HEALTH DATA HUB

Health Data Hub

and HealthData@EU pilot

14/11/2023

The French Health Data Hub

The Health Data Hub is a project driven and supported by major public policies

The uses of health data are increasing and it has become essential to ensure access to data sources as quickly as possible. Created at the end of 2019, the Health Data Hub is a public body tasked with facilitating access to health data for projects in the public interest, following the granting of open access to the French National Health Data System (Système national des données de santé – SNDS) in 2016.

A **Single Gateway** for health data in France

A **secure,** state-of-the-art platform

A **data catalogue including** one of the world's largest healthcare claims databases

A project driven and supported by major public policies

Created following the **Villani Report** promoting the establishment of large data-sharing platforms to foster AI

Flagship project and an active contributor to the French **National Strategy for Artificial Intelligence**

One of the major projects of the **Public Action Transformation Fund (FTAP)**

One of the actions of the French Ministry of Health and Prevention's **Digital Health Roadmap** for 2019-2022

The Health Data Hub is a public body tasked with facilitating access to health data for projects in the public interest

As unique gateway the HDH provides support to prospective data users and transparency to citizen

Requesting access

- The HDH is the one-stop shop for data access.
- Data access applications are submitted online to the HDH through a **dedicated platform**.
- The HDH verifies the completeness of the file and transmits it, if necessary, to the Ethic and Scientific Committee for evaluation.
- The HDH does not play the role of **data permit authority** today.

Transparency on all projects

- Transparency promise: All projects are published on the **public project register**. Also for projects not requiring an authorization ("MR")
- A standard information template for each project, including:
  - Context, objectives, study population and methodology
  - Data sources mobilised
  - Involved actors
  - Timeline of the project

#6000
registered projects

The **first results** of these projects are soon to be published.

Train and support

- Regular **trainings** for data users
- "**Starter kit**", including templates and pedagogical documentation to guide project leaders through the process.
- **Support desk** service to the user community to follow regulatory requirements

Kit de démarrage

1 De quelles données ai-je besoin pour mon projet ?
2 Qui sont mes partenaires ?
3 Quelles sont les démarches administratives à réaliser ?
4 Où vont être traitées mes données ?
5 Quelles pièces dois-je rassembler pour constituer mon dossier ?
6 Comment aller plus loin ?

Aide au remplissage

Nos conseils

Définition

Guide pédagogique
Note d'information aux personnes

Guide pédagogique pour les expressions de besoins SNDS à destination de la Cnam

The HDH technical offering enables project coordinators to access data in state-of-the-art secure processing environments

Complementing not replacing services that data holders already provide

A need formulated by the ecosystem

Complementary technological solutions were identified as a need during the auditions in the prefiguration phase of the HDH

200 candidate projects for the HDH's first call for projects

A service offering that complements existing offers

Existing technological services remain relevant:

- Cnam platform for processing SNDS data
- Hospital platform for processing of data from a hospital or hospital grouping

The Health Data Hub is the only **French cloud technology platform** :

that allows health data projects to have access **to elastic storage and high computing capacity**

- Ex : The **ORDEI** project led by ANSM calculates the adverse effects of medicines on 2000 substances and five years of history: 400 days of calculation would be necessary with the Cnam platform

- Ex : the imaging **APRIORICS** project needs 32 To of data

- Ex the **REXETRIS** project measuring drugs adverse effects needs 3 different sources of data

that allows **different data sources to be linked**

which is designed to be used by a large number of users

that meets **the highest security requirements**

The HDH provides services building on previous efforts to scale up support and further boost projects...

