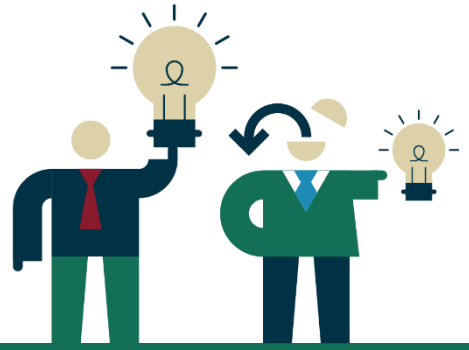
Dealing with healthcare data
An overview of the key European markets

Handling health data can be a challenge. Depending on where you are based, you'll need to have a strong grasp of the national landscape in order to benefit from the resources available to you. In 2019, the French Health Data Hub was born and with it, with increased focus on the wealth and complexities of patient data, we created this toolkit so you can access the guidelines for Germany, Belgium, Italy, Spain, UK and of course France.



At the European Level, a project for a European Health Data Space has been kicked-off recently and a public consultation was launched in May 2021. Its aims are to:

- promote safe exchange of patients' data and citizens' control over their health data
- support research on treatments, medicines, medical devices and outcomes
- encourage the access to and use of health data for research, policy-making and regulation, with a trusted governance framework and upholding data-protection rules
- support digital health services
- clarify the safety and liability of artificial intelligence in health.

Companies that operate in the healthcare space, including sponsors of research or medical studies will want access to existing patients' health data and not all countries have Real World Data (RWD) available to them. France is well advanced with the Health Data Hub.

In Spain, for example, there is currently no public database for patients/health data but the Spanish government intends to remedy this in the next three years through the use of a digital platform.

As such, the French part of this toolkit has been expanded more as there have been more developments regarding health data, including specific procedural steps.

Health and patient data are incredibly sensitive. This is an important area for people to navigate, and we've tried to answer the following questions by country. As you will be able to see, the information we have gathered is disparate so you'll notice different levels of input.

- Is there any public database of patients/health data in your jurisdiction? At which level (national, regional)?
- How can one access such a database?
- For which kind or research / project is it possible to access the database?
- What is the process and timeline, in a nutshell?
- What is the relevant jurisdiction or agency?
- What are the conditions? Does the participating organisation need to share the results of the study to feed the database / to publish its results and does it need to pay a fee?

If you would like to find out more, please get in touch with any of the contacts listed in this toolkit for further information.

France

Système National des Données de Santé (SNDS) – the first public patients' data base opened for research in 2016 to 'French Health Data Hub' in 2019, including Artificial Intelligence (AI)

In 2016, France enacted a Law to set up the so-called SNDS, which is a public database for patients' personal data gathering important databases operated by various health administrations in particular the "SNIIRAM" – database of the social security administration in charge of the National Health Insurance Program - and the "PMSI" – central base for patients' data collected from their stays in hospitals.

The SNDS Law of 2016 opened access to those patients' public databases. Operators in the private sector, such as Life Sciences Industry Players, could benefit from this access to conduct projects if they were of a public interest. By way of illustration, the industry has got the opportunity to conduct research analysing patients' health data with the view of better understanding their care journey and demonstrating the contribution of pharma products to improve their quality of life.

In 2018, a public report to the Parliament made the SNDS a priority to increase the development of AI:

– *"Artificial intelligence in health opens up very promising prospects for improving the quality of care for the benefit of patients and reducing its cost - through more personalised and predictive care - but also its safety - thanks to enhanced support for medical decision-making and better traceability. It can also contribute to improving citizens' access to healthcare, thanks to pre-diagnostic medical devices or assistance in finding their way through the healthcare system".*

This report had recommended the setting up of an extended health system platform to meet the needs and expectations around the development and training of AI and to continue to ease the conduct or research on existing health data.

In 2019, the French Health Data Hub extended patients' databases to develop AI for the ultimate benefits of patients. This extended health system platform is the so-called French "Health Data Hub" (HDH).

The HDH has been created by the Law of July 24, 2019. It aims to cross-reference into a catalogue of the SNDS health data base together with other health databases in order to facilitate access for research on patients' health data, with full respect for the privacy of such patients.

