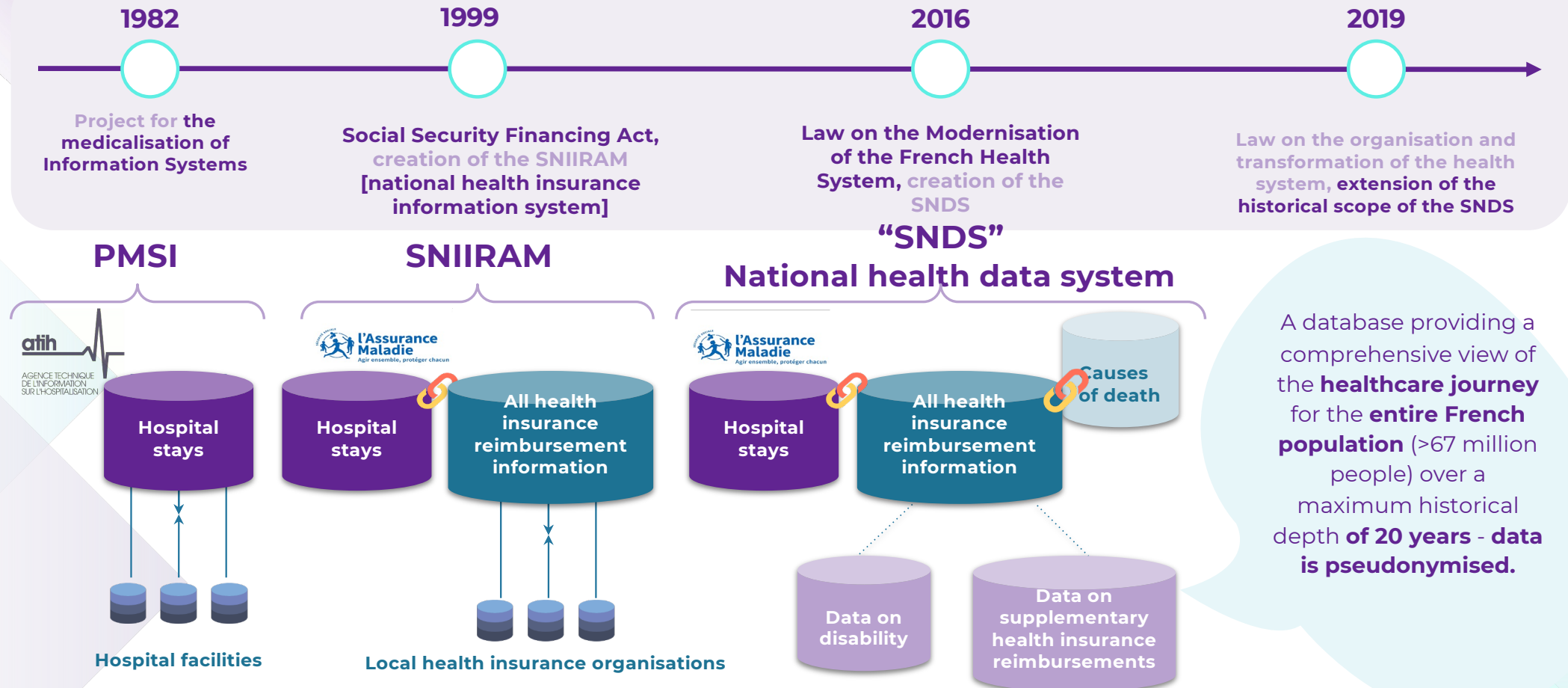


Plateforme des données de santé

EHDS Implementation in France: An HDAB perspective



Health data heritage in France: The extended SNDS



The French Health Data Platform, a key player serving research stakeholders in France



A **single gateway** for health data in France



A **data warehouse**, as well as access to one of the largest medico-administrative databases in the world



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

Created 6 years ago, the French HDH plays an important role in **structuring and making health data available in France and Europe**. The French HDH supports projects aimed, for example, at **improving diagnostics or patient care pathways, with extensive partnerships across the entire ecosystem** (hospitals, industry, research organizations).



An action in the service of and in partnership with the ecosystem



The governance of the French HDH includes **56 stakeholders representative of the health data ecosystem**.



The French HDH supports **291 research projects**, 220 of which aim to leverage its technological platform.



The French HDH is actively involved in the implementation of the “AI and health data” strategy, particularly within the working groups of the **National Digital Health Council**.

Following the law of 2019, the scope of the SNDS has been expanded with the HDH's data warehouse

2019

Law on the organisation and transformation of the healthcare system, expansion of the historical scope of the SNDS

SNDS main database

Centralised SNDS

National data warehouse

“historical” SNDS

1

SNIIRAM
DCIR

PMSI

CépiDc

2

Nationally exhaustive databases linked with the historical SNDS. To date, these include :

