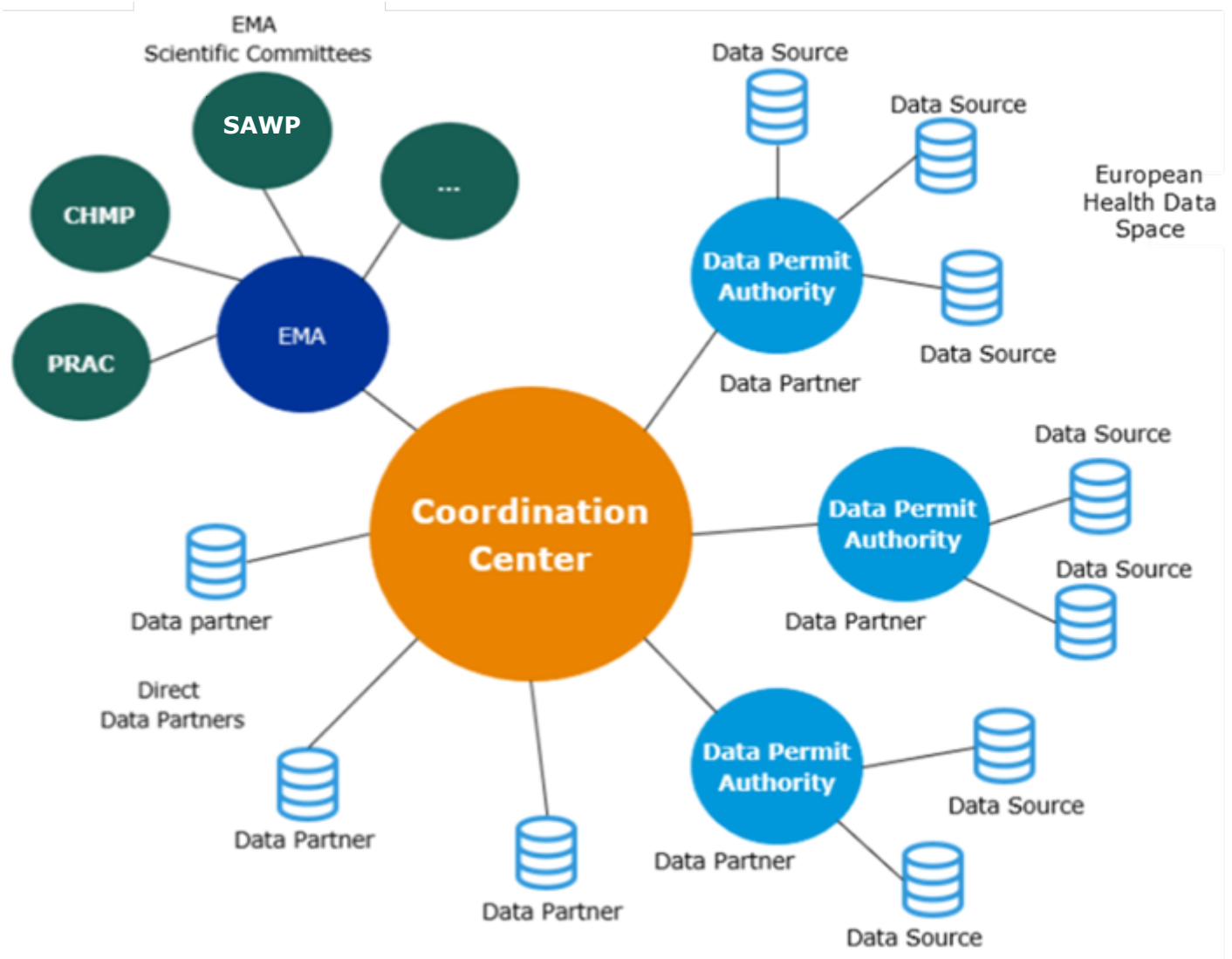
Disclosure

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.

How to increase the generation and use of RWE?



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**



FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of Common Data Model** (where applicable) to perform studies in a timely manner and increase consistency of results

What will DARWIN EU® do?

- Provide scientific expertise in formulating and executing studies and analyses
- Maintain a catalogue of known, relevant data holders, continually ensuring the discoverability & quality of data held by data holders
- Maintain & expand the federated network of data partners, assisting new data holders in conforming with required standards for usage in regulatory context
- Conduct scientific studies and analyses on behalf of the EMRN and EMA scientific committees
- Deliver training, governance, support of business services
- Enable the EMRN, EMA and the scientific committees to make use of the EHDS in the context of medicines regulation, acting as EHDS 'pathfinder'

What analyses and studies will DARWIN EU® deliver?