Thanks to AI, the HDH can contribute to various health improvements:

– better detect the symptoms and make a predictive follow-up of the spread of a disease;
– exploit the results of analysis (medical imaging, etc.);
– submit new diagnostic hypotheses;
– formulate more personalised therapeutic proposals;
– improve the detection of side effects of a drug during clinical trials;
– facilitate the analysis of basic research results through automatic data mining;
– better detect pathologies and reduce medical errors.

France

Procedure

– Any project leader from the private sector willing to access the HDH for research purposes is first required to show that the research project is of public interest: the project is first reviewed by the “CESREES” (Ethics & Scientific Committee).

– Projects of public interest which are eligible for access to the HDH further to the CESRESS prior opinion are then submitted to the CNIL (French Data Protection Authority) either through the standard pre-authorisation procedure applicable to the treatment or personal health data, or through the simplified compliance certification process (commitment of the research leader to treat the personal health data in compliance with the technical specifications pre-determined by the CNIL and called “Reference Methodologies”).

– The HDH administration informs the concerned data controllers (e.g. the social security administration for research calling access to the SNIRAM – database of the national health insurance program)

– The achievement of those preliminary steps opens the signing of the appropriate contract that will set out the terms and conditions of access to the HDH (note: operators from the private sector are required to pay access fees).

Key steps

1. Management of access requests

2. Use of Data

3. Valuation of expertise and remuneration of data controllers

Roadmap and vision for 2022

– Pursue and accelerate the development and implementation of the platform;

– Enhance the data catalogue, in particular:

• the so-called "BNDMR" - a separate database dedicated to hospital patients suffering from rare diseases (today operated by the AP-HP – Group of Public Hospitals of Paris – under an agreement with the Ministry of Health) will be included into the data bases catalogue of the HDH by the end of 2021,

• Since March 2021, the HDH administration has being coordinating with the Health Insurance administration to collect patients' data regarding Covid vaccinations and treat such data for the purposes of managing the sanitary emergency and improving knowledge on Covid.

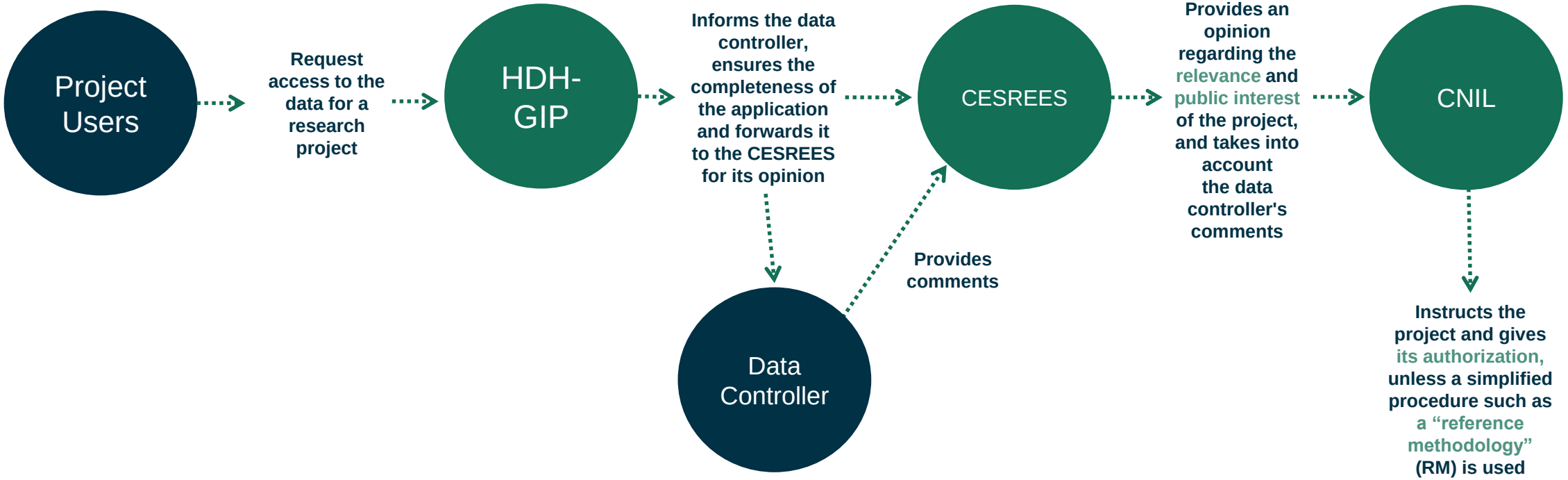
– Develop a range of services to facilitate data processing and their use;

