EU Big Data Stakeholder Forum 2023

04 December 2023

Session 2: Enabling the use and establishing the value of Real-World Evidence – EHDS2 Pilot first insights

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Outline

- EHDS – what is it and what's its aim?

- HealthData@EU pilot

- Preliminary insights and learnings

1

European Health Data Space - User perspectives

MyHealth@EU

HealthData@EU pilot

Empower citizens to have control over their health data

Assist policy makers and regulators in accessing relevant health data

Better health policy, greater opportunities for research and innovation

Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Health data from apps and medical devices

Facilitate access to health data for innovators in industry

Health data in registries

Electronic health records

Enable healthcare professionals to have access to relevant health data
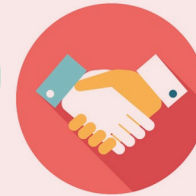
Grant access to health data for researchers

Slide extracted from the EHDS Pilot GA Oct 2023, Courtesy of M. Berneaux, EC Policy Officer.

HealthData@EU – a vision

- **New infrastructure for secondary uses of health data**

- Connecting health data access bodies and data sharing infrastructures

- Several health data access bodies are established, or in the process, across Member States

CORE Services provided by EC

GENERIC Services provided by authorized participants

SPE — Secure Processing Environments

LOCAL Services provided by/to local partners

HealthData@EU pilot

EHDS
HealthData@EU Pilot

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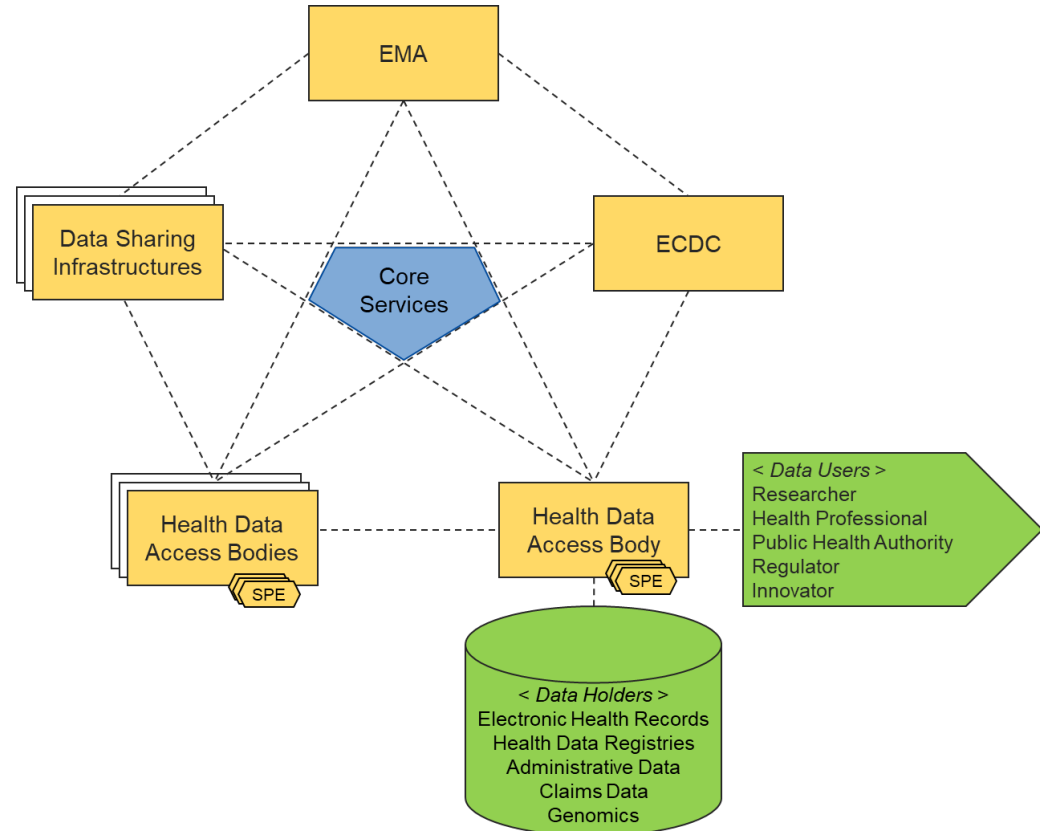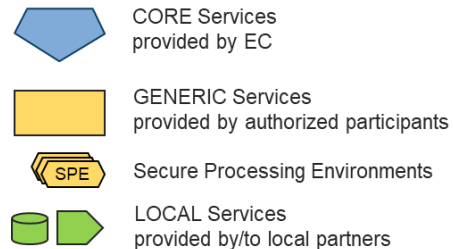
A 2-year pilot kicked off in Oct 22 - **Five use cases** to inform design, development, and deployment of HealthData@EU frameworks (**secondary use of data)**

