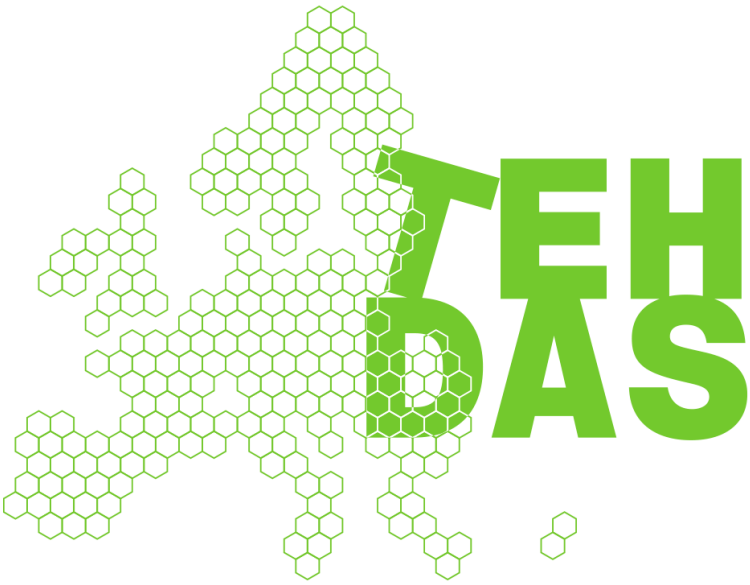

Towards European Health Data Space

Milestone 5.4

Description of steps in accessing individual-level data for national and EU researchers in a selection of centralised systems and decentralised systems

6 April 2022

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0 Document info

0.1 Authors

Author	Partner
Mario JENDROSSEK	French Health Data Hub
Océane XAYAKHOM-DAUVERGNE	French Health Data Hub
Imane ZIDI	French Health Data Hub

0.2 Keywords

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Contents

1 Executive summary

As part of the TEHDAS joint action, coordinated by Sitra, the Finnish Innovation Fund, and gathering more than 25 Member-States, this report aims at describing the steps in accessing health data for national and EU researchers, across a range of different national settings, and more precisely in selected centralised (Finland, France) and decentralised (The Netherlands, Spain) systems. The focus has been broadened to obtain a better understanding of the selected institutions' functioning and scientific impact, at both national and international levels. Thus, the report also looks for information on institutional structure, strategic objectives, relationships with data custodians and with citizens, but also the scientific activity and outreach within and outside the health data ecosystem at national, EU and international levels.

This report relies on a tailored methodological approach, that consists in designing an exhaustive questionnaire that covers and addresses the main areas of interest. It was supplemented with additional desk research on the selected institutions. Steps in accessing health data for the secondary use have been divided as follows: 1) defining the end-user categories; 2) defining the data access procedure and requirements; 3) looking at the review process and committees involved in the process; 4) providing further information on the authorisation process (final decision regarding a request, mainly a permit issue and/or the signature of a data use/access agreement); 5) the preparation of the data for the purpose of the approved research study, which implies the deployment of a specific secure project environment or a data file transfer and preparation, along with software included. Every one of these steps have been presented in more detail in this document and reveal the similarities in the approaches of the structures interviewed, and even allowed us to sketch out a generic health data access procedure.

Studying the health data access procedures in different national contexts demonstrates the importance of a one-stop shop for health data in national settings and the need to foster the implementation of national nodes and centralised health data access review processes.

This report acts as groundwork for recommendations based on the solutions identified to address health data platforms related challenges: governance, ensuring a trustworthy approach for data holders and citizens, facilitating the data user journey by developing specific tools while continuing to work on guaranteeing data interoperability.

2 Context

Fostering and facilitating the secondary use of health data, as well as health data sharing is an objective shared across European Union member-states. The European Commission encourages member states to invest in the digital transformation of their health services, by making good use of health data, (often characterised as a "goldmine" by experts), while ensuring that the re-use of health data supports health research and innovation for better public health systems.

The TEHDAS ("Towards the European Health Data Space") project was launched within that context. Its fifth work package (WP5) develops options for a transparent and FAIR[1] operational framework and governance models for the exchange and secondary use of health data, based on trust, citizen empowerment and a common good.

The activities carried out in this work package include **the review of the steps in accessing individual-level data for national and EU researchers**. The following report addresses these steps in a selection of centralised systems (Finland, France) and decentralised systems (The Netherlands, Spain).