– Increase national and international visibility, in particular:

• The HDH administration has been representing France since February 2021 in the EU program (EU Commission + 26 Member States) aiming at creating a European Health Data Space in the next two years for encouraging research and innovation

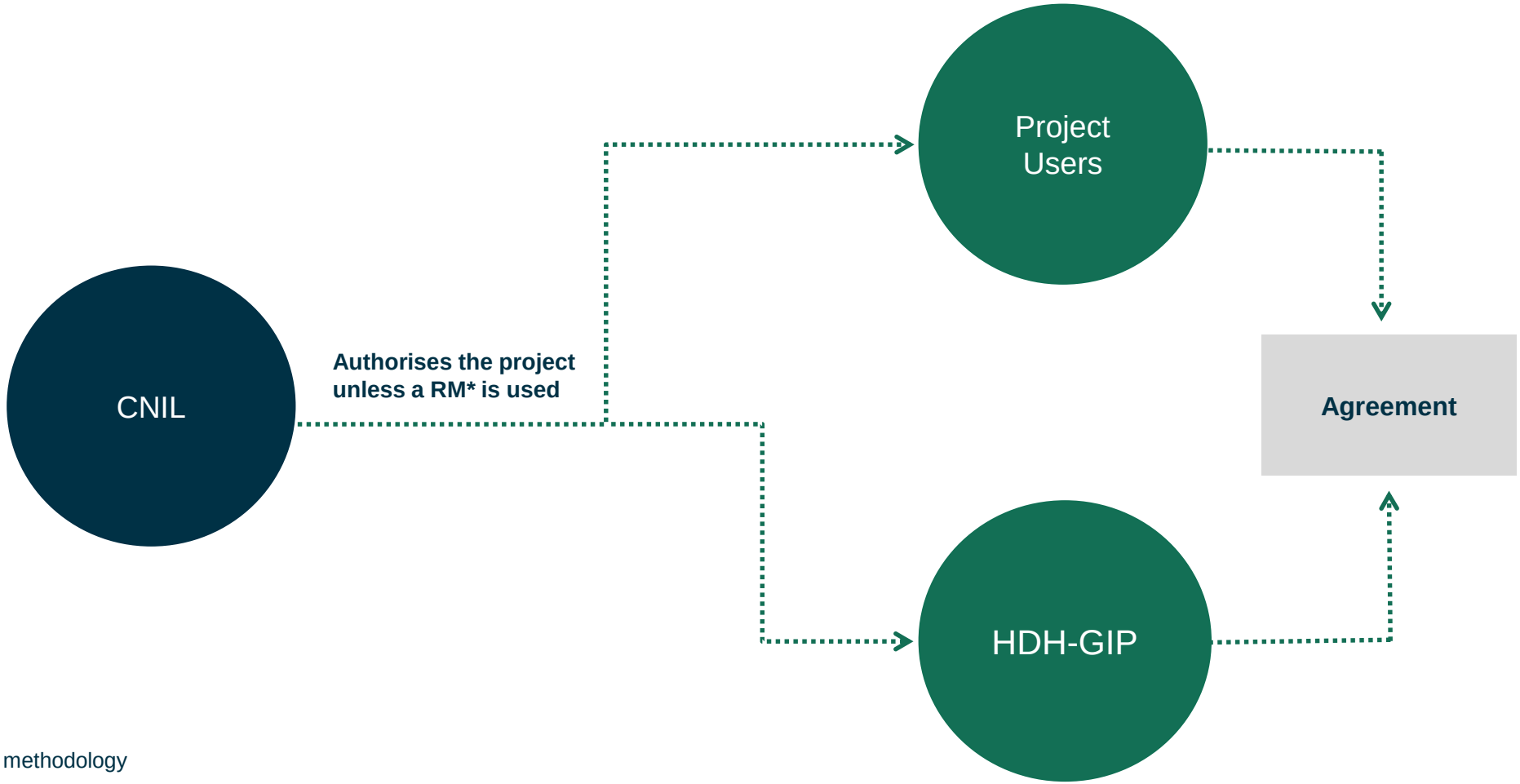
France

Step 1: Management of project users' requests for access to the HDH



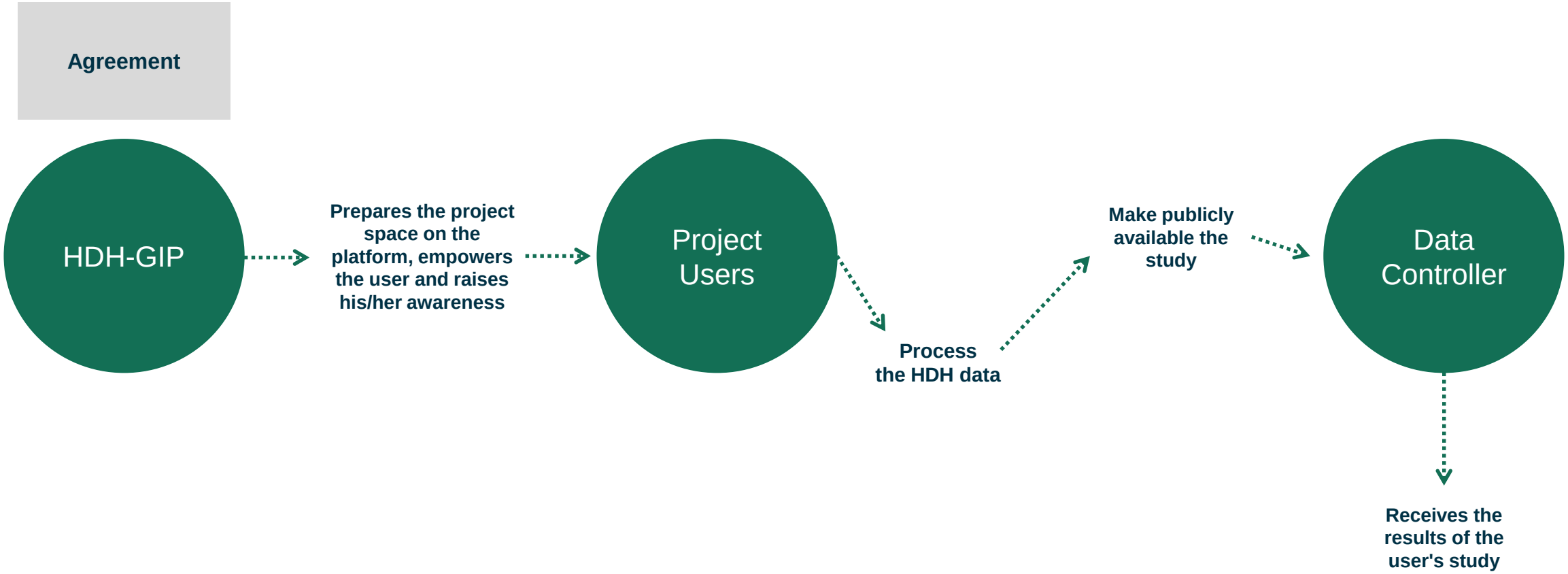