Building a **catalogue**

and supporting the **creation of new strategic databases**

... including **one of the world's largest healthcare claims databases**

- Collection of priority databases for the ecosystem that justify optimizing their visibility and sharing them via the HDH
- Great diversity: cohorts, registries, hospital data warehouses, administrative databases - one of the main interests lies in the systematic enrichment of these databases by the main database.
- Built progressively, with partners and under the umbrella of the Strategic Committee on Health Data

Healthcare facilities

- 1 UNIBASE call for projects programme aiming to create a collection of reference databases in oncology in 3 years.
- Winner of a call for tenders from the European Medicines Agency alongside 4 hospitals
- Participant in a call for projects led by the Ministry of Health, which aims to promote the deployment of health data warehouses (75M€)

Primary care medicine

The HDH is a member of a consortium aiming to set up a data warehouse for community care : "Project Platform for Data in Primary care - P4DP" (11M€ for three years)

Databases of national interest

Prospective reflections on the development of databases of national interest, in conjunction with the Strategic Committee on Health Data on :

- Databases that could contribute to health data assets, such as the National Medical Biology Data Warehouse (Entrepôt national de données de Biologie médicale)
- Enrichment of the main SNDS database - particularly with contextual data

… including services for projects taking place outside of the HDH technological platform

Developing and deploying a metadata catalogue to make it easier for project leaders to identify the data available, its content and its quality.

Metadata catalogue

Developing an information system that will **industrialise** the **linkage** of **data from different sources**

Data linkage
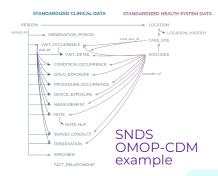
Rights of natural persons

Building and **implements** a **form** to **facilitate** and **industrialise** the **exercise of personal data rights** for data subjects, for the main database and the catalogue.

Interoperability standards

Investigating and implementing interoperability standards for research such as **OMOP**

SNDS OMOP-CDM example

The HDH contributes to innovation by supporting pioneering projects and fueling the strategic thinking

Support innovative projects

Organisation national and international calls for projects.

Topics include oncology, environmental health, AI in health, and many more.

Reflect on issues of strategic interest

Participation in discussions on issues of strategic interest for the use of health data (NLP, synthetic data, standards).

NLP working group

The coordinator of the French national strategy on AI has asked the Health Data Hub to **coordinate a focus group on the national strategy on Natural Language Processing (NLP) applied to health data**

12 expert researchers

7 workshops

3 actions on pseudonymisation

Facilitate national strategic working groups

The HDH facilitates the working groups of the Strategic Committee on Health Data.

Three working groups have been established so far:
- Reflection on core national health data assets and minimum standard dataset of hospital data warehouses
- Sustainable financing of health databases
- Harmonization of rules for sharing: access governance, fees and standardized agreements

The HDH is also a national actor in the dialogue with the citizens

Listen to civil society and co-construct a health data culture

- **Regular organisation of citizen consultations / public debates :**
  - Public consultation on the second life of health data and the future EHDS framework
- **Perception studies**

+10 partnerships in the framework of the **Open Government Partnership** (Patient associations, Students, Journalists, Think tanks...)

Listen   Involve

Train   Inform

About the data available through the Health Data Hub

What data are available on the Health Data Hub's technological platform ? is it true the Health Data Hub will be a gigantic health database ?

About information for citizens, consent and the exercise of rights

How will citizens be informed of the projects carried out with their data ?

Is citizen's consent sought before the data is transferred on the Health Data Hub's technological platform ?

How can citizens exercise their rights ?

FAQs and trainings to get a better understanding of the issues related to health data, based on the questions raised by the citizens

- Implementation of **educational tools**
- **Monthly newsletter**

Votre infolettre citoyenne - Données de Santé #15

Retrouvez l'infolettre commune du Health Data Hub et France Assos Santé sur les données de santé !

PAROLE D'ASSOCIATION

After three years, where do we stand?

Production launch of a technology platform in just one year

Rapid recruitment of staff to reach 89 people by 31 December 2022

Support for 97 projects, a third of which are led by industrial actors

Major European involvement, notably as leader of the HealthData@EU Pilot project, to **build the first version of the EHDS**

More than 100 active partnerships, resulting in the development of links with the entire ecosystem, including civil society

A major impetus for the constitution of new databases: AAP on health data warehouses (€50M), P4DP project (€10M)

300 public talks since 2021 and **participation in major projects such as PariSanté Campus, FIAC, DARWIN**

99
projects supported by the HDH,
of which 71 use the technology platform

30 projects in the regulatory phase (data access request)

31 projects in the data preparation phase

38 projects running on the platform by the end of 2023

15 projects completed, or with intermediary results

+20 **Calls for project**

What projects and supported by the HDH?