Category of observational analyses and studies	Description
Routine repeated analyses	Routine analyses based on a generic study protocol • Periodical estimation of drug utilisation • Safety monitoring of a medicinal product • Estimation of the incidence of a series of adverse events
Off-the-shelf studies	Studies for which a generic protocol is adapted to a research question • Estimate the prevalence, incidence or characteristics of exposures • Health outcomes • Describe population characteristics
Complex Studies	Studies requiring development or customisation of specific study designs, protocols and Statistical Analysis Plans (SAPs), with extensive collection or extraction of data • Etiological study measuring the strength and determinants of an association between an exposure and the occurrence of a health outcome considering sources of bias, potential confounding factors and effect modifiers
Very Complex Studies	Studies which cannot rely only on electronic health care databases, or which would require complex methodological work • Studies where it may be necessary to combine a diagnosis code with other data such as results of laboratory investigations, or studies requiring additional data collection

Budget and expected number of studies

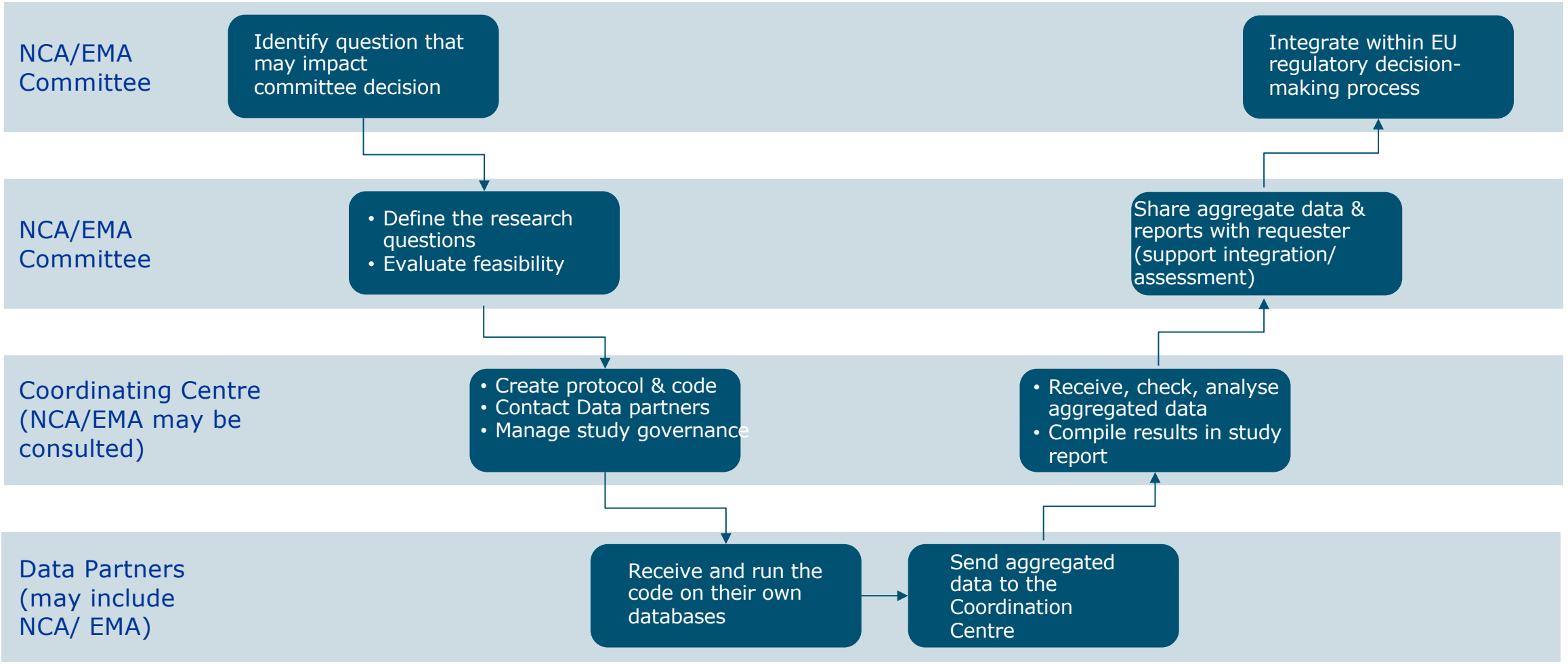
PHASE I Establishment – 1st year → PHASE II Establishment – 2nd year → PHASE III Operation – 1st year → Operation 2nd year → Operation 3rd year

	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

Establishment of Data Network

	Year 1	Year 2	Year 3	Year 4	Year 5
Data Partners On-Boarded	up to 10 additional	up to 10 additional	up to 10 additional	up to 10 additional	.
Data Partners Connected & to be Maintained		Up to 10 following the ones already on-boarded in Year 1	Up to 20 following the ones already on-boarded in Years 1 and 2	Up to 40 following the ones already on-boarded in Years 1, 2 and 3 (i.e 30), plus 10 estimated to be on-boarded the same year	40 following the ones already on-boarded in Years 1, 2, 3 and 4.