France

Step 1: Management of project users' requests for access to the HDH



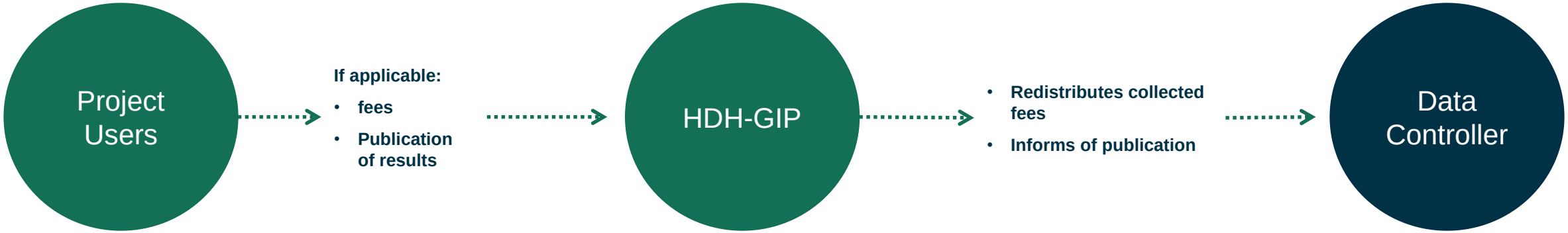
*RM = reference methodology

France
Step 2: Use of data



France

Step 3: Valuation of expertise and remuneration of data controllers



France
French Health Data Hub - illustrations

Since the implementation of the HDH in 2019, around 40 research projects have been submitted, 8 of which are currently running. Three examples by way of illustration:

- **DeepSarc:** aims at identifying the best therapeutic strategies for the treatment of sarcoma, a very complex and varied cancer. For nearly 40 years, studies have been conducted without being able to determine the value of chemotherapy to treat sarcoma, and whether it should be used before or after surgery;

- **HUGO-SHARE:** aims at limiting drug interactions and drug discontinuations for at-risk hospitalised patients. During their stay in hospital, elderly patients already treated for chronic diseases very often receive additional treatments. These patients may therefore be exposed to a significant risk of drug interactions or, on the contrary, suffer from the interruption of their treatment, which may lead to more or less serious health consequences;

- **REXETRIS:** aims at improving the personalisation of immunological treatments for kidney transplant patients. The project is studying the relationship between exposure to immunosuppressive drugs and the long-term future of the kidney transplant patient. In the context of lifelong treatment, knowledge of the relationships between patients' exposure to drugs and long-term effects would allow to optimise therapeutic strategies, doses and also the formulas of these drugs.

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Belgium

In Belgium the FAIR portal centralises metadata and data on health-related databases funded or owned by the government. The portal aims to provide an overview of existing health databases and to make data findable and available to the public in order to increase public health knowledge and to adjust health care policy, with respect for the privacy of the patient, the healthcare professional and medical confidentiality.

The FAIR portal is the open data platform of healthdata.be, a department of Sciensano ((federal scientific institution and the federal research centre for public health, animal health and food safety in Belgium). The mission of healthdata.be is to facilitate the exchange of data between healthcare professionals, patients and researchers and the re-use of data.

One of the external sources of the FAIR portal is metadata.healthdata.be. Metadata.healthdata.be is an internal data-entry application intended for authenticated users to enter, edit or manage information and metadata about Belgian healthcare-related databases and/or data collections. In particular, a manager of a Belgian healthcare-related database or data collection can enter information about their project on metadata.healthdata.be. After review and approval, the information about the data collection will automatically be published on the FAIR portal under the source Metadata.

Legal framework (federal level)

Section 9 of the Law of 10 April 2014 contains various provisions on health. This Section 9 allows Sciensano and the National Institute for Health and Disability Insurance (INAMI-RIZIV) - a federal institution that organises, manages and controls the "compulsory insurance" in Belgium - to collaborate in the systematic collection of their health data. The objective of this collaboration agreement is to provide authorised users with a secure and high-performance data warehouse that enables research and vigilance, improvement, management and continuous learning in the field of health and healthcare.

In particular, the cooperation has led to the creation of a technical service, healthdata.be, which makes applications, processes and knowledge available so that the data collection and data dissemination of the scientific databases take place in an efficient and safe manner.

How can one access the database

One can access the databases and/or datasets by filling in a Request Form. After completion of the Request Form, a notification will be sent to the data manager of the database of interest. The data manager will review your request and will approve or reject it, or contact you for more information.
It should also be noted that the control of steering group of the Healthdata.be platform and the Information Security Committee must give their approval to the access to the database.

Submitting a request can not only be done by researchers, but also by service providers and knowledge institutes active in the field of healthcare (including drug development, medical device development, …), health economy, information management, privacy and security, legislation (universities of applied sciences, …). …, both public and private organisations, profit as well as non-profit (data science communities, open data communities, open Knowledge communities, …) organisations.

Belgium

Timeline
The estimated timeline depends on the owner of the dataset or database and how often the committee that has to give its approval meets. The duration can easily pass a period of six months.

Conditions
Paying a cost or sharing the result will depend on the owner of the database or dataset. The participating organisation and the owner have to conclude a protocol to further specify the conditions.

Attention: in any case a cost must be paid to Healthdata.be to facilitate access to the database (for example: in order to create a view so that only the necessary data from the database is made available).

The relevant jurisdiction or agency

- Control (or steering) group of the Healthdata.be platform
- The Sectoral Committee for Social Security and Health (Privacy Committee) = federal
- The Sectoral Committee of the National Registry (Privacy Committee) = federal

Other remarks

I. Healthcare providers will gradually be asked to pass on their data to the platform. Healthcare providers providing data to the platform will receive regular reports analysing the data they send.