Five health data platforms have been included across four member states: Health Sciences Institute in Aragon (IACS) in Spain, Health-RI and Statistics Netherlands, as three structures evolving in decentralised frameworks, and Findata and the French Health Data Hub (HDH) as two national nodes (centralised) for health data access. The institutions included in this report have been chosen in collaboration with TEHDAS partners involved in WP5.

The results of this report stem from an exhaustive questionnaire that has been developed with the purpose to better **understand the health data access process across a range of data custodians in four national settings across the European Union**. The questionnaire responses provide us with an overview of the structures' functioning and strategic roadmaps.

For the purpose of this report, a specific questionnaire was developed with a focus on 16 categories, each including more detailed questions:

1. Institutional Governance and Structure
2. Legal basis of the institution
3. Institutional strategy
4. Decision-making
5. Organisational structure
6. Data types and Sources
7. Data access request procedure
8. Process review
9. Access permit
10. Effective Data Sharing
11. Technological Capabilities
12. Business Model and Sustainability
13. Pricing Model
14. Sustainability
15. Scientific Activity and Outreach

[1] The FAIR principles contain guidelines for good data management practice that aim at making data FAIR: findable, accessible, interoperable, and reusable.

16. COVID-19 data centralisation initiatives

For each category of analysis general trends (general observations among the five structures) were identified with a more detailed description of whether they represent ad hoc or internationally recognized practices.

3 Institutional summary

This section aims to provide an overview of data access procedures and specificities by drawing general portraits of selected institutions: a short description, elements of background information regarding the institution's implementation, specific know-how and best practices.

3.1 Statistics Netherlands, The Netherlands

CBS (Centraal Bureau voor de Statistiek) is the Central Bureau of Statistics in the Netherlands (Statistics Netherlands), implemented by law. This is an autonomous administrative authority (in Dutch: ZBO), STATISTICS NETHERLANDS performs public service tasks but operates independently; the Minister of Economic Affairs is politically responsible for relevant legislation. Statistics Netherlands is financed mainly from the State budget. Established in 1899, the institution benefits from decades of national data collection and management expertise. **There are two main types of data access offered by Statistics Netherlands**: access to statistical-level data and access to microdata. The statistical data is available for download through the Statistics Netherlands website (Statline data portal) or may be (automatically) retrieved via the OData protocol. The micro-data requires a specific data permit request.

The access to (health) microdata is only provided to institutions - which must have a research or statistical core activity -, not to single individuals. International institutions are preferred to apply through joint collaboration with Dutch institutions. CBS started this facility about 20 years ago; this is evidently reflected in the know-how and the efficient turnaround times for processing data permit requests (2-8 weeks, if the requesting institution is pre-registered).

Microdata access is done through 2 steps: 1) Pre-registration (authorisation) of the requesting institution, which takes 1-2 month. It is done once and is not required for future projects submitted by the requesting institution for as long as the authorisation is valid. 2) project review by Statistics Netherlands. This is a review conducted by Statistics Netherlands to ensure the scientific validity of the project. The microdata is available in a secure environment and may only be used for statistical purposes; moreover, the research description must be well-defined in view of the purpose limitation as prescribed by the General Data Protection Regulation (GDPR).

The datasets collected and/or managed by Statistics Netherlands include other domains: economic, social, construction, agriculture, labour, trade and numerous others. This facilitates linking data of different themes for the purpose of conducting interdisciplinary research projects.

The types of health data available at Statistics Netherlands includes health insurance claims data, causes of death, DRGs, and other healthcare administrative data (including hospital data). Disease-specific registries, biobanks, and other clinical databases are not available through Statistics Netherlands. COVID-19 testing data from the municipal health services is also available and soon will be linkable to economic, social and environmental datasets. In

collaboration with prominent data suppliers, CBS also facilitates in its secure environment the possibility of linking CBS microdata to external data, like Lifelines (a large, multigenerational cohort study with health-related data from the northern population of the Netherlands) and SHARE (The Survey of Health, Ageing and Retirement in Europa, a multidisciplinary and cross-national panel database of micro data on health, socio-economic status and social and family networks.

3.2 Findata, Finland

Findata is the Finnish Social and Health Data Permit Authority, founded in 2019 and operational since January 2020. Findata has the authority to grant secondary use permits for all Finnish health and social care data gathered within primary care, such as examination and treatment, as well as for national registries. It receives and processes the data and provides it in a secure environment for analysis. Findata's goal is to streamline permit processing, secure the use of health data and enhance data protection for individuals.