What is the DARWIN EU® process for conducting studies?



Which data sources will DARWIN EU® use?

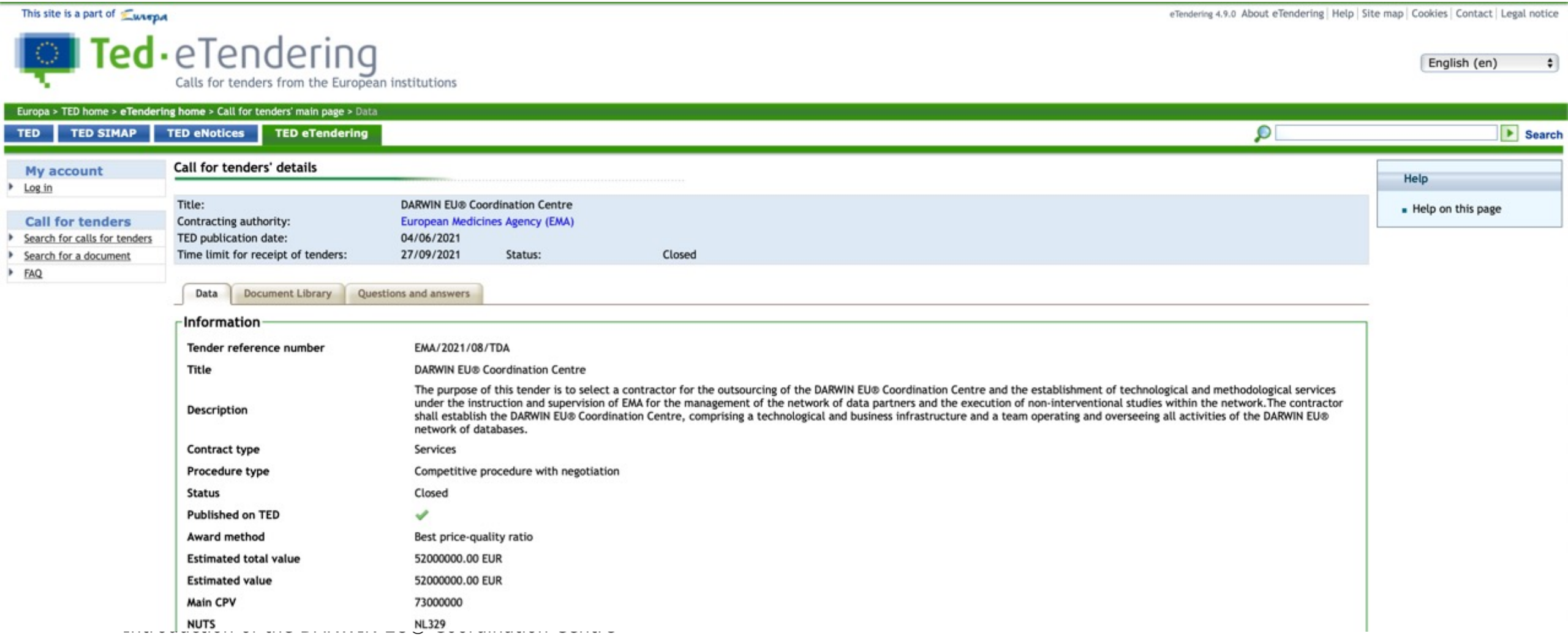
Data sources will be onboarded over time taking into account the following criteria:

- Data sources collecting health data routinely and representative of the different types of real-world data in terms of data elements, setting (primary & secondary care), population, origin (e.g. electronic health care records, claims)
- Data sources which collectively provide a broad geographical cover
- Data sources containing patient-level data with a unique patient identifier linking all records relating to a given patient
- Medicines prescribed or dispensed identifiable with quantities (e.g. doses, package size) and dates allowing to calculate cumulative doses and duration of use and linked to individual but unidentifiable patients
- Clinical events formally coded, with accurate dates and linked to individual but unidentifiable patients
- Data already converted or planned to be converted into a common data model