II. reference is also made to the 'eGezondheidsplan 2013-2018' by the Interministerial Conference on Public Health (IMC VG; Interministeriële Conferentie Volksgezondheid): Action point 18 “Inventory and consolidation registers”

III. The data collected in Healthdata.be may be communicated solely for purpose of improving the quality and management of the Belgian healthcare system. They are therefore only transmitted to duly authorised researchers and doctors responsible for monitoring certain diseases. In addition, registration on the Healthdata.be platform must be done with an eID card.

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Italy

In Italy a public database for patients/health data having the same features and scopes of the French public Health Data Hub is not available.

Under Law Decree No. 179/2012 (the "Decree"), Italy has adopted the electronic health records (HER – Fascicolo Sanitario Elettronico) at regional level for patients both of the NHS and private healthcare services providers.

HER is an IT tool that brings together data and documents (digital or digitalised) concerning each patient's health which are generated by the NHS and private healthcare services providers (including medical and pharmaceutical prescriptions, bookings, medical records, and certificates). Its function is to share patients' medical history between HCP or HCO.

The update of HER is carried out by HCO and doctors of both the NHS and private healthcare providers.

The patient and the authorised HCP can access the HER with safe modalities (smart cards or public identification service "SPID"). Additionally, the access to HER is not permitted to third parties (e.g. insurances, employers).

However, under section 12(5) of the Decree, the consent to access HER shall be provided once from the relevant patient, except for emergency cases which shall be regulated with specific procedures.

In any case, the patient's failure to provide consent must not affect its right to healthcare.

At the beginning, the insertion of the patient's health and personal data in the HER was subject to prior patient's consent. Anyway, pursuant to the art. 12(3) of the Decree as recently amended, patient's consent for these operations is no longer required.

Moreover, irrespective of the patient's consent, the government bodies involved in the management of public health (such as Ministries and the Regions) can access data included in the HERs – without the use of the patient's identification details – in order to plan the therapies or to manage health emergencies and for research purposes.

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Spain

Is there any public database of patients/health data in your jurisdiction? At which level (national, regional)?

There is currently no public database for patients/health data in Spain. There are, however, other kind of databases which are relevant in so far as making accessible certain type of patient and health data, but they do not encompass the characteristics of the French public Health Data Hub.

For instance, Royal Decree 577/2013, of July 26, which regulates the pharmacovigilance of medicinal products for human use, sets forth the functions of the Spanish Healthcare Agency (Agencia Española de Medicamentos y Productos Sanitarios) in the field of pharmacovigilance.

Among others functions within this field, the Agency promotes, creates and uses computerised health databases that serve as a source of information for conducting pharmaco-epidemiological studies with the participation of health administrations of the Autonomous Communities and health professionals. It also stimulates the creation and maintenance of a unified registry of available databases.

In virtue of the above, there are some relevant databases in Spain, none however with the characteristics of the French public Health Data Hub.

Lastly, the Spanish Ministry of Health has recently announced a project to create, in the next 3 years, a digital platform which will include all the medical information of citizens, for the massive analysis of data within the National Health System, using artificial intelligence techniques for its application, both in clinical practice and in research, and to unify/merge all public and private health systems' information.

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Germany

Is there any public database of patients/health data in your jurisdiction? At which level (national, regional)?

In Germany, several (local) registries exist, which contain real-world data about specific diseases or fields of application (such as the cancer registries of the Bundesländer). Yet, there is a lack of a such databases on a federal / national level.

Under the recently enacted Digital Healthcare Act ("*Digitales Versorgungs-Gesetz" - DVG*), health data from the statutory health insurance companies in Germany will be made available and processed for research and development in aggregated and anonymized via a central Research Data Centre (so-called "Forschungsdatenzentrum") according to Sec. 303a of Book V of the German Social Code (SGB V). Upon request, these data can be made accessible to research institutions, in certain cases individual data sets may also be disclosed.

For which kind or researches / project is it possible to access the database?

Access to the data collected in the Research Data Centre is currently limited to non-commercial research. Lobbying initiatives to open the database also for commercial research have not been successful.

What is the relevant jurisdiction or agency?