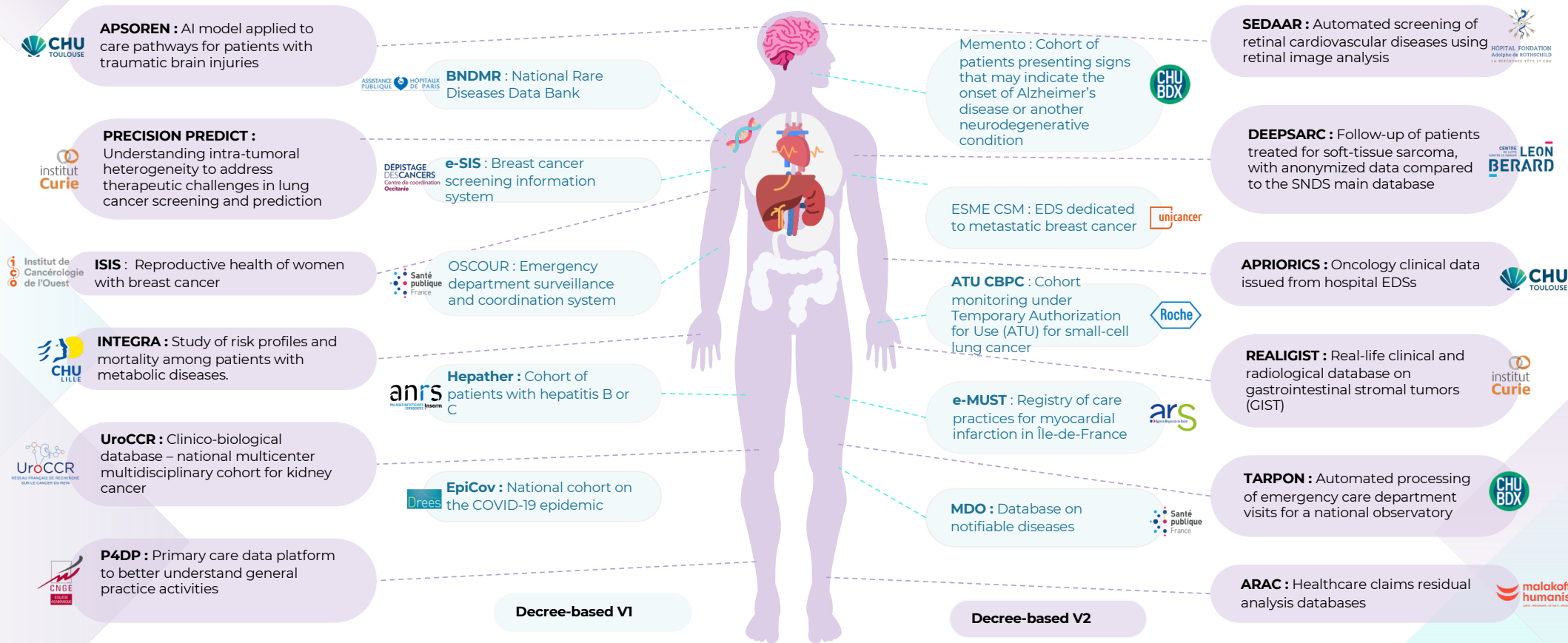
SIDEP : Covid-19 national population-based screening information system

Covid vaccine information system

3

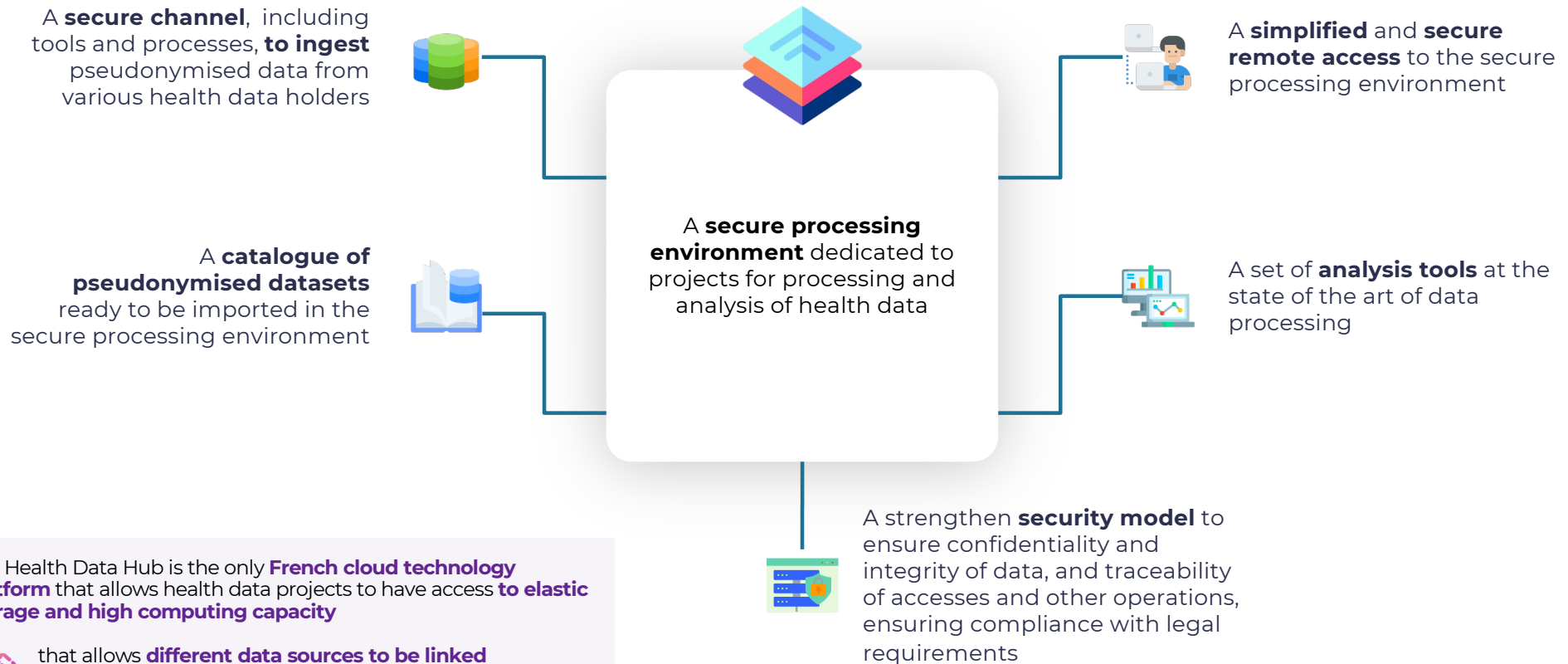
The **HDH's data warehouse**, which brings together copies of health databases deemed relevant to research and innovation.