⇨ Selection criteria are currently under discussion

Setting up the DARWIN EU® Coordination Centre

Call for tenders: a two stage process from june 2021 – feb 2022



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Call for tenders' details

Title:	DARWIN EU® Coordination Centre		
Contracting authority:	European Medicines Agency (EMA)		
TED publication date:	04/06/2021		
Time limit for receipt of tenders:	27/09/2021	Status:	Closed

Data | Document Library | Questions and answers

Information

Tender reference number	EMA/2021/08/TDA
Title	DARWIN EU® Coordination Centre
Description	The purpose of this tender is to select a contractor for the outsourcing of the DARWIN EU® Coordination Centre and the establishment of technological and methodological services under the instruction and supervision of EMA for the management of the network of data partners and the execution of non-interventional studies within the network. The contractor shall establish the DARWIN EU® Coordination Centre, comprising a technological and business infrastructure and a team operating and overseeing all activities of the DARWIN EU® network of databases.
Contract type	Services
Procedure type	Competitive procedure with negotiation
Status	Closed
Published on TED	✔
Award method	Best price-quality ratio
Estimated total value	52000000.00 EUR
Estimated value	52000000.00 EUR
Main CPV	73000000
NUTS	NL329

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DARWIN EU® Coordination Centre

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Deputy Director
Associate Prof. Katia Verhamme
Erasmus MC

Contractor

Erasmus MC
Universitair Medisch Centrum Rotterdam

Sub-contractors

University of Oxford

SYNAPSE
RESEARCH MANAGEMENT PARTNERS

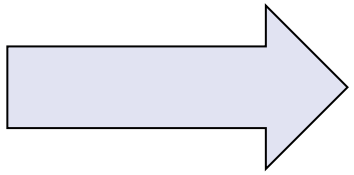
IQVIA

The Hyve

ODYSSEUS
DATA SERVICES INC

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.

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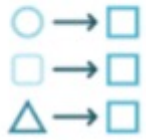
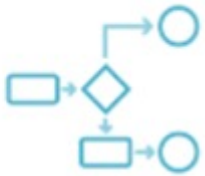
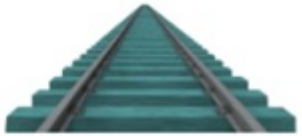
What is needed to facilitate observational studies at scale?