Context

Approach and first results
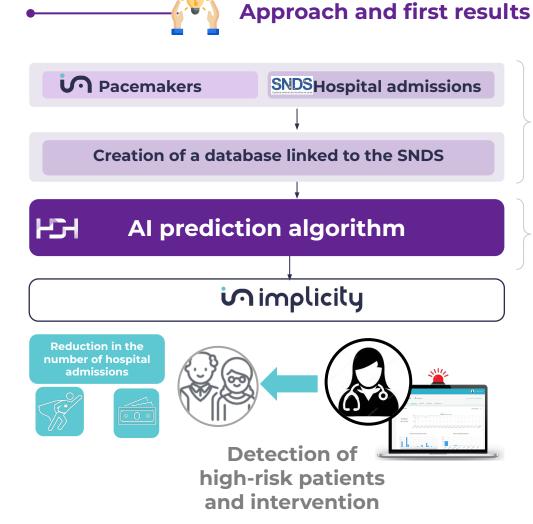
The HYDRO project aims to **predict heart failure crises leading to hospitalisation** for patients with pacemakers in a context where **existing solutions are generally not predictive**

45 000 data from pacemakers

3,8 M French patients data from the SNDS

Pacemakers

SNDS Hospital admissions

Creation of a database linked to the SNDS

Support from the HDH and CNAM in carrying out the linkage (improvement of the rate from 50% to 85%)

HDH **AI prediction algorithm**

implicity

Development of the algorithm on the HDH technical platform with the support of the HDH

Reduction in the number of hospital admissions

Detection of high-risk patients and intervention

Do you have questions?

EHDS and the HealthData@EU pilot project

HEALTH
DATA HUB

Background and follow-up to the proposed EHDS Regulation

The European Commission has presented its proposal for a regulation on the European Health Data Area on May 3rd, 2022

EUROPEAN COMMISSION

Strasbourg, 3.5.2022
COM(2022) 197 final
2022/0140(COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

(Text with EEA relevance)

The proposal is being discussed in the **European Parliament** and the **Council of the European Union**

The regulation is planned to apply **1 year after** its formal adoption
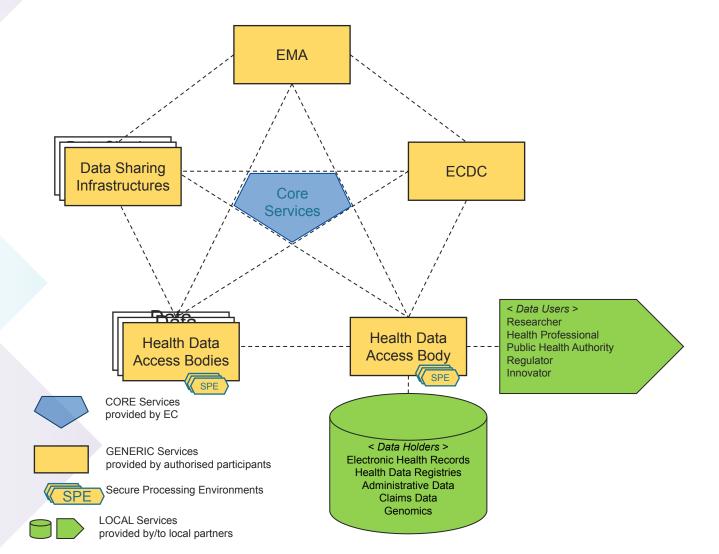
The proposal includes the empowerment of the Commission to adopt **implementing** and **delegated acts**

EU regulatory framework: GDPR, Data Governance Act, Data Act (draft), IA Act (draft), etc.

