HEALTH DATA HUB

Health Data Hub

Multi-stakeholder workshop RWD quality and RWE use

26th of June 2023

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**

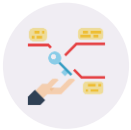
One of the major projects of the **Public Action Transformation Fund (FTAP)**

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

… in a context where uses are multiplying and Europe is getting organised

Multiplication of data uses

Growing demand for accessing SNDS data with an average of 30 projects submitted to the CESREES per month and a 15% increase in CNIL authorisations



This phenomenon should be accelerated by the **publication of the Reference Methodologies**

Complementarity between the **French Insurance System** and the **HDH** allowing for **more use case** on different platforms

Organisation of national actors

Increasing interest of **national agencies** (e.g. HAS - Health national authority) in **real world data** at national level

In its 2020 **Action Plan for the evaluation of innovative medicines, and then in its 2021 Methodological Guide,** the **HAS** stressed the importance of monitoring medicines in real life to verify initial promises : **RWD are complementary to clinical trials**, and make it possible to observe the extent to which trial conditions are verified in real life.

The state of play in France

RWD prove to be strategic in the healthcare system

The 2018-2023 national healthcare strategy promotes:

- **The use of RWD for ongoing evaluation of medical and technological healthcare innovations,** in particular monitoring the therapeutic efficacy of new treatments,
- **The establishment of patient monitoring registers, observatories or cohort studies** "for complex and innovative practices and to encourage research based on health data".

In 2021, the HAS published a **methodological guide entitled "Real-life studies for the evaluation of drugs and medical devices"**, and set up a **RWD unit** within the new Department of Evaluation and Access to Innovation (formerly the Department of Medical, Economic and Public Health Evaluation).

RWD play an increasingly important role in access to reimbursement and pricing

The use of RWD and their complementarity with data from clinical trials is now **recognized at all stages of the evaluation of health products, drugs, medical devices and health technologies.**

It is a prerequisite for the **early access procedure** (observational studies using the **PUT-RD** protocol).
The HAS recommends the integration of patient interest measures, in particular through the use of PROMS and PREMS, for the evaluation of healthcare products.

The SNDS is one of the largest largest RWD databases in the world

With no equivalent in Europe, the French National Health Data System (SNDS) is a **very large RWD database** grouping together several databases.

It has the advantage of **covering virtually the entire French population for all treatments submitted for reimbursement**, over a period of several years.

Expanded by the 2019 law, the SNDS includes numerous data sources, some of which are intended to be copied into the HDH to facilitate their accessibility

Main Database

- A **unique database** in the world that brings together all the **drug and hospital care consumption** of the French population
- This is a huge potential for research.

*However, it does **not contain clinical data**.*

Catalogue

- 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

Other sources

Expanded by the 2019 law, the SNDS refers to **all health data associated with public funding**.

Several **partnership programs** are currently being designed and deployed to explore the best way to work with healthcare institutions (AAP EDS), CLCCs (Unibase program), community medicine (P4DP) or other data hubs (GD4H).