Data interoperability



Standardised analytics



Technical Infrastructure

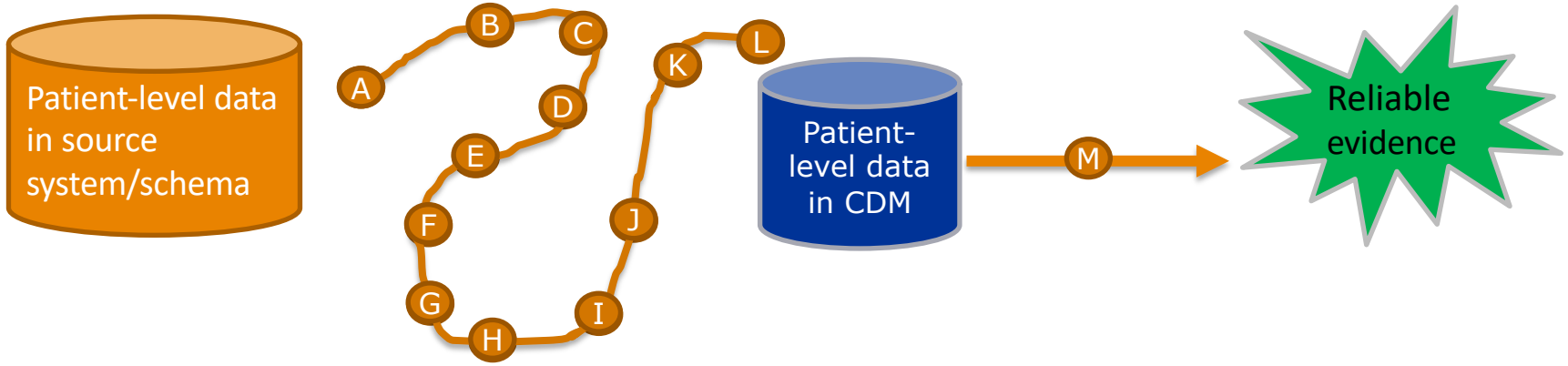
Data network

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

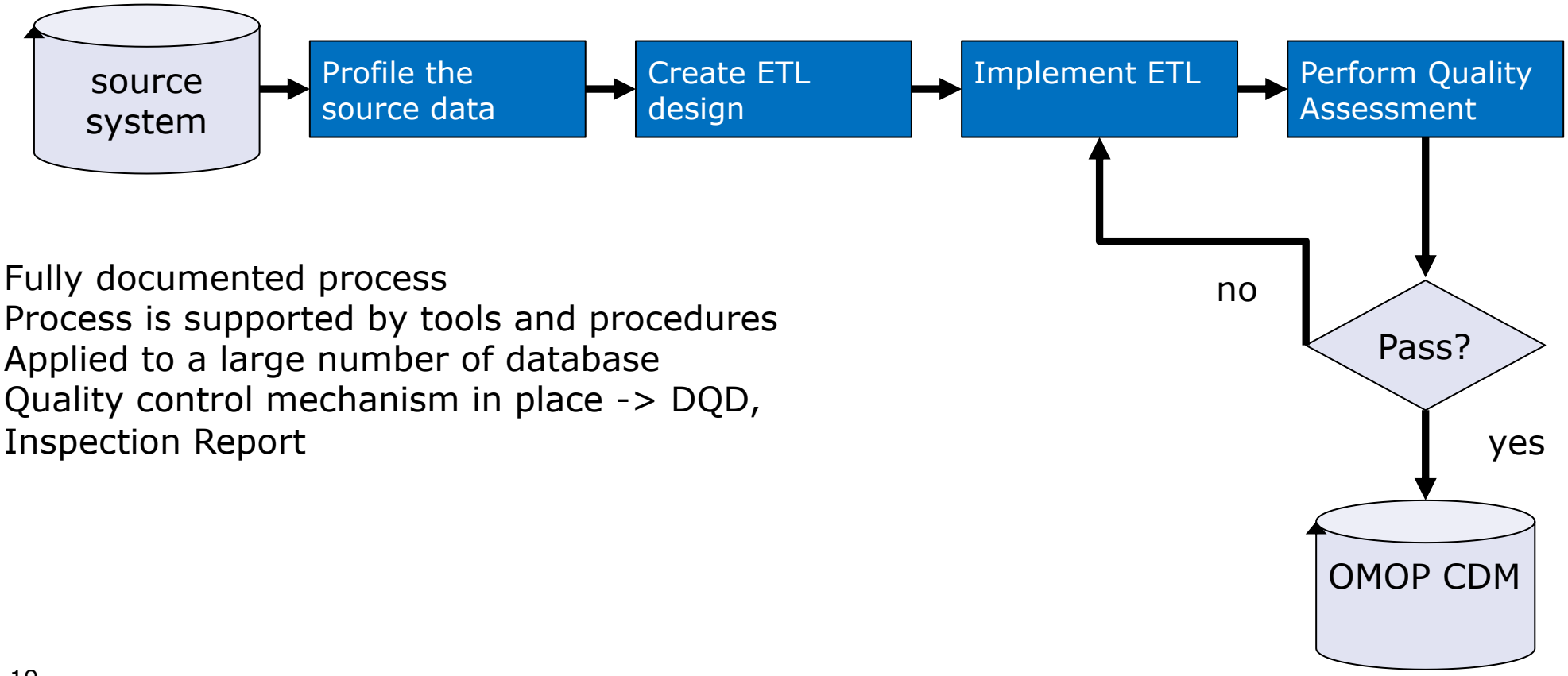


A Common Data Model will enable standardised analytics to generate reliable evidence.

The OMOP Common Data Model

- It is maintained by the Observational Health Data Sciences and Informatics (OHDSI) initiative with an active European Chapter (www.ohdsi-europe.org).
- Many tools are available for data standardisation, data quality, and data analysis.
- It is designed for federated querying and analytics, whereby applications are run locally by the data partners and only aggregated results are shared. This privacy-by-design approach is compliant with data protection requirements.
- It has been used in many observational studies including studies that informed regulatory decision-making.
- The European Health Data and Evidence Network (EHDEN) project is investing €17M private/public funding in standardising health data to the OMOP-CDM through the Innovative Medicines Initiative (www.ehden.eu).

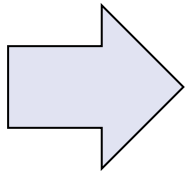
From Source Data to the OMOP CDM: Extraction Transform Load (ETL)



- Fully documented process
- Process is supported by tools and procedures
- Applied to a large number of database
- Quality control mechanism in place -> DQD, Inspection Report

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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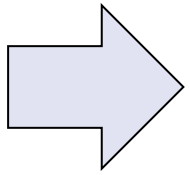


Will require alignment on the priority and choice of the analytical methods, and the standardised output!