The institution was established through a legal reform[2] driven by political will and organised based on previous national experiences and projects. This one-stop-shop encourages users to look into multiple sources when designing a research study. Services of data linkage are provided by Findata when needed. The databases included in the catalogue are numerous from multiple national data holders, contributing to a diverse portfolio of available health and social data sources (pension, social benefits, disease-specific registries, prescriptions and medications, health insurance claims, …). Data can be requested by individual citizens, not just researchers. Data is currently not accessible to European or international policy makers.

The data permit request includes both the data request and the access permit when the query involves multiple national data sources. Ethical and data protection reviews are not required by Findata but might be overseen in some cases by:

- the Ethics Committee of the National Institution of Health and Welfare when a data permit is requested for data collected based on consent before 1 May 2019, and a data permit decision needs to be supported by an assessment of whether the planned purpose and disclosure of the data corresponds with the purposes for which the data have been originally provided. (Approximately 5 to 6 weeks)
- the Office of the Data Protection Ombudsman (Approximately 2 to 3 weeks or more)

The target time for permit request processing is 1-3 months. The target time for data processing following a decision is 60 working days. Overall timeline for the data access process ranges between 3 and 5 months. A main finding is that the impact of administrative coordination between multiple data holders affects the timeliness of data access.

3.3 Health Data Hub, France

Officially instituted in 24, July 2019 through the Law No. 2019-774 of 24 July 2019 on the organisation and transformation of the healthcare system[3], the Health Data Hub (HDH) is the

[2] Ministry of Social Affairs and Health. "Secondary Use of Health and Social Data." Accessed January 10, 2022. https://stm.fi/en/secondary-use-of-health-and-social-data.
[3] LOI n° 2019-774 du 24 juillet 2019 relative à l'organisation et à la transformation du système de santé (1), 2019-774 § (2019).

unique national gateway to health data in France. The HDH's vision is to ensure a simple, unified, transparent, and secure access to health data for public interest research with the goal to improve the quality of care and patient support.

To that end, the Health Data Hub centralises health data requests from any type of project coordinators and verifies the data requests completeness before sending them to the French Scientific and Research Ethics Committee (CESREES), which renders a decision before sending it to the French Data Protection Agency (CNIL), that has a 2-month period to render a final decision regarding the health data access authorisation (data permit). Beyond providing support throughout the regulatory permit request process to access data, the HDH also strives to provide a state-of-art and secure platform available for researchers, a documented data catalogue built in a progressive manner along with a range of tools to bring together key stakeholders in the health sector. This data catalogue consists of copies of databases belonging to the National Health Data System called SNDS first created by law in 2016 and enlarged in 2019 by the same law initiating the creation of the HDH. The SNDS is a French specificity and one of the richest databases in the world. It compiles three major pre-existing databases covering nearly the entire French population and providing data associated with health insurance reimbursement, hospital stays and consumption of care as well as medical cause of death.

Thanks to its technological platform, the HDH will be able to make available data extractions of the SNDS and allow cross-referencing of databases to authorised public interest research projects in a partitioned and secure project environment.

At this time, the catalogue of the HDH is in the implementation phase, meaning that not all databases identified to be added to the catalogue can be accessed through the platform and access is granted on a project-to-project basis. To date, 18 priority databases have been identified to be added to the catalogue building on the SNDS database (amongst which 3 Covid databases). New databases will be added gradually to enrich the catalogue.

In a nutshell, while the HDH acts as a unique gateway centralising health data permit requests, it does not act as a data permit authority and the regulatory processes for authorisation and access are decentralised. Data permit requests have to be examined by the Ethical and Scientific Committee for Research, Studies and Evaluations in the field of health (CESREES) before being authorised by the French data protection agency (CNIL). The HDH is only allowed to make data accessible to projects authorised by the CNIL.

3.4 Health-RI, The Netherlands

Health-RI is a public-private partnership of organisations involved in health research. It is a foundation that gathers more than 70 stakeholders in the Netherlands. Health-RI missions focus on the building of an integrated health data research infrastructure accessible to researchers, citizens and care providers, facilitating and fostering the optimal use of knowledge, tools, facilities, health data and samples to enable a learning healthcare system and accelerate sustainable and affordable personalised medicine and health.