1

Antimicrobial resistance surveillance

led by **ecdc**
EUROPEAN CENTRE FOR
DISEASE PREVENTION
AND CONTROL

2

Identifying the risks of coagulation disorders in patients with Covid-19

DARWIN EU

led by
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3

Test use, hospitalizations and vaccination adherence in vulnerable sub-populations

led by **sciensano**

4

Project to anticipate care pathways in cardio-metabolic diseases using AI

led by **HDH HEALTH DATA HUB**

5

BBMRI-ERIC

Identify genomic signatures characteristic of different types of colorectal cancers

led by **elixir**

4

Expected results

Recommendations on common data models and standards terminologies

Design and deploy an IT infrastructure federated by central services

including eDelivery implementation and evaluation, provision of discovery services like SML and SMP and reuse of CEF & DEP building blocks.

Develop and deploy a Health-DCAT AP extension

a standardized descriptive metadata template for health data portals respecting the FAIR principles and user needs.

Recommendations for an EHDS node

Including an overall economic model.

Define a Common Data Application Form

study and assess regulatory and ethical differences for the provisions of access to health data. Establish guideline to build user journey.

Demonstrate the added value of cross-country health data reuse on specific use cases

Slide extracted from the EHDS Pilot GA Oct 2023, Courtesy of M. Berneaux, EC Policy Officer.

European Commission

HMA
Heads of Medicines Agencies

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2

Identifying the risks of coagulation disorders in patients with Covid-19

led by

EUROPEAN MEDICINES AGENCY
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Testing DARWIN EU® as a node within EHDS

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

PRAC
OTS

DUS of medicines at risk of **shortages**

EMA TRS
OTS

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

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

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

CHMP
OTS

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

CHMP
Complex

OTS = off-the-shelf study

Use case factsheet

Stakeholders

Use case leader

EUROPEAN MEDICINES AGENCY
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Research teams

- DARWIN EU
- Denmark Health Data Authority, DK
- Health Data Hub, FR
- Croatian Institute for Public Health, HR
- Finnish Institute for Health and Welfare (THL), FI

Nodes

- Findata, FI
- HDH, FR
- DHDA DK
- CIPH, HR

DARWIN EU network

Objectives

The use case will aim to address 5 research questions of growing complexity - **estimate the incidence of venous and arterial thromboembolic events** among:

1. the general population;
2. patients with COVID-19;
3. patients with SARS-CoV-2 vaccination ;
4. estimate the impact of clinical risk factors and prior SARS-CoV-2 vaccination on the incidence of venous and arterial thromboembolic events among patients with COVID-19 and worsening of COVID-19
5. the incidence rate ratios for such events among patients with COVID-19 during the period when Omicron was the dominant variant and people vaccinated against SARS-CoV-2, compared to background rates as estimated in objectives. 1, 2 and 3.