- Development will be driven by initial studies taking different complexity levels into account.
- The standardised analytics will be based on available tools and methods developed in the OHDSI community.

Creating a strong technical infrastructure

Required components:

- Collaboration Space for CC and Study Teams
- Analytics Platform
- Study Execution Platform
- Training Platform
- Service Desk
- Source Control Repository
- DARWIN EU Website
- …

Will build on prior work

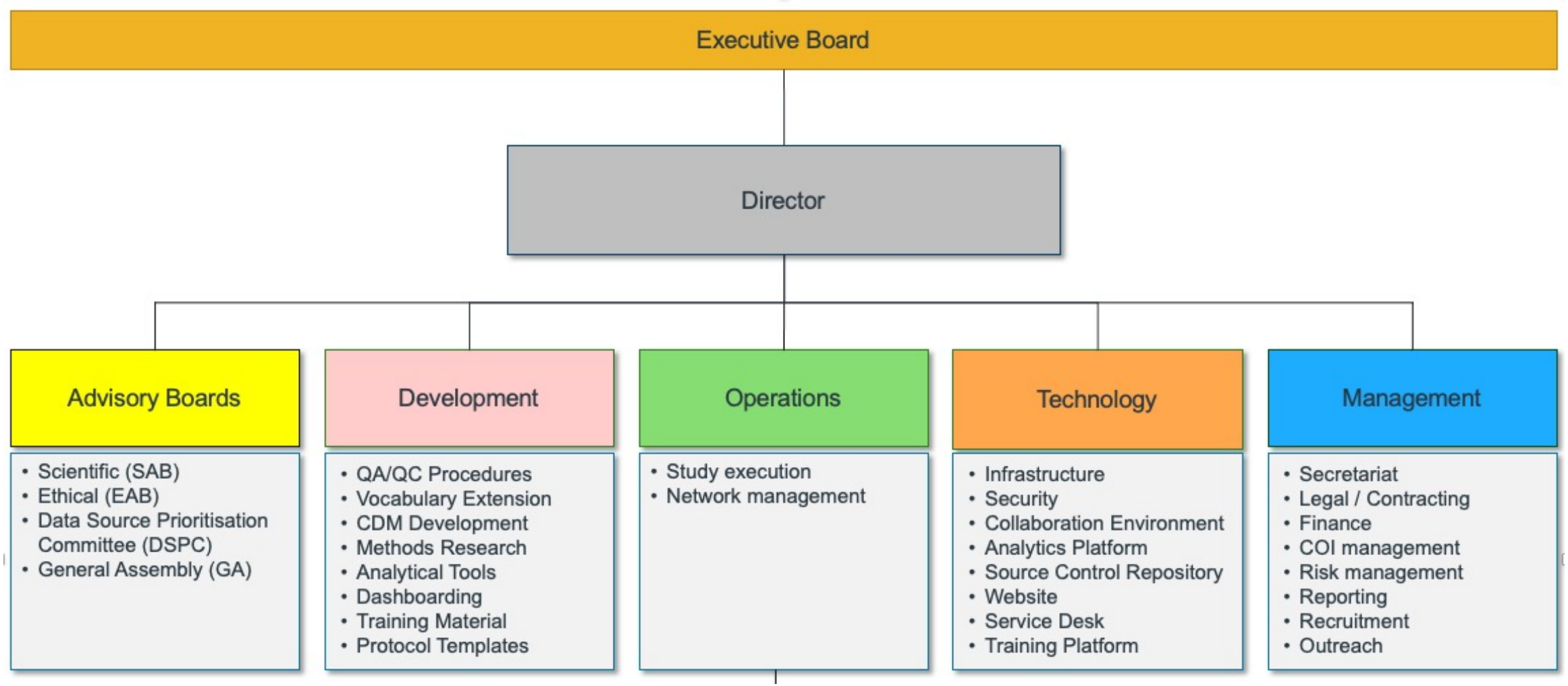
Will be developed using short sprints during the establishment phase

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 will go through a quality control process approved by EMA