The proposal aims to establish the **first sectoral data space** in the framework of the **European Data Strategy**

HealthData@EU: vision and reference architecture

- **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

Legend:

- CORE Services provided by EC
- GENERIC Services provided by authorised participants
- SPE — Secure Processing Environments
- LOCAL Services provided by/to local partners

Diagram elements:

EMA · ECDC · Data Sharing Infrastructures · Core Services · Health Data Access Bodies · Health Data Access Body · SPE

< Data Users >
Researcher
Health Professional
Public Health Authority
Regulator
Innovator

< Data Holders >
Electronic Health Records
Health Data Registries
Administrative Data
Claims Data
Genomics

The HDH was developed with a strong European vision in mind, and is at the heart of the implementation of the future EHDS

The European Commission presented its **proposal for a regulation** on the European Health Data Space
May 3rd, 2022

2021　　2022　　2023　　2024　　2025　　2026

Framing

TEHDAS Joint Action

provides **studies**, **concepts**, **recommendations** on secondary use of health data on a European scale

25 countries　　　**4,17 millions € grant**

TEHDAS II

Implementation

Testing

EHDS **HealthData@EU Pilot**

creates and **tests a first version** of European Health Data Space network

17 partners, 9 countries　　　**5 millions € grant**

3 **instruments proposed by the European Commission**

Scaling-up

Direct Grant

Speeds up the implementation of **Health Data Access Bodies (HDABs) in the Member States, and/or expand their capacities and missions**

Number of countries TBC　　　**37M € grant (EU4Health)**

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

HealthData@EUpilot

17 partners, 9 countries

2 years

5 million euros of european fundings

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

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

...tested by concrete cross-border use cases

HEALTH DATA HUB

Bundesinstitut für Arzneimittel und Medizinprodukte

DANISH HEALTH DATA AUTHORITY

BBMRI-ERIC

CROATIAN INSTITUTE OF PUBLIC HEALTH

eeszt elektronikus egészségügyi szolgáltatási tér

EBRAINS

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

ecdc

IACS Instituto Aragonés de Ciencias de la Salud

elixir

FINDATA Social and Health Data Permit Authority

EUPHA

GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD

orphanet

The Norwegian Directorate of eHealth

sciensano

The project covers important pieces of the overall EHDS user journey

... building on the **IT infrastructure** connecting the data platforms and EU **central services** in a network allowing information exchange

Single access application form and conditions of use

Data permit request

Data transfer protocol (if applicable)

Informing citizens and respecting **GDPR** rights

Use of data

Data discovery

Data preparation

Finalisation

Metadata standards (Health DCAT-AP)

Federated queries

Interoperability standards, quality control and data preparation

Publication of the study and valorisation

The HDH, co-leader of building the technical backbone of the HealthData@EU pilot

... based on a **technical infrastructure** allowing the exchange of information between nodes

✓ Design and deploy a **technical infrastructure** for the **network of nodes** and the link with **central services**

✓ Use European building blocks (eDelivery), open source standards and establish **security standards**

✓ After a **scoping phase**, development of a **POC**, then **MVP** and **deployment** of the network

National platforms - POC nodes

National platforms - other nodes

Metadata
Access form

Central services

eDelivery

Research infrastructure nodes

European agencies nodes

BBMRI-ERIC®

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ecdc
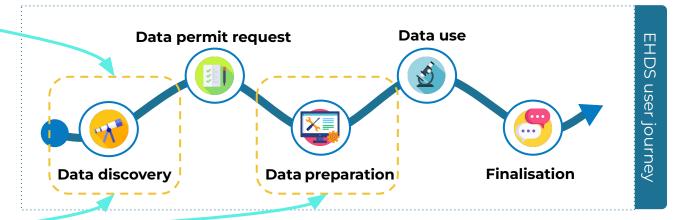
Two work packages related to data discovery and interoperability

WP6
Metadata standards

- Develop a **standardised descriptive metadata** (**Health DCAT-AP**) respecting the FAIR principles and User needs of the EHDS
- Implement Health DCAT-AP in the nodes
- Contribute to the implementation of a central search portal