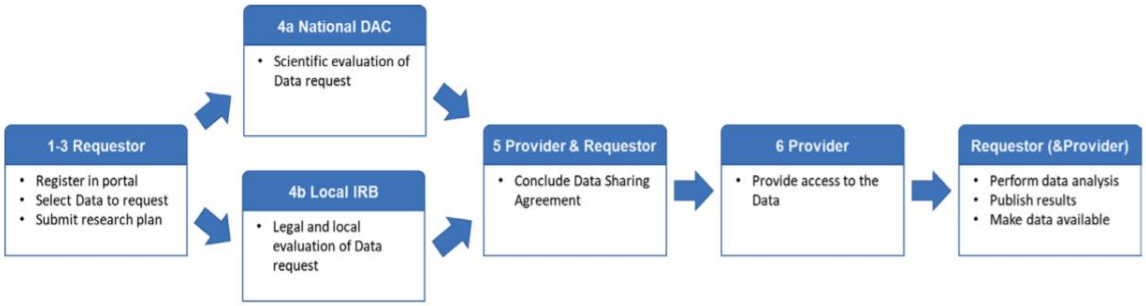
The institution is neither a data permit authority nor a data holder. Health-RI is a network organisation, that provides tools and standards to support health data reuse. The federative approach of the institution, by bringing the wealth of data sources closer to the research community, mimics the Dutch healthcare system and its design. Health-RI has inherited and

further developed the BBMRI-NL catalogue[4]; which enlists the metadata of tens of bio- and data banks in the Netherlands.

There are currently several authorised Institutional Review Boards (IRBs), and their requirements vary. Going forward, there is a vision to bring entities together in a national data access committee. This step is currently being tested for COVID-19 data; where Health-RI and its partner entities are preparing a pilot set-up with a hybrid approach: first, a scientific review by a national Data Access Committee (DAC), and second, a legal review by a local IRB. The process to request access is largely channelled via the individual data holders. It is very fragmented and can range from a well-organised online request to an unofficial ad-hoc request via email. Health-RI offers an online request service named Podium[5]. New users and researchers that are not familiar with the individual data holders are encouraged to use Podium for a smoother experience. However, it is still very new and most national researchers still reach out directly to data holders if they have worked with them before.

There are ongoing efforts piloted on COVID-19 data to streamline the processes of data request and review using 'Podium' as an entry point, and national committees for the review process. Health-RI and its partners published a guidelines document that describes the steps for researchers, accessible through the Health-RI ELSI Servicedesk (https://elsi.health-ri.nl/). There are major disparities in quality and timeliness of data access (ranging from 2 weeks to several months), depending on data holders' capabilities.

Figure 1: Request Procedure for Access to Data for Health-RI



3.5 BIGAN platform, Aragón, Spain

The Aragón Regional Health Authority BIGAN platform (BIGAN platform) is established by Executive Order SAN/ 1355/ 2018 of 1st of August as an element of the health information system in Aragon, BIGAN is managed by the Instituto Aragonés de Ciencias de la Salud (IACS) which is responsible in Aragon for overseeing, promoting and managing biomedical research activities and producing evidence-based guidance on health technology and health policy assessment, and medical practice.

BIGAN platform is a data infrastructure implemented to reuse any kind of existing data for the purposes of planning, quality management and health research. BIGAN is composed of

[4] "BBMRI-NL Catalogue." Accessed January 17, 2022. https://catalogue.bbmri.nl/menu/main/background.
[5] "Podium | Health-RI." Accessed January 17, 2022. https://www.health-ri.nl/services/podium.

three different portals according to their purposes, services are offered for: 1) Healthcare Planning and Quality Management, 2) Research and 3) Training and capacity building.

BIGAN platform, which processes secondary use data permits´ requests, has put together individual records from all the population registered as beneficiaries of the Aragonese Health System (Aragon current population of approximated 1.3 million lives) in a data lake of pseudonymised patient data to render it accessible to the policy makers and the scientific community as a one-stop shop service.

BIGAN works on a broad range of population health and health related data including primary care, specialized care, hospitalizations, ER episodes, drug prescription, image diagnosis, laboratory analytical determinations, diagnostics, vaccination, anamnesis and demographics.

The timeline to access this data depends on the completeness of the research protocol and the data permit request form and depends on the complexity of the data request scope and specification as data is prepared manually. The timeline can range from a few days to a couple of months in the most complex data linkage dispositions.

This Platform will be referred to as “IACS/BIGAN” in this report.