Databases made available through the HDH data warehouse and linked to the SNDS core database



All these databases are securely linked to the SNDS core database, which makes it possible to reconstruct comprehensive patient care pathways, combining real-world reimbursement data with richer clinical and hospital information.

Majority of HDH-supported projects leverage our state-of-the-art secure processing environment to access data



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**

 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**

Technological offer | current offer*

	Programming languages and IDEs	Big Data infrastructures	Data visualisation	Data storage	Images	Collaboration
Available tools						
Use	• Data exploration • Machine learning • Image processing	• Queries and processing of a high volume of data	• Visualisation of data	• Structuring of data • Queries	• Visualisation and annotation of images	• Code versioning • Development follow up

*Complexity to take into account if a project leader wishes to use a tool outside the current technological offer

The Hydro project example : predicting Heart Failure crisis to prevent aggravations and reduce hospitalisations



Context

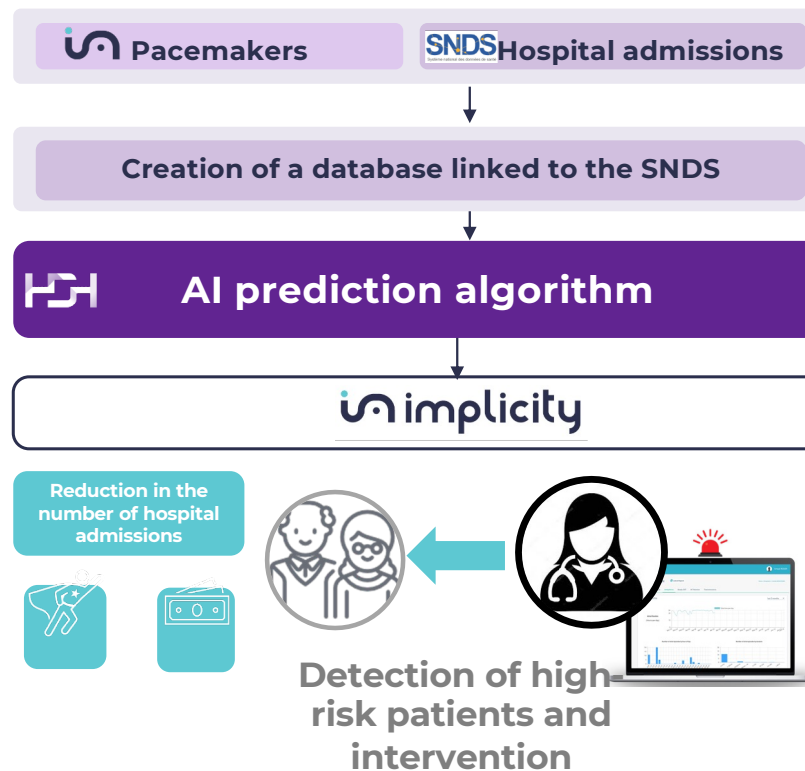
The HYDRO project aims to **predict heart failure crises leading to hospitalisation** for patients with pacemakers in a context where **existing solutions are generally not predictive**

45 000 data from pacemakers

3,8 M French patient data from the SNDS



Approach and first results



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

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



the medical device created thanks to the HDH has been certified by the Food and Drug Administration (FDA)

The HDH commitment beyond French borders: several initiatives to prepare & implement the EHDS for 2ndary use



The project *French_HealthData@EU* will receive funding to prepare for the implementation of the EHDS on the French scale

Context and objective

Accelerate the **implementation of Health Data Access Bodies (HDABs)** in Member States and/or **expand their capabilities and missions**.

Main objective 1

Objective 1 - National services and infrastructures

Strengthening HDH as one of the HDAB with:

- A metadata catalog based on a European standard
- Creation and translation of HDH documentation

Objective 2 - Cross-border services et infrastructures

- Contribute to the scale-up and deployment of the HealthData@EU infrastructure based on the outcomes of the pilot project
- Participation in European EHDS CoP

Main objective 2

Objective 3 - Data quality

Structuring the national ecosystem and its integration into the EHDS through the following activities:

- Filling in the metadata catalog
- Standardization and quality enhancement activities
- Creation of secure connections between HDH and data holders



HDH HEALTH DATA HUB

PLATEFORME DES DONNÉES DE SANTÉ
FRENCH HEALTH DATA HUB

EHDA Symposium - 06/10/26 Heidelberg

The HDH metadata catalogue: a tool to facilitate the search for and access to databases

► The objectives of the metadata catalogue



Strengthen transparency and data quality

- **Structure and standardize** the documentation of health databases, aligning with European standards
- Facilitate the identification of databases for researchers through **standardized** descriptions and an **intuitive** interface.