The Research Data Centre will be located at the Federal Office for Drugs and Medical Devices (BfArM) and the Robert Koch Institute (RKI) will act as a trust centre.

By joining the MII-initiative it will be possible for all participants to collaboratively use data by the research community and health care system across institutions and locations.

How can one access to such data base ?

In order for the eligible research entities to gain access to the data at the Research Data Centre, inter alia the following requirements which are enshrined in the Data Transparency Order (Datentransparenzverordnung – DaTraV) must be met:

The applicant must be an authorised user;

The stated purpose of use corresponds at least to one of the legally allowed research purposes;

The data processing is necessary for the fulfilment of research tasks and it is clearly stated in the application that the scope and structure of the requested data is appropriate and necessary to answer the question under investigation.

What is the process (helicopter view?) What is the approximate timeline?

The Research Data Centre shall decide within three months after the application has been filed.

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Germany

What are the conditions? Does the participating organisation need to share the results of the study to feed the database / to publish its results and does it need to pay a fee?

Due to the fact, that the data collected in the Research Data Centre is not available for commercial research, other sources of Real Wold Data played an important role in Germany. An important development in Germany in this respect is the introduction of a voluntary provision of data for research purposes via the electronic patient record in accordance with the new Patient Data Protection Act.

In addition, there is a “Medical Informatics” funding scheme, which is also known as the “the German Medical Informatics Initiatives (MII)”. In four funded consortia, institutions of medical faculties at German universities will be cooperating with research institutions, commercial enterprises, health insurers and patient representatives to develop a framework for the use of research findings for the direct benefit of patients.

Access to this database will be restricted to those who are mainly involved in treatment. The MII is currently in its funding phase and the German Federal Ministry of Education and Research (BMBF) is investing a total of 150 million euros in the Initiative trough 2021, this phase is also called the “Development and networking phase”. The next step from the end of 2021 to 2025 will be the “Consolidation and further development” phase, in which results and solutions will be developed further and consolidated.

By joining the MII-initiative it will be possible for all participants to collaboratively use data by the research community and health care system across institutions and locations.

UK

Is there any public database of patients/health data in your jurisdiction? At which level (national, regional?)?

There is no single unified public health database.

The NHS hosts a national database where all patient data and records are held and accessed by healthcare staff and service providers, but this is not publicly available.

How can one access such a database?

For non-public data, agreements can be reached with NHS Digital whose legal duties include collecting, analysing and publishing health and care data. In the future, NHSX will be responsible for overseeing data-sharing agreements with industry partners.

Patients can make subject access requests through NHS Digital to access their own data.

What is the relevant jurisdiction or agency?

For the NHS database mentioned above, NHS Digital (officially, the Health and Social Care Information Centre), an executive non-departmental public body reporting to the Department of Health and Social Care.

For clinical trial research, the responsible body is the Medicines and Healthcare products Regulatory Agency (MHRA).

For which kind of research / project is it possible to access the database?

If confidential patient information is being used to develop a new technology or product which is not for direct care, this is classed as research and should conform to the UK Policy Framework for Health and Social Care Research. It must also meet the standards and criteria for research undertaken in the NHS, including information governance standards.

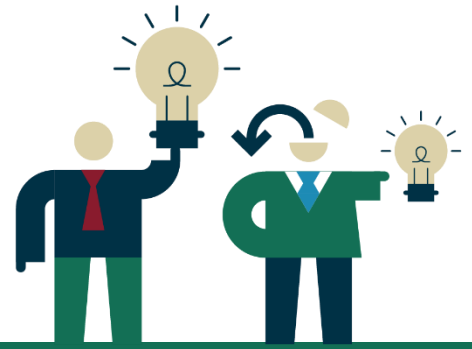
Research and data from clinical trials is made public at the end of the trial, with patients involved anonymised. All clinical trials must be registered on a publicly accessible database within 6 weeks of the recruitment of the first participant. The research can be privately requested (e.g. at the request of pharmaceutical companies), or requested by Public Health England, the NHS or Universities for example.

Patients are entitled to opt out of their confidential patient information being used for research and planning purposes, and can do so via the NHS Digital National opt-out service.

What is the process (helicopter view?) What is the approximate timeline?

Clinical trials often last a year or longer, after which the results are made public (see below).