Figure 2: Institutional function

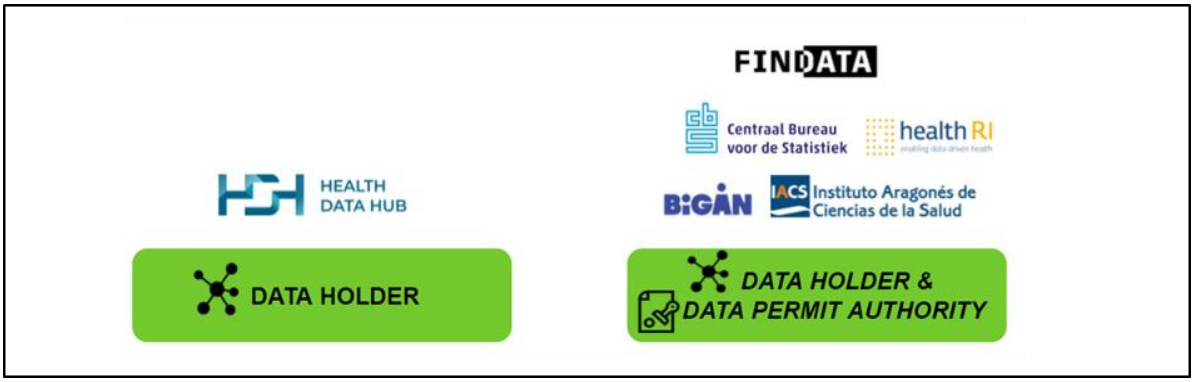
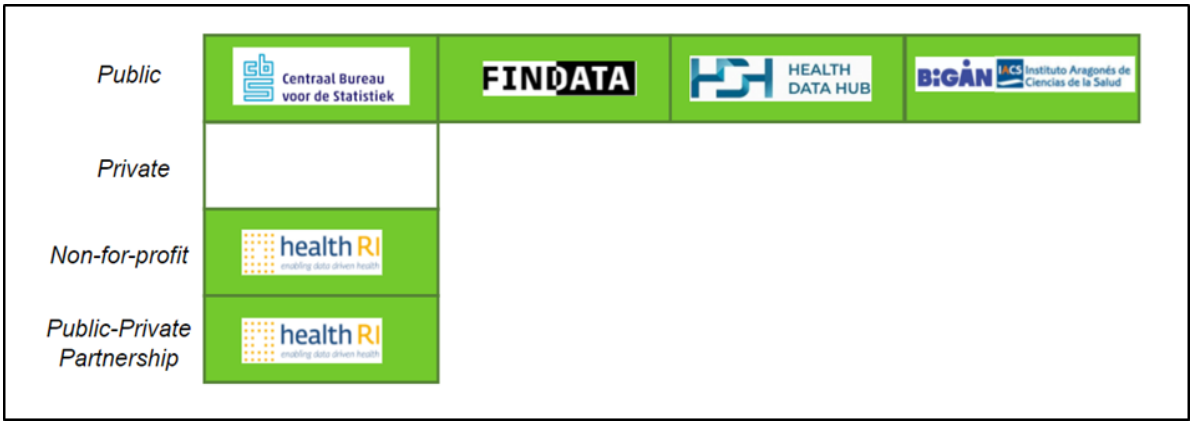


Figure 3: Institution type



4 Areas of analysis

The areas of analysis include the 16 questionnaire's categories presented above, distributed in macro categories, gathering the key topics and putting them into perspective common where relevant. The areas of analysis are divided as follows:

- **Systems and policies** (including the information on institutions, governance and structure; legal basis of the institution; institutional strategy; decision-making elements; organisational structure)
- **Data access elements** (data types and sources; data permit request; process review; access permit granting; effective data sharing and technological capabilities; and pricing model)
- **Scientific activity and outreach**
- **Business model and sustainability**
- **COVID-19 highlights** for entities participating in COVID-19 support

4.1 Systems and Policies

Introductive Note
Introductive Note: This part presents the structural relationship of the five health data platforms and organisations with other related institutions by specifying: • whether these are supervised or overseen by external bodies • the legal mandates or specific plans responsible for their implementation, This part focuses on the internal institutional strategy, the decision-making process and the organisational structure.