Accelerate research projects and innovation

- Increase the **visibility of partner databases** in France and Europe
- Simplify **partner contributions** through guided forms and preconfigured fields, reducing the technical effort required
- Provide a **customizable** white-label catalogue solution



Meet European regulatory requirements

- Promote the **dissemination of metadata at the European level** while maintaining local autonomy in the management and publication of information

► The online catalogue



The metadata catalogue makes it possible to **document, manage, and publish** the metadata of health databases according to the Health DCAT-AP standard, ensuring European compliance and EHDS interoperability.

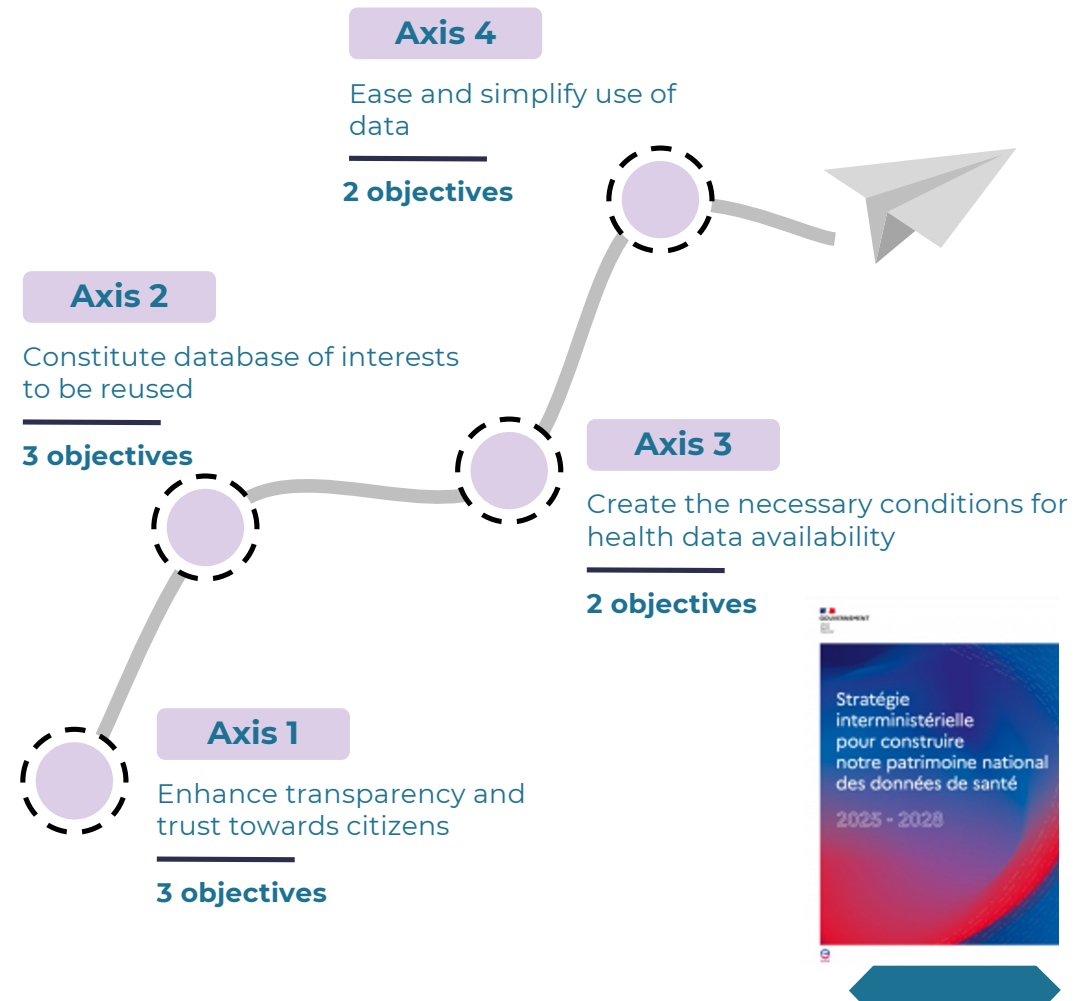
The HDH supported the elaboration of the strategy for secondary use of data, included in the national strategy for AI & health data

As the national health data operator, the HDH has been a key stakeholder in the **interministerial strategy** to build **our national health data assets**. This strategy aims to drive the initiatives required to prepare for the **implementation of the EHDS** (European Health Data Space).

To this end, the strategy has built upon the work of the **Strategic Committee for Health Data**, to which the HDH contributed

- **Harmonizing health data governance** and management practices —particularly for hospital data
- **accelerating data availability**,
- identifying and establishing **Health Data Access Bodies** (HDABs)

are among the key initiatives to which the HDH actively contributes.



All projects leveraging health data in France are registered in the HDH public register, counting more than 8000 projects

~1500
projects with
pharma industry
as Data Controller

[here](#)
GSK

A Real-world Study to Evaluate Clinical Outcomes of dostarlimab in Patients with Previously Untreated Stage II/III dMMR/MSI-H Locally Advanced Rectal Cancer

OBJECTIFS **COMPRÉHENSION DES MALADIES** **PRÉVENTION ET TRAITEMENT** **DOMAINES**
CANCÉROLOGIE CATEGORIES
INFORMATIONS RECUEILLIES À L'OCCASION D'ACTIVITÉS DE PRÉVENTION, DE DIAGNOSTIC, DE SOINS OU DE SUIVI SOCIAL ET MÉDICO-SOCIAL



Learn more about **rectal cancer** and how the **disease and treatment with dostarlimab** affect individuals in their daily lives.