Sciensano

Norwegian Directorate of eHealth

Data permit request

Data use

Data discovery

Data preparation

Finalisation

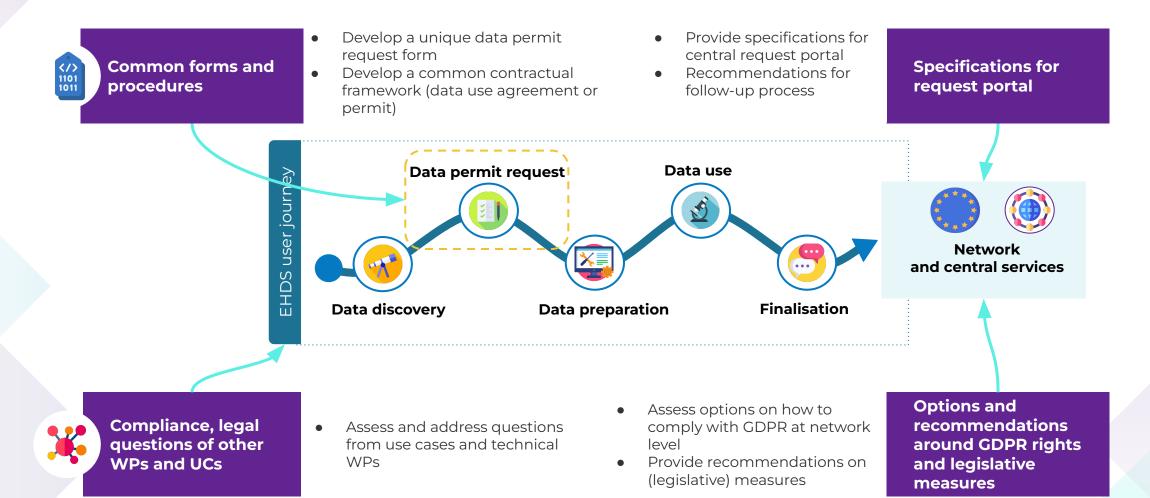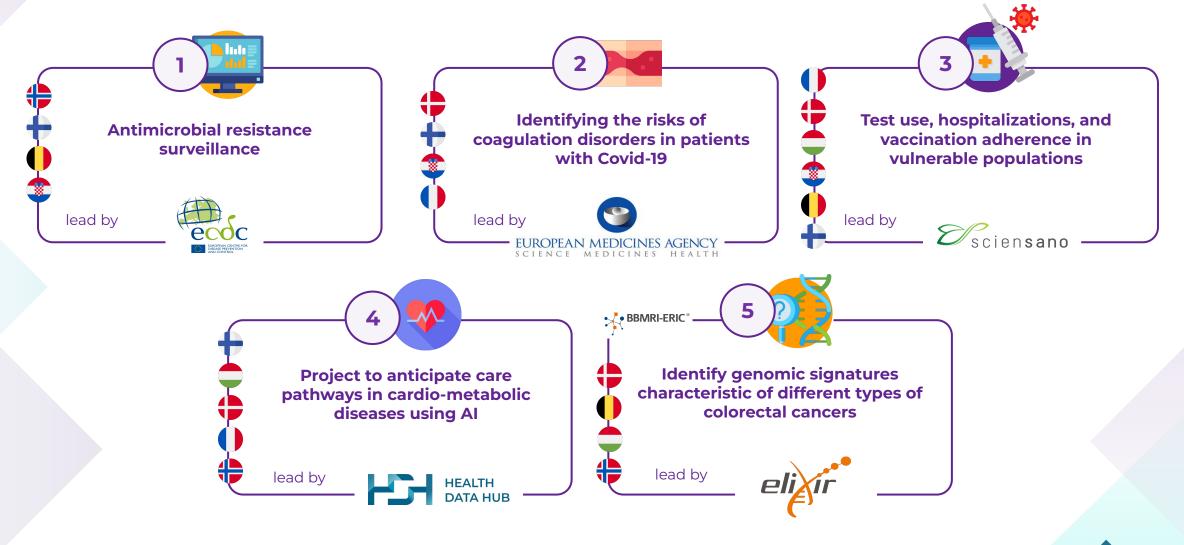EHDS user journey