The example of the HYDRO Project

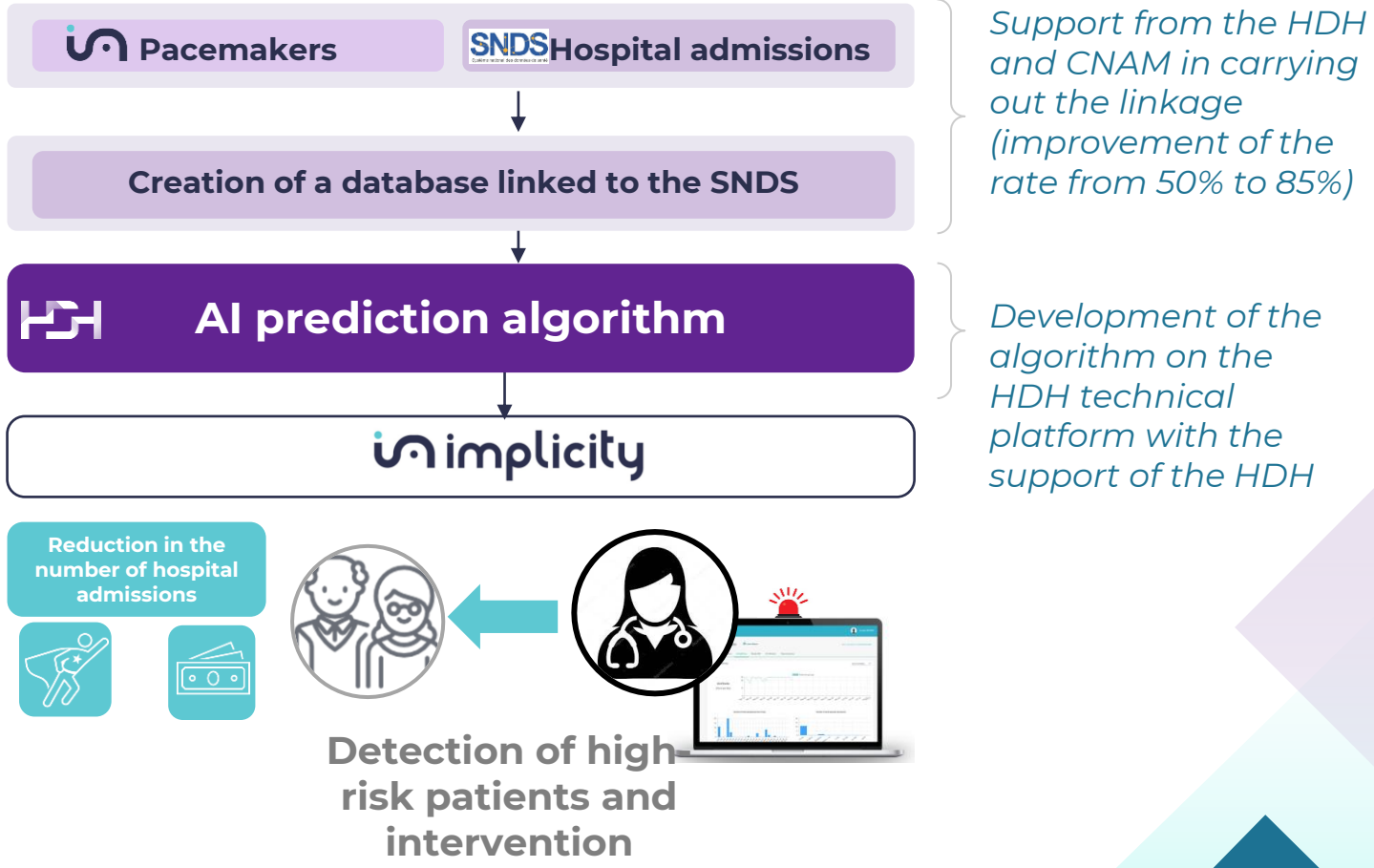
Context

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 patients 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 HDH POC use case: the CombO project

Project

To succeed in the challenge of curing millions of patients suffering from a multitude of different cancers, we need to **analyze a large number of omics, clinical, scientific and medico-administrative databases** and **cross-reference these analyses** to be able **to predict the best therapeutic combinations** by capitalizing on the effects of synergies while reducing the risks of toxicity for the benefit of our patients.

The CombO project aims **to develop an innovative methodology** to **predict which drug combinations are most likely to be effective and safe to move into Phase I clinical trials using several types of data including RWD** in order to rapidly create effective new treatments for patients.

Methodology and operation

CENTRE LEON BERARD — Inria — sanofi

Knowledge graphs	Genomic data
RWD	Clinical trial data
Clinical data	Expert's opinion

Successive data ingestion and study conduct in the Gilles Thomas platform of the CLB

SNDS PMSI, SNIIRAM

Linkage with the SNDS and creation of a predictive model

Support of the HDH and Cnam in the realization of the linkage and the realization of the study in the technological platform of the HDH

Prediction of relevant combinations of molecules to be sent to the clinical phase in oncology

Contribution to the development of innovative medicine in oncology

However, fostering the use of this data means solving some major challenges over the next few years

Organize and promote the collection of RWD

Create simple, clear and secure **governance rules.**

Make these data available quickly to meet research or monitoring needs.

Develop a **policy of mass funding** for healthcare data, which can be very costly to collect and process.

Provide reference methodologies for the collection and use of harmonized data.

Enhance their quality and interoperability

Increase the quality of RWD through extensive standardization of data collection, processing, terminology and design principles, in order to achieve a **high level of quality and reliability** that enables them to be used at different levels.

Encourage interoperability between players (between registers (population-based and practice-based) and other databases, such as the SNDS) to enable efficient data feedback.

Develop innovative methodologies

Develop innovative methodologies for cross-referencing and processing data, in particular using artificial intelligence. For example:

the use of AI to optimize the identification of promising molecules for clinical trials.

the creation of **synthetic control arms** in a clinical trial or to provide contextual evidence to support a marketing authorization.

Do you have any question ?