[here](#)
MERCK

TERENCE: Analysis of treatment sequences in recurrent and/or metastatic head and neck squamous cell carcinomas in France: a population-based study

OBJECTIFS **PRÉVENTION ET TRAITEMENT** **DOMAINES** **CANCÉROLOGIE** CATEGORIES
INFORMATIONS RECUEILLIES À L'OCCASION D'ACTIVITÉS DE PRÉVENTION, DE DIAGNOSTIC, DE SOINS OU DE SUIVI SOCIAL ET MÉDICO-SOCIAL



Generate **RWE for various treatment options** in patients with recurrent and/or metastatic head and neck cancer, in light of the **limited comparative clinical data** currently available

[here](#)
Lilly

RETROSPECT: Use of selpercatinib in real life setting in France among patients with NSCLC (Non-Small Cell Lung Cancer) or MTC (Medullary Thyroid Cancer): a retrospective study from the French nationwide claim database (SNDS)

OBJECTIFS **PRISE EN CHARGE DES PATIENTS** **DOMAINES** **CANCÉROLOGIE** CATEGORIES
INFORMATIONS RECUEILLIES À L'OCCASION D'ACTIVITÉS DE PRÉVENTION, DE DIAGNOSTIC, DE SOINS OU DE SUIVI SOCIAL ET MÉDICO-SOCIAL



Following approval of selpercatinib in France for 2 diseases: describe **patients treated and newly treated** with selpercatinib for each of the two conditions + describe **the duration of treatment** and the **utilization** of selpercatinib

[here](#)
Pfizer

RealWorld Treatment Patterns and Clinical Outcomes Among Patients with Metastatic Castration-Resistant Prostate Cancer: European Medical Record Review

OBJECTIFS **COMPRÉHENSION DES MALADIES** **DOMAINES** **CANCÉROLOGIE** CATEGORIES
INFORMATIONS RELATIVES AUX PATHOLOGIES DES PERSONNES CONCERNÉES



Improve the **understanding of metastatic castration-resistant prostate cancer (mCRPC)** for both **healthcare providers and the research team**; the findings from this study may facilitate the **advancement of mCRPC therapies**

Including Pfizer Global

Data discovery tools provided by the Health Data Hub



Data holders

Referencing form

Metadata editor

White label catalogue



National database directory

Citizens rights



National metadata catalogue

List of variables



European metadata catalogue

Public project registry

DAAMS



Data users

The HDH commitment beyond French borders: several initiatives to prepare & implement the EHDS for 2ndary use

Creation of the EHDS



2021

2022



2023

2024

2025

2026

Entry into application

2029



Framing / regulatory



TEHDAS Joint Action

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



TEHDAS Joint Action II

Prepares the **implementation** of EHDS

29 countries

Community of Practice (with HDABs and CAs)



Testing & EU collab.



EHDS HealthData@EU Pilot

creates and **tests** a first version of European Health Data Space network
17 partners, 9 countries



SHAIPEP

Mobilises the EHDS to **deploy AI in healthcare**

30 partners, 11 countries

National strategy secondary use



Scaling-up & National implem.

Direct Grant

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

Contribution to EU projects



- **DARWIN EU** : to promote the use of real-life data to study the use, safety and efficacy of medicines and vaccines for the human use
- **TEF - Health** : Testing and Experimentation Facility for AI solutions
- **QUANTUM** : Developing and implementing a data quality and utility label

SHAIPED aimed at enhancing AI in medical devices in Europe by leveraging HDABs and their role in RWD reuse

HDH is leader of SHAIPED consortium that leverages the french health ecosystem and the **main existing HDABs** to enhance usage of AI in Europe via HDABs

3 main objectives:

1. Reinforce the current offering (services & tools) of HDABs to support AI development via RWD* use
2. Foster synergies between EHDS and AI Act
3. Conduct concrete use cases with real AI models and get learnings for the future