Key Takeaways
❖ Selection of two types of healthcare systems: centralised (Findata and the HDH act as unique national health data hubs) and decentralised (IACS/BIGAN and Health-RI are evolving in federal national contexts). ❖ Country-level overview for each institution revealed that except for Health-RI, as a public-private partnership, all structures are mandated by law, constituted as independent bodies but relying on a competent ministry for supervision and political guidance. ❖ Besides complying with national legislation, every structure complies with the GDPR dispositions. ❖ Three out of the five selected institutions are both **data permit authorities** and **data holders**

4.1.1 Legal basis of the institution

One focus of this report is to describe the legal basis and nature of each one of the institutions: whether the structure is a data permit authority (referring to an institution responsible for providing permission to access health data), a data holder (referring to an institution that stores and manages health data), or both.

Statistics Netherlands, Findata and IACS/BIGAN are at the same time data permit authorities and data holders, while HDH does not operate as a data permit authority (function held by the French Data Protection Agency or CNIL) and Health-RI is organised as a not-for-profit foundation managing a public private partnership that stores and manages health data. Except for Health-RI in the Netherlands, all the structures were mandated by national/regional law, and take the form of public institutions, whether independent or under ministerial supervision.

The French and Finnish national legal frameworks applicable to the Health Data Hub and Findata respectively, stand out with laws specifically implemented to act as a strategic roadmap, defining the scope and tasks of both national data platforms respectively. However, Finland goes one step further with the *Act on the Secondary Use of Health and Social data*[6] which defines the purposes of the secondary use of health and social data that underpin the eligibility of data requests: statistics, scientific research, development and innovation activities, education, knowledge management, steering and supervising social and health care by authorities and planning and reporting duty. In that sense, the Finnish Act, defining the purposes for the secondary use of health data can be considered a frontrunner at the European level.

Table 1: Detailed legal framework applicable per institution

Statistics Netherlands	Statistics Netherlands Act Data Acquisition Decree Regulation on trade in goods statistics Regulation on the provision of data on causes of death Also subjected to the GDPR
Findata	Act on the Secondary Use of Health and Social Data (552/2019) Also subjected to the GDPR

[6] "Finnish Act on Secondary Use of Health and Social data". Accessed January 14, 2022.

IACS/BIGAN	IACS: established by the Regional Health Law (6/2002), as a public independent entity within the Health System in Aragon (Aragon is one of the 17 autonomous regions in Spain with full health care responsibilities). The Aragón Regional Health Authority BIGAN platform is established by Executive Order of the Regional Ministry of Health (SAN/1355/2018) as an element of the health information system in Aragon, governed bythe Health Law of Aragon (Law 6/2002), the Decree on social and healthcare information system (Decree 164/2000) and the Law on Research and Innovation in Aragon (Law 17/2018). Also subjected to the GDPR
Health Data Hub	The July 24, 2019 law on the Organisation and Transformation of the Health System A new decree known as "SNDS" implementing the Law on the Organisation and Transformation of the Healthcare System was published on June 29, 2021. It reviews the governance and operating procedures of the SNDS, whose scope had been extended to new databases by the law. The Health Data Hub can now permanently host the data of the"main database" of the SNDS, which covers the entire population, and constitute a "catalogue" bringing together a set of databases that do not concern the entire population but are of significant scientific interest. Also subjected to the GDPR
Health-RI	Health-RI is a foundation, defined by institutional statutes and is registered at the chamberof commerce. Also subjected to the GDPR

4.1.2 Institutional model: Centralised or Decentralised platforms

Institutions are rooted in two types of broader institutional models, either centralised or decentralised platforms, the choice of the latter being strongly correlated to the nature of the national system in place in each country.

Different health data access systems may present various degrees of centralisation on multiple levels, among which:

- The processing of data permit requests
- The exposition of metadata catalogues
- The storage of health data and provision of analysis tools, on a “per project” basis
- The persistent storage of health data (outside of specific projects)

Although the actual situations may greatly vary, typical centralised systems will leverage all of the aforementioned levels. Using a unique access request process, aggregating multiple databases available across the country (or metadata catalogues thereof), often providing a

secure space to analyse the data once collected, they focus on providing the user / requester a single-entry point to help streamline the data access process.

Conversely, decentralised systems tend to give local stakeholders control over several of those levels. Typically, in the absence of a unique, centralised platform, databases are scattered throughout multiple local data holders, and the user is expected to provide a secure space to collect and analyse the data required for their project. Decentralized systems also often require that the data permit request is made to each data holder independently, each one possibly using their own criteria.

Regardless of the degree of centralisation in place, an ethical and/or legal independent committee may sometimes be involved in the data permit review process.