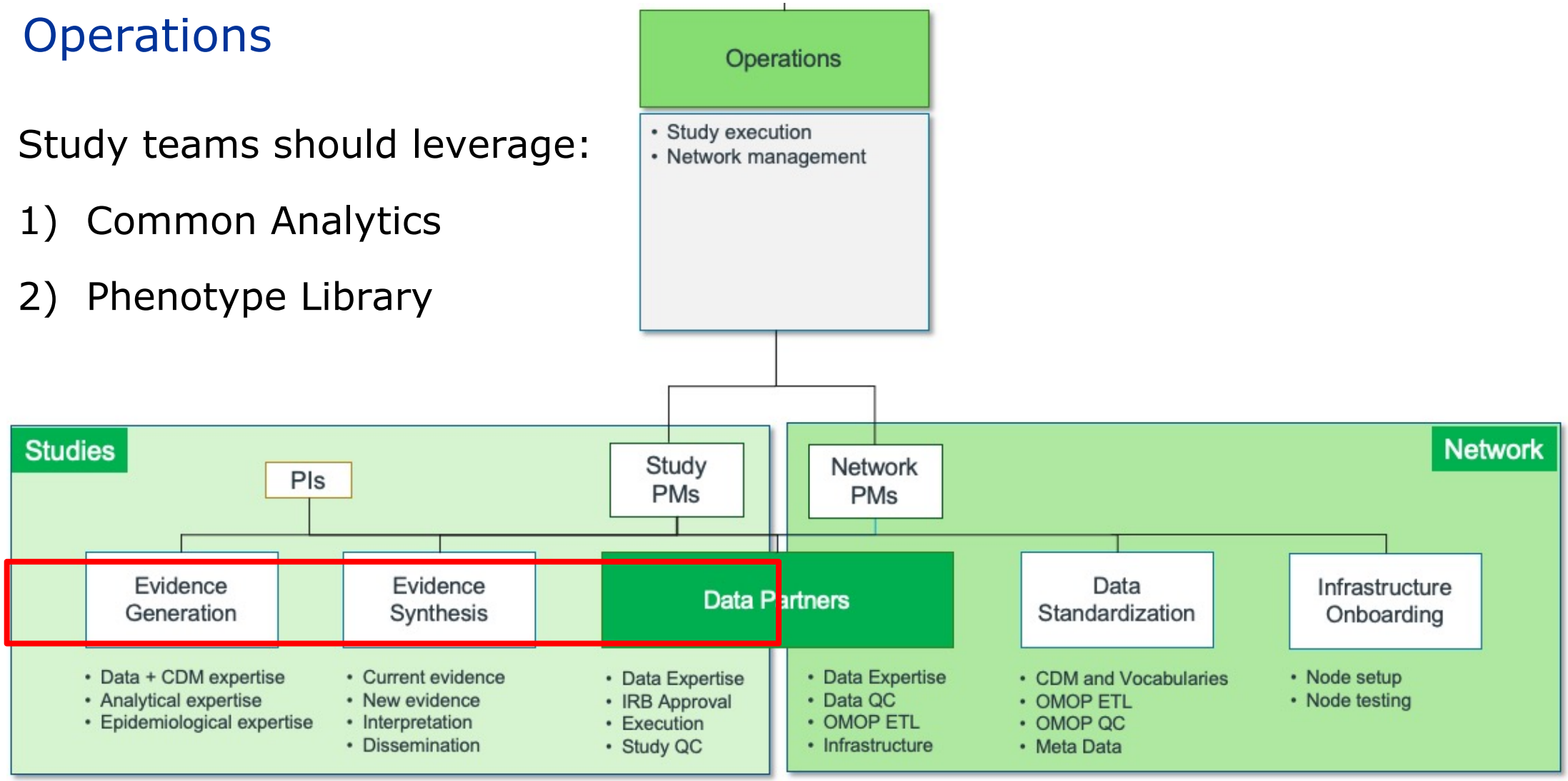
Establishment and Evolution of the Coordination Centre



