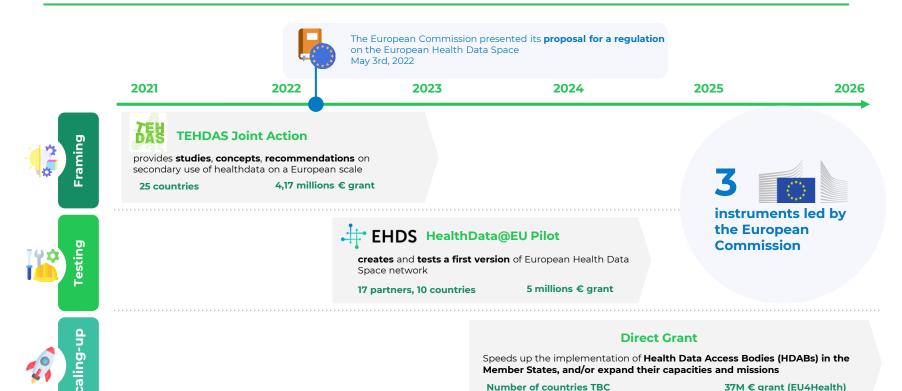


HealthData@EU Pilot & DARWIN EU





The European Commission has identified the creation of a European Health Data Space (EHDS) as top priority of the European health policy



The HDH, leader of a European consortium to build and operate a first version of the EHDS



17 partners, 9 countries 2 years

> 5 million euros of **European fundings**



Create and test a beta version of the **European Health Data** Space



Build a network of data platforms on a European scale...



...tested by concrete crossborder use cases























orphanet







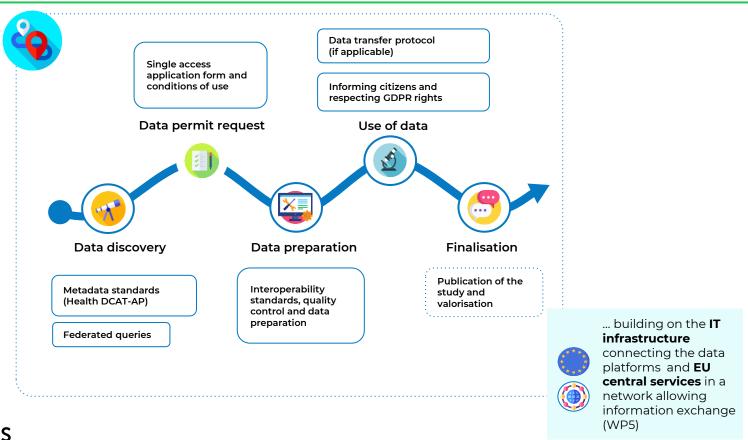






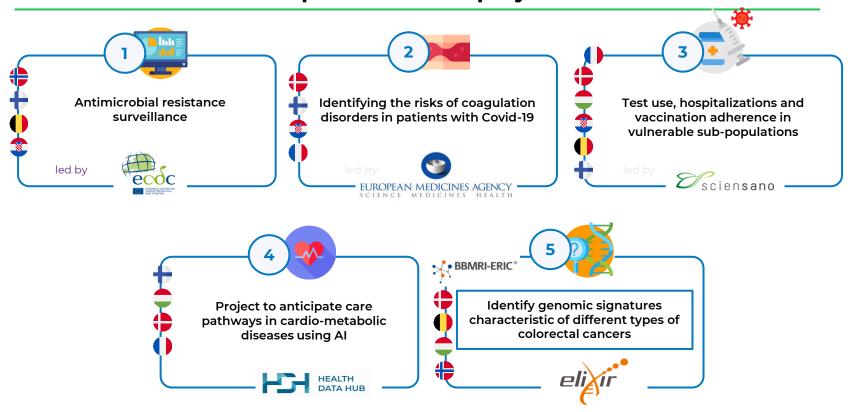


The project will cover important pieces of the overall EHDS user journey





5 concrete research use cases to demonstrate the feasibility and added value of European research projects





Use case factsheet







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

National nodes







CIPH, HR



DARWIN EU network

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; estimate 4/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, as well as 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.





Objectives





Data

Research approach

Coagulopathy related events

Use of thrombotic agents

Risk factors

Vaccination

Covid-19 worsening

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.



1

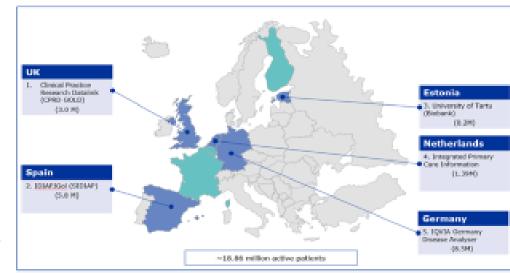
Ouput: aggregated results from each node that can then be pooled together or do comparative analysis between nodes.





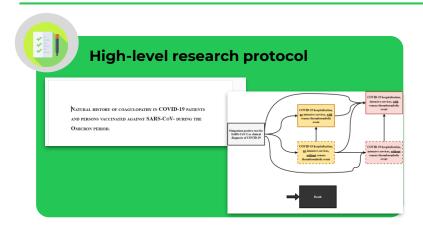
DARWIN EU – EHDS Use Case: Natural history of coagulopathy in COVID-19 patients and persons vaccinated against SARS-CoV-2 in the context of the OMICRON variant

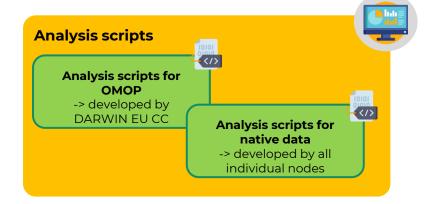
- DARWIN EU to execute all 5 research questions with their increasing complexity <u>versus</u> other nodes to chose what is feasible based on data availability and team capacity
 - Study type: complex study, population-level cohort
 - 5 databases across 5 European countries, >18M active patients
- DARWIN EU's analytics script available for other nodes to leverage for some research questions where they might have an OMOP version of their

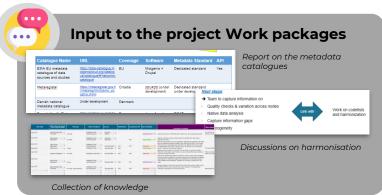


n data

Expected deliverables









Summary - interdependencies DARWIN EU & HD@EU

EMA as an authorised participant in the HealthData@EU infrastructure & consortium partner within the EHDS2 pilot project => Darwin EU as pathfinder

EMA use case on thrombosis leveraging DARWIN EU® network as a pilot for EMA participation in EHDS2

Work on data standardization, data preparation, data quality and processing => very valuable within pilot project for WP8 and on data access for WP7

DARWIN EU® and EHDS2 pilot projects as 2 complementary and synergetic projects for the secondary use of health data. Strong involvement of EMA in the project as success factor.







Co-funded by the European Union



in

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https://linkedin.com/in/ehds2





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rti-stakeholder Workshop on Real World Data (RWD)