Findata and the HDH are centralised platforms in centralised countries while, on the contrary, the Netherlands and Spain operate in decentralised systems. IACS-BIGAN platform is centralized at regional level, mandated by law to operate in the region of Aragon exclusively, as the official data permit authority in this region.

4.1.3 Institutional strategy

Each structure has a set of priorities at the core of their inception, which is up to evolve yearly, as the health data sector is constantly shifting, facing new and diverse challenges. These priorities are therefore likely to be adapted according to the evolving national public health agenda. The structures rely on national or regional plans for innovation in Health, and even in specific health data initiatives at the national/regional scale, e.g. Aragon Health plan 2030 includes the BIGAN platform in Aragón. On the other hand, in the Netherlands, there are no specific legislative rules nor framework for health data organisations, including Health-RI. Overall, it is observed that, regardless of the type of institutional structure and/or national setting (whether it is centralised or decentralised), the 5 structures have a common mission: federating both national and international actors of the health data ecosystem.

Table 2: Institutional strategies in detail

Institution	Institutional strategy
CBS (Statistics Netherlands)	CBS (Statistics Netherlands) benefits from decades of national data collection and management expertise. Statistics Netherlands institutional strategy relies on a multi-annual programme, focusing onseveral objectives: 1) Ensuring a society-oriented, reliable and innovative foundation for the institution; 2) Participating in the “data revolution” with Statistics Netherlands as a data hub; 3) Improving data collection practices with new data sources and observation techniques; 4) Continuing the implementation of a regular statistics programme towards 2023; 5) Making data around social issues and phenomena more accessible (open data); 6) Working on customised research and statistics (ensuring a user-

	focused approach); 7) Ensuring quality, privacy and information security; 8) Continuing building the infrastructure; 9) Participating in high value sharing at the national and international level.
Findata	Findata's main objectives are to: improve data security and the data protection of individuals; speed up and streamline the utilisation of social welfare and health care data resources; decrease the duplication of work in permit processing and develop the data descriptions for the social welfare and health care sector together with the controllers.
Health Data Hub	The HDH takes the legal form of a public interest group whose mission is to federate the French health data ecosystem. For example, seven priorities have been set by the HDH 2022 roadmap, including the following: enhance SNDS database and catalogue; reduce the time required to access health data; consolidate technological platform; be attentive to the society questions and concerns; contribute to the development of a financing strategy of the databases to foster their sharing and development; contribute to the framing of the EHDS and keep structuring the organisational structure of the platform. The HDH takes also into account the main SNDS orientations that will be set by its Strategic Committee, having been created by decree in June 2021. The Committee has positioned itself on the bases integrating the first version of the catalogue and its field of intervention is important since it will have to specify the evolution of the catalogue perimeter, be a force of proposal as for the development of the SNDS, to support the policy of data sharing, their valorisation and financing, etc.
Health-RI	Regarding Health-RI's mission, the foundation aims to assemble all stakeholders and to create a sustainable infrastructure providing access to health data for research and innovation. Health-RI receives financial support from the Ministry of Economic Affairs.
IACS/BIGAN	IACS is responsible for overseeing, promoting and managing biomedical research activities and producing evidence-based guidance on health technology and health policy assessment, and medical practice. The Plan "Aragon Health-2030" includes a regional strategy for the common exploitation of all the health and health related information systems in Aragon with big data tools; thus, harnessing the potential of the reuse of real-world (big) data (RWD) in Aragon for population health research. BIGAN platform is a data infrastructure implemented to reuse any kind of existing data for planning, quality management and health research. BIGAN is composed of three different portals according to their purposes, 3 different services are offered, for: 1) Healthcare Planning and Quality Management, 2) Research and 3) Training. BIGAN has put together individual records from all the population registered as beneficiaries of the Aragonese Health System (The Aragon population is approximately 1.3 million) in a data lake of pseudonymised patient data to render it accessible to the policy makers and the scientific community as a one-stop shop service.

4.1.4 Decision-making

These five structures are organised with "*authority layers*". The first one would be the supervision by a national or regional ministry, according to the country's political structure. All platforms include specific bodies that provide guidance and the platform's activities are run day-to-day by internal managing bodies.