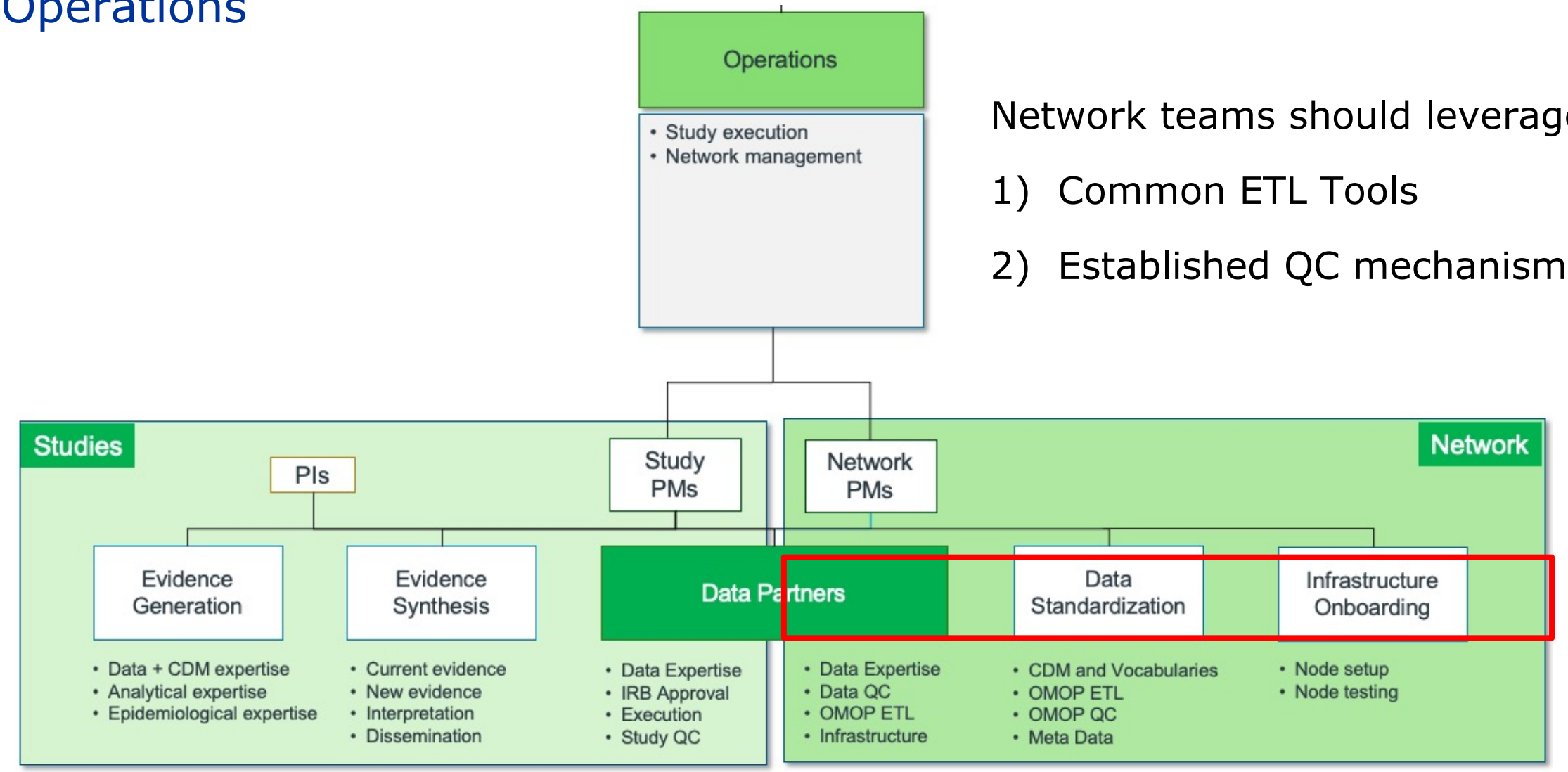
Operations

Study teams should leverage:

1) Common Analytics
2) Phenotype Library



Operations



Network teams should leverage:

1) Common ETL Tools
2) Established QC mechanisms

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**

DARWIN EU® - Coordination Centre immediate next steps

- **Formation** of the coordination centre: governance team, technology operations team, governance & boards
- **Project management** (e.g. project plan, risks management, reporting)

- **Strengthening** of the coordination centre:
  - Requirements & solution design
  - Conflict of Interest management process
  - Mandate and composition of the Scientific Panel
  - Change management plan
- **Strategic oversight** of the coordination centre:
  - Management plan and Business plan
- **On-Boarding of data sources templates**:
  - On-boarding specifications, data use agreement
- **Execution of studies templates**:
  - Feasibility assessment form, study outline/protocol/report, Agreement for Study Participation

More Information

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

Coordination Centre website – coming soon in 2022!

- 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

01 Issue 1 February 2022

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

An agency of the European Union

Editorial

Peter Arlett

Co-chair of Big Data Steering Group/ Head of Data Analytics and Methods Task Force, EMA

Jesper Kjær

Co-chair of Big Data Steering Group/ Director of Data Analytics Centre, DKMA

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!


EUROPEAN OHDSI SYMPOSIUM
EUROPE
Symposium: June 24th
Workshops: 25-26th
"All aboard!"
We'll meet again for one journey ahead
Organised by:
Erasmus MC
Health Data Science
Call for participation
Deadline May 6th