WP8
Data interoperability and quality

- Provide guidelines for **data standards** to address **semantic interoperability**, including **data quality assurance** and the definition of **security prerequisites** for transfer
- Investigate, and if feasible, test **solutions for query** (data discovery)
- If applicable, definition of data transfer protocol for the use cases

BBMRI

WP7, normative laboratory of the project

Common forms and procedures

- Develop a unique data permit request form
- Develop a common contractual framework (data use agreement or permit)

- Provide specifications for central request portal
- Recommendations for follow-up process

Specifications for request portal

EHDS user journey

Data permit request

Data use

Data discovery

Data preparation

Finalisation

Network and central services

Compliance, legal questions of other WPs and UCs

- Assess and address questions from use cases and technical WPs

- Assess options on how to comply with GDPR at network level
- Provide recommendations on (legislative) measures

Options and recommendations around GDPR rights and legislative measures

5 cross-border use cases show the added value of HealthData@EU

1 Antimicrobial resistance surveillance

lead by — ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

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

lead by — EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

3 Test use, hospitalizations, and vaccination adherence in vulnerable populations

lead by — sciensano

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

lead by — HEALTH DATA HUB

5 Identify genomic signatures characteristic of different types of colorectal cancers

BBMRI-ERIC®

lead by — elixir

Overall timeline - already half-way through!

Oct. 2022 | March 2023 | Oct. 2023 | March 2024 | Sept. 2024

Coordination

- Kick-off meeting
- Mid-term event
- Interim report
- Final event
- Final report

Technical developments

- Framing and landscape analysis
- IT Infrastructure **Proof of Concept**
- **MVP** deployed
- **Infrastructure scaled up** with all nodes
- Common **data application form**
- **Legal recommendations**
- **Health DCAT-AP**
- **Implementation** in the **national nodes**
- **Initial recommendations**
- **Standards for data interoperability**, **querying** & **exchange**, quality controlling
- Recommendations **data security**

Use cases

- **Use case selection**
- **Use case framework & data access requests**
- Use case research
- **Use cases report**

Be sure to follow our communication channels to keep up to date

Thinking about sustainability

Communicate and share achievements, challenges, and lessons learned
WP2

WP5
Building an **infrastructure** that can be **handed-over** and **scaled-up** in the future

WP4
Summarising the **key learning** and developing **recommendations** for being a EHDS node

EHDS
HealthData@EU Pilot

European Commission Central Services

Work with the central services to make sure that the **central portal will cater to needs** over medium/long term

Contributing to building a community of practice

Direct grant community

Other projects on the EHDS (TEHDAS II, Data quality and utility label, etc.)

Providing feedback and inputs to the legislative process

WP6   **WP7**   **WP8**
Building services that can be **scaled-up** for future use within EHDS

WP9
Testing the services

The Health Data Hub is strongly involved in EU projects

Establishment of the EHDS

- The HDH as *competent authority* within the **TEHDAS Joint Action**
- The HDH as **Coordinator** of the **HealthData@EU project**
- The HDH as *competent authority* within the Direct grant *Setting up services by Health Data Access Bodies*
- Contacts with other **major European projects and initiatives** established around the EHDS (Darwin EU, Genomics Data Infrastructure, Healthy Cloud, etc.)

Involvement in strategic projects

- **Data standardisation** and **interoperability: Laureate** within the **EHDEN project**
- **Creating databases of interests**: Laureate of an EMA call to establish a OMOP-multicenter-database with data from 4 hospitals
- Partner within the **Testing and Experimentation Facility (TEF) Health** providing testing services for AI and robotics products

Scaling-up French participation in EU calls

- The HDH is **monitoring EU calls, especially** within the **Horizon Europe, "DIGITAL" Europe** and **EU4Health** programmes
- Given its central role within the **establishment of the EHDS** and its strong commitment to supporting **data access** and **data interoperability**, the HDH will apply to upcoming calls in 2023
- As part of its offering to partners, the HDH will involve and collaborate with **data holders and project partners to jointly respond** to EU calls

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![EHDS HealthData@EU Pilot logo]

**Co-funded by
the European Union**

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