The NHS must respond to an individual's data subject access requests within one calendar month. NHS Digital is not otherwise obligated to share data according to a particular process or timeline.



UK

What are the conditions? Does the participating organisation need to share the results of the study to feed the database / to publish its results and does it need to pay a fee?

NHS Digital currently controls the NHS database, whilst NHSX will in the future be responsible for overseeing data-sharing agreements with industry partners and will do so according to the following “guiding principles”:

Any use of NHS data, including operational data, not available in the public domain must have an explicit aim to improve the health, welfare and/or care of patients in the NHS, or the operation of the NHS. This may include the discovery of new treatments, diagnostics, and other scientific breakthroughs, as well as additional wider benefits.

Where possible, the terms of any arrangements should include quantifiable and explicit benefits for patients which will be realised as part of the arrangement.

NHS organisations entering into arrangements involving their data, individually or as a consortium, should ensure they agree fair terms for their organisation and for the NHS as a whole.

Any arrangements agreed by NHS organisations should not undermine, inhibit or impact the ability of the NHS, at national level, to maximise the value or use of NHS data.

Any arrangements agreed by NHS organisations should be transparent and clearly communicated in order to support public trust and confidence in the NHS and wider government data policies.

Any arrangements agreed by NHS organisations should fully adhere to all applicable national level legal, regulatory, privacy and security obligations, including in respect of the National Data Guardian’s Data Security Standards, the UK General Data Protection Regulation (UK GDPR) and the Common Law Duty of Confidentiality.

NHS Digital is not allowed to sell data for profit but operates on a cost recovery basis. It is allowed to charge for the cost of processing and delivering the service, but not for data itself. The charge depends on the type of application, amount of data requested, and the amount of work that NHS Digital will need to do.

For clinical trials, results are made public within 6 months for paediatric trials, or within a year for non-paediatric. The UK makes information about trials being conducted in the UK available to the public, patients, researchers and clinicians via the Health Research Authority (HRA) website and UK Clinical Trials Gateway. Further, the results of clinical trials are usually published in specialist medical journals and online libraries of evidence.

Some of the most well-known examples are:

- **The Lancet medical journal**
- **British Medical Journal (BMJ)**
- **The New England Journal of Medicine**
- **Cochrane Library – a collection of high-quality evidence**
- **NHS Evidence database**

Information on clinical trial fees can be found here.

NHS COVID-19 data

In response to COVID-19, the NHS created the NHS COVID-19 Data Store. This data remains under the control of the NHS. No confidential personal data will be shared unless:

- applicants can demonstrate an involvement in the COVID-19 response;
- there is a specific supporting legal basis to do so i.e. where another organisation in receipt of a Control of Patient Information Notice issued by the Secretary of State; and
- applicants requesting confidential patient information have gained ethical approval from the Health Research Authority.

Further information and step by step guides for different applicants are available here.

UK

Any other points to note?

Post-Brexit heath data flow between the EU and UK

The European Commission (EC) has carefully assessed the UK's law and practice on personal data protection and has concluded that the UK continues to ensure an essentially equivalent level of protection to the one guaranteed in the EU under the GDPR and the Law Enforcement Directive and the EC has adopted an adequacy decision allowing for transfers of personal data (including heath data) to continue to flow freely between the EU and UK.

The formal adoption of the adequacy decision has a number of benefits for the European health sector, including enabling continued cooperation between EU and UK researchers on clinical trials, the management of cross-border threats such as COVID-19 and the facilitation of information exchanges between regulators.

UK General Practice Data for Planning and Research (GPDPR)

The General Practice Extraction Service (GPES) is the centrally managed, primary care, data extraction service which is currently used in the UK. Data is collected either as anonymised data or patient-identifiable data from general practitioners and used to improve patient care.

NHS Digital has been consulting on a new framework for ways to improve data collection from general practitioners to support the improvement of healthcare research and planning.

As a result of concerns raised about the use of health data, the implementation of GPDPR, which was intended to commence on 1 September 2021, has been delayed to permit further time for consultation. As of 19 July 2021, a new start date has yet to be confirmed.

The framework once implemented is intended to reduce the administrative burden to access patient data, improve data security by implementing mechanisms for reviews of access applications and provide more transparent information which is easier to understand for patients in relation to how their data is used.

The existing GPES will continue to operate until the GPDPR is put in place following approval and appropriate testing.

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