Data

- Coagulopathy related events
- Use of thrombotic agents
- Risk factors
- Vaccination
- Covid-19 worsening

Research approach

- Each of the nodes participating in the project will be expected to select the research questions outlined above.
- Based on the questions and variables defined the protocol, data analysis will be conducted on both native data and OMOP data.
- Data analysis will focus on the following aspects:
  - Descriptive statistics of the observed characteristics of each population study;
  - Incidence of study outcome (venous thromboembolic events, arterial thromboembolic events, cardiovascular events)
  - Assessment of the impact of identified risk factors
  - Assessment of the risk of Covid-19 worsening
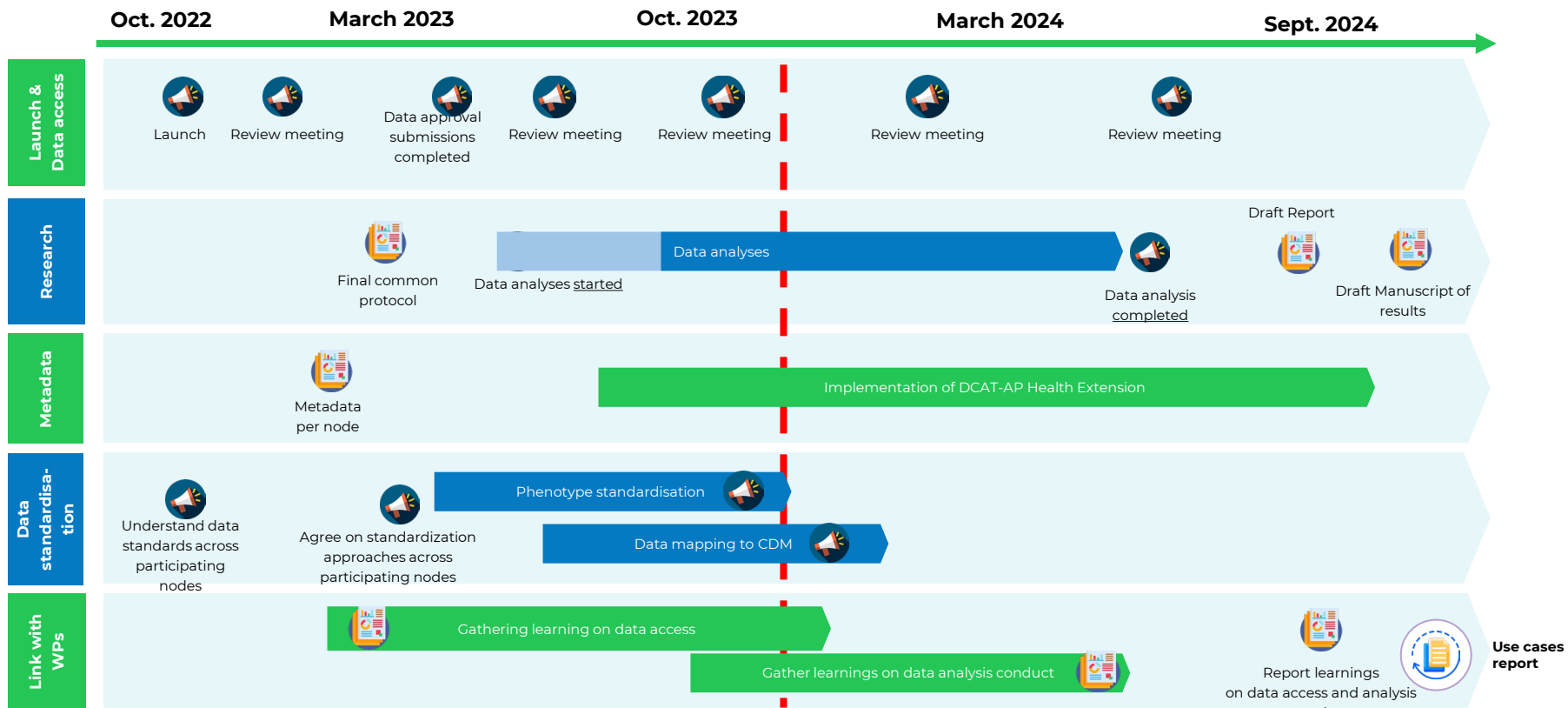 - Contextualisation of incidence rate of thromboembolic events.

Outputs

Aggregated results from each node that can then be pooled together or do comparative analysis between nodes.