4M€ EU funding

3 years

30
FR & EU
partners

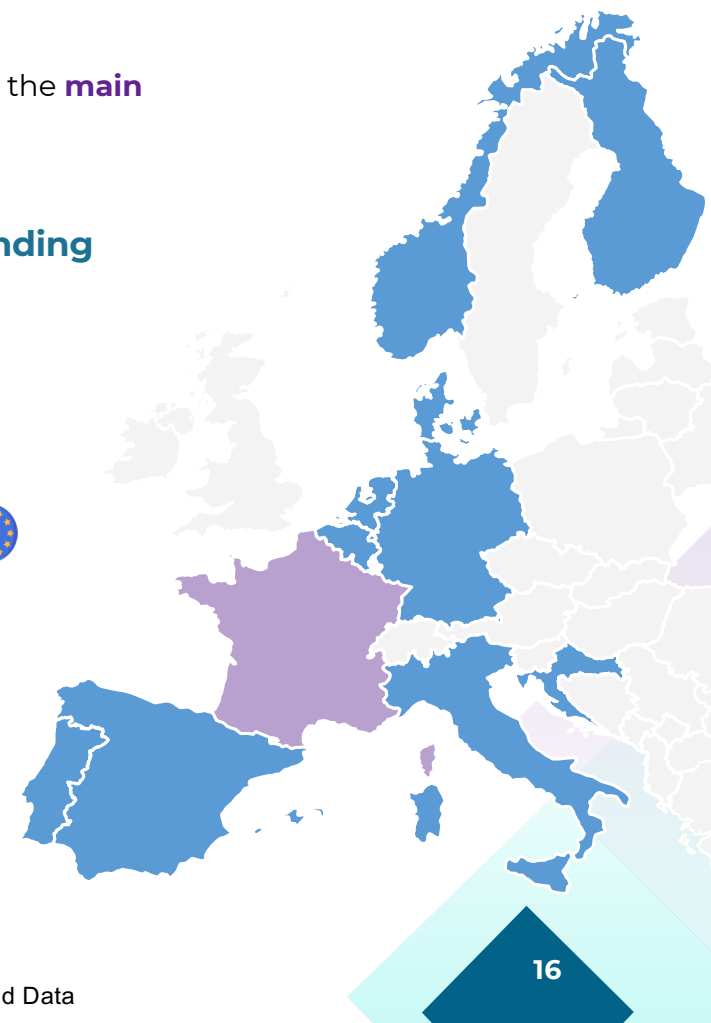
11
EU member
states



7 FR partners



HDH leading a group of 11 HDABs

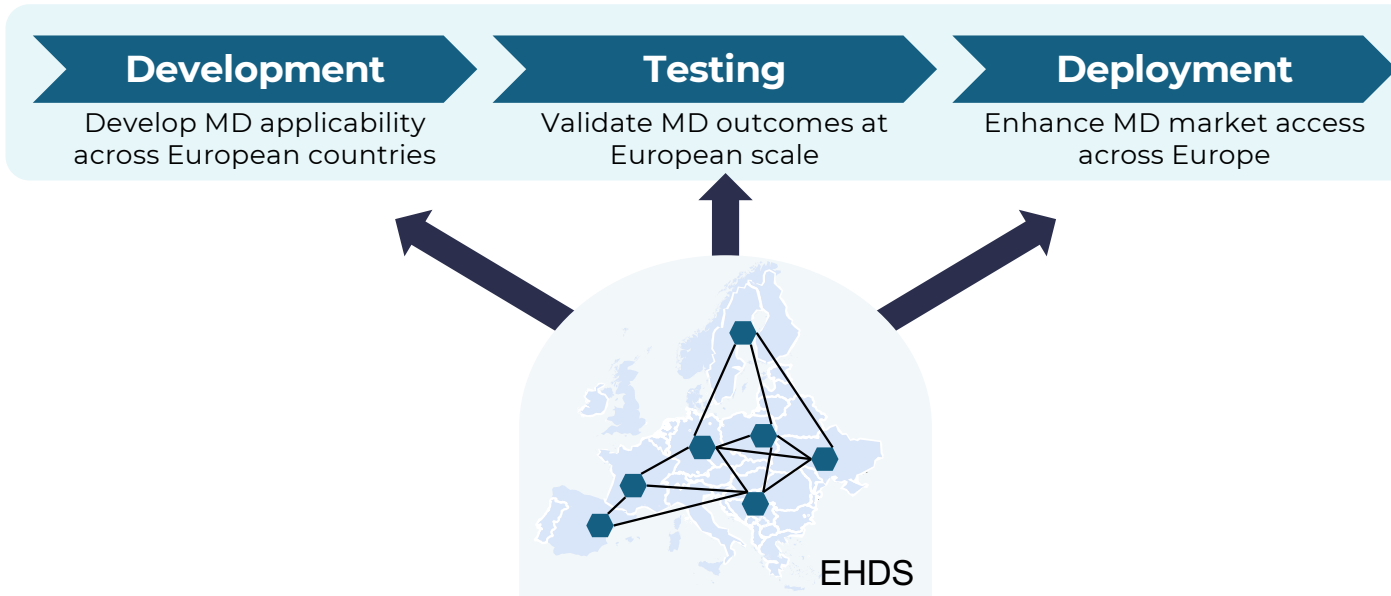


SHAIPED aims at enhancing usage of AI in medical devices across Europe by improving accessibility to health data

Supporting **H** Health Data Access Bodies to establish **AI** Pathways **E** Enabling **D** Deployment of AI as medical device tools

SHAIPED Approach

Define how real world data accessibility across Europe can enhance main steps of **AI Medical Devices lifecycle**



Key Objectives

- Reinforce the **capacity of HDABs** to **provide support** (services, tools) for AI solutions deployment
- Build **methodological guidance** for **enabling RWD use** for AI/MD deployment
- Foster **synergies** with the **EHDS** and the **AI Act**
- Conduct **concrete use cases** and assess **outcomes**



Suivez-nous sur les réseaux sociaux !



HealthData@EU Pilot: the project laid the foundations for the implementation of the EHDS

Numerous deliverables and concrete lessons learned thanks to the pilot project's work



Development of a **European metadata standard** (Health DCAT-AP) and cooperation with the European Commission to create a European metadata catalogue, fed by national catalogues to facilitate data discovery at EU level.



Creation of a **single access request form** to simplify procedures, which vary greatly between European countries, and reduce access times. This form has enabled the establishment of a **European-level access request portal**.



Design and deployment of an **infrastructure connecting the various countries** and the European Commission in a secure information exchange network. This network enables the creation of services through interaction with the central European portal.



The five use cases demonstrated the **feasibility and added value** of using data at European level for different types of use. Their feedback is a valuable asset for continuing the creation of the EHDS.