EHDS
HealthData@EU Pilot

Use case timeline

Timeline markers: **Oct. 2022** — **March 2023** — **Oct. 2023** — **March 2024** — **Sept. 2024**

Launch & Data access
- Launch
- Review meeting
- Data approval submissions completed
- Review meeting
- Review meeting
- Review meeting
- Review meeting

Research
- Final common protocol
- Data analyses started
- Data analyses
- Data analysis completed
- Draft Report
- Draft Manuscript of results

Metadata
- Metadata per node
- Implementation of DCAT-AP Health Extension

Data standardisation
- Understand data standards across participating nodes
- Agree on standardization approaches across participating nodes
- Phenotype standardisation
- Data mapping to CDM

Link with WPs
- Gathering learning on data access
- Gather learnings on data analysis conduct
- Report learnings on data access and analysis conduct
- Use cases report

Caption
- Milestones
- Deliverables

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Classified as public by the European Medicines Agency

Key learnings so far

Summary of main learnings & outputs

- **Variable requirements and timelines for access to data** across nodes/countries (data availability, data minimisation and GDPR interpretation)
- **Variety of clinical coding systems and interpretation**, requiring more time for creating (standardized) phenotypes in native data
- Use of a **common data model has accelerated the process** (so far)
- Opportunities and challenges of **testing while building**

Different routes, forms, standards, sample size and speed to access data

Heterogeneous interpretation of phenotypes across data sources

Data access application

Data use

Result output

Data discovery

Data preparation and provision
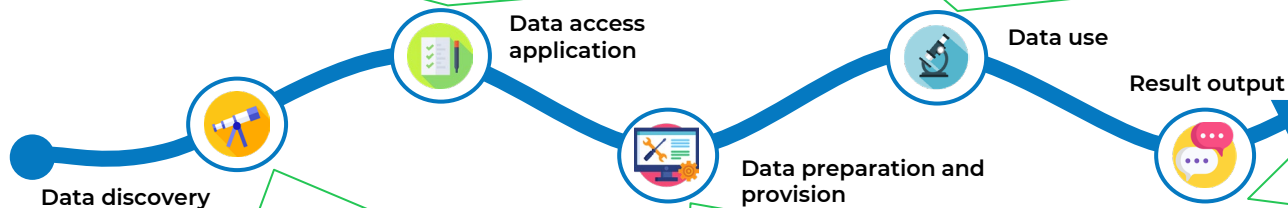
Leveraging existing processes & tools within DARWIN EU for selecting the right databases for a research question through feasibility assessments and metadata. Inspiration for some nodes to equip themselves with data catalogues

Time gained in having the entire database already mapped to a CDM vs. mapping data on a study-by-study basis.

N/A

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EHDS & HealthData@EU
Opportunity to enable a Rapid, Wide and Deep access to healthcare data ?

Opportunities…

- **Increased EU representativeness** in studies (geographic coverage, care settings, size of studies…)
- **Rapid, Wide, Deep** access to healthcare data to support better and faster decision making

… enabled by key principles

- **Implementation & readiness** - potential tensions between common EU vs each MS interpretation and/or timelines
- **Transparency & trust** – adopted mechanisms need to remain compatible with the need for rapid, wide and deep secure access
- Data access - **smooth governance & interoperable infrastructures**
- **Data protection & data security** – balancing anonymisation and pseudonymisation with possible tensions related data linkage

Closing

- ❖ EHDS has the potential to **strengthen** and **accelerate the use of RWD/RWE** and **broaden impact**

- ❖ Ability to leverage a **large population sample** to conduct the study in (estimated 40+ million patients)

- ❖ **DARWIN EU** model means results expected first before end of the year

- ❖ Various learnings on the benefits of using a **common data model** (OMOP in this case)

- ❖ Opportunity to **test the legal proposal** with EMA as data processor within EHDS, with HDH as HDAB

- ❖ Transparent and trustful **collaboration**

THANK YOU !
Any questions?

Further information

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