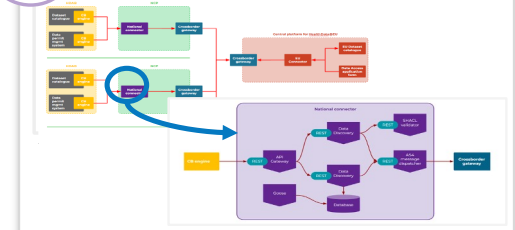
Health DCAT-AP metadata standard



3 sets of recommendations based on use cases



IT Infrastructure HealthData@EU



Single access request form

Summary of Direct Grant partner's work on standardisation & quality enhancement initiatives

Data collection / QUANTUM



- **5 partners** will test the **QUANTUM label** to deduce **quality enhancement initiatives** to be financed under the Direct Grant
- **10 partners** will work on **measures for data documentation and data collection**

Semantic formats



- Around **8 partners** will work on **semantic standardisation**
 - OSIRIS-RWD,
 - OMOP
 - HL7
 - European standards in line with their respective therapeutic fields

Syntactic formats



- Around **4 partners** will work on **syntactic formats** (tables and variables)

Special formats



- **2 partners** will work on standardisation of **imaging data** (BIDS, DICOM)



The framework report on the various standardization initiatives is work in progress

The HDH works with the Government to prepare a national doctrine for hospital data warehouses



In 2022, the French government has launch a call for project to support the definition of a **national vision** for the creation of a national network of **hospital health data warehouses**.

Announce of **laureates** in two waves : April 2023 & 2024 T1
Call closed in April 15, 2023



Role of the Health Data Hub

- 1 Provide operational support for the interministerial committee in organising the call for projects
- 2 Support the laureates in the implementation of their project
- 3 Manage the community



75M€ allocated to laureates of the call

50% of expenditure covered
3 research and innovation projects to be launched min.

12 to 40 months

Creating a National doctrine for hospital data warehouses will allow to :



Standardise practices and tools at the national level



Define a target territorial coverage



Build a sustainable financial model



FINALISED



Create a Common data foundation for hospital data warehouses



Healthcare data access governance



Common database standardization and interoperability

WORK IN PROGRESS



Data catalogue

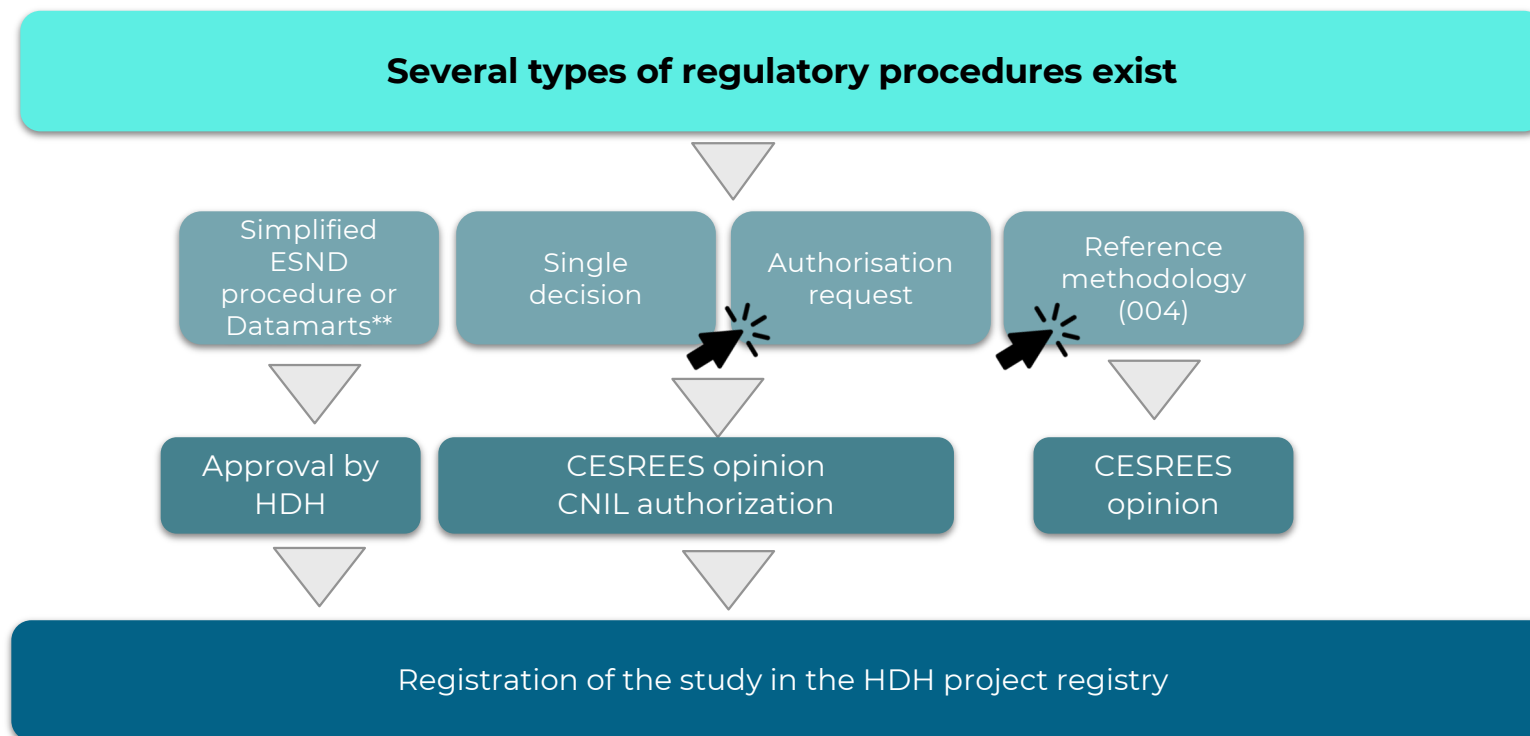


Sustainable financing of health databases and fees for the provision of healthcare data



Standard data provision contract

How to access data from the main database or, more generally, health data ?



* For research involving human subjects, including mixed research that involves data specifically collected for the study along with matching data from the main SNDS database (RIPH), the competent committee is the Committee for the Protection of Persons instead of CESREES.

**To learn about the submission procedures and to submit an access request under these simplified procedures, a guide for each of them is [made available](#).

Requesting access to data | The support of the HDH



Health data



without
starter kit

with
starter kit



The HDH is the **one-stop shop** for data access. Data access requests are made online via a dedicated platform. It provides a **starter kit** to guide applicants throughout the process.

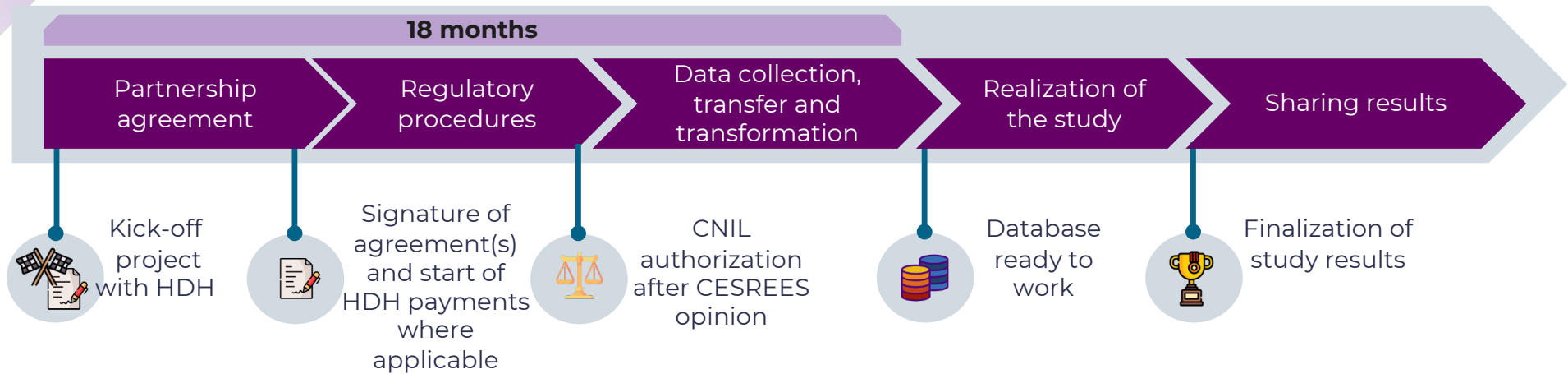


The HDH checks the completeness of the application and, if necessary, forwards it to the **Ethics and Scientific Committee (CESREES) for evaluation**. The committee provides an opinion within one month on the research's **objective** and **methodology**; the need for the use of personal health data; **ethical** relevance; **scientific quality** of the project; and the **public interest** of the project.



If CESREES gives a favourable opinion, and at the applicant's request, the **CNIL** (data protection agency) evaluates the data access request for approval within a two-month period, which can be extended once.

Key stages in a healthcare data project



Some feedback from HDH on the key stages of a health data secondary reuse project:

- Preparation of regulatory file before submission to CESREES: 2 months
- CESREES opinion : 1 month
- CNIL analysis for authorization : 2 to 4 months
- Preparation of CNAM data and agreement with CNAM: 6 months
- Data ingestion and HDH platform deployment: 2 weeks

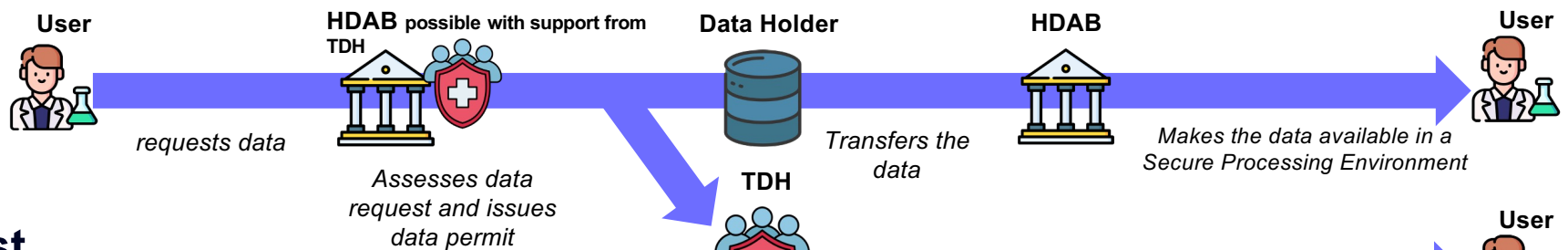
These timescales may vary depending on the complexity of the project.

Changes in data access governance to come with the EHDS regulation

Two harmonised data access procedures across the EHDS

Data Access Application

Pseudonymised data
8 month



Data request

Anonymised data
9 month