Table 3: Decision-making among the five selected institutions

Institution	Decision-making
CBS (Statistics Netherlands)	CBS (Statistics Netherlands) acts as an autonomous administrative authority, under which the Minister of Economic Affairs is politically responsible for relevant legislation, budget and conditions. Internally, the Advisory Council provides the General Directorate of CBS with pieces of advice and general guidance.
Findata	Findata operates under the performance guidance of the Ministry of Social Affairs and Health and the Ministry appoints both a separate director for the organisation and a steering group. The Findata management group is responsible for managing the operations of the data permit authority. The Findata management group includes the Director, Head of Data Services, Head of ICT, Legal Advisor, Head of Communications and Development Manager. The steering group guides and develops Findata's operations. The members of the steering group have been appointed from the Ministry of Social Affairs and Health, the Finnish Institute for Health and Welfare, the Social Insurance Institution of Finland, the Finnish Centre for Pensions, the Digital and Population Data Services Agency, Statistics Finland, the Finnish Institute of Occupational Health, the Finnish Medicines Agency Fimea, and representatives of social welfare and health care service providers. Findata's operations are supervised by the Parliamentary Ombudsman and the Data Protection Ombudsman, among others. The National Supervisory Authority for Welfare and Health Valvira monitors Findata's data secure user environments. In addition, Findata must give an annual report to the Data Protection Ombudsman regarding the processing of health and social data and the related log data.
Health Data Hub	The HDH is constituted as a Public Interest Group. This status allows actors to be gathered around a common project while having a legal entity. The members of the organisation join by signing the constitutive agreement and must contribute financially or in other ways. The General Assembly of the Health Data Hub brings together its 56 members, divided into 9 colleges: the State; health insurance funds; supplementary health insurance organisations; research organisations; health establishments; health professionals; agencies; operators and independent public authorities; representatives of users of the health system and industrialists. A representative of each college is a member of the Board of Directors, except for the State, for which the Ministries of Solidarity and Health on the one hand (DREES), and of Higher Education,

	Research and Innovation on the other (DGRI) are part of the Board. CNAM, UNOCAM, INSERM, CHU de Limoges, UNPS, France Asso Santé, Santé Publique France and SNITEM are members. Their vice-president is also the president of "France Assos Santé"': an organisation gathering all the patient organisations and associations in France. Since January, the HDH also gets scientific advice and guidance from the Scientific Advisory Board (CSC) composed of experts from various fields, including a panel of 7 international experts
Health-RI	Constituted by executive management consisting of four members (CEO, CSO, CTO, and chief alliance officer), board overseeing the executive management. On top of that there are advisory committees etc. Governance is outlined here: https://www.health-ri.nl/about/governance
IACS/BIGAN	The public care system in Aragon is governed by a Regional Authority (Department of Health at the Government of Aragon) through the SALUD who acts as a Healthcare services provider. It is organized in eight healthcare sectors, providing primary care, hospital care, outpatient specialized care, A&E care, rehabilitative care, mental health care and home care. Social care is organized separately although linkage is promoted particularly in the case of living assisted and nursing homes. In BIGAN Platform, IACS is in charge of granting access to the data. Specifically, the Projects Management Unit at IACS is the unit responsible for managing the day-to-day operations of the data permit authority. BIGAN Oversight Committee controls and follows up BIGAN activities. BIGAN Oversight Committee has representatives of the data controllers: the Department of Health and the Aragon Health Service at the Government of Aragon and it is presided by a representative from the Aragonese Department of health.

4.1.5 Organisational structure - Internal structuring

Besides the decision-making authorities, usually 3 types of committees stand out: an Advisory Board, a Steering Committee and a Strategic/Management Committee, alongside other specific departments, running the specific topic-related activities such as communication, scientific valorisation or interaction with the health data ecosystem.

Table 4: Internal management

Institution	Organisational structure
CBS (Statistics Netherlands)	CBS (Statistics Netherlands) includes an Executive Board, a General Director, a Deputy General Director, a Chief Information Officer (CIO), an internal audit service (CAD) and a Department of Corporate Strategy and Management advice. The main directorates are the following: Operations, IT and methodology; CBS Communications and News; Data Services, research and innovation; Economic and business statistics and national accounts unit and socio-economic and spatial statistics unit.

Findata	At the moment, Findata consists of Executive group responsible managing the operationsand Data Services (lead by Head of Data Services), responsible for operational functions. Findata includes an Executive group (Findata Management Group), Data Services and a Communication Team.
Health Data Hub	The HDH includes three types of directions and services: sectoral, strategic and transversal. Sectoral directions (Technical department, Data management, Data Access department, Project Support and Partnerships department), Strategic directions (Scientific department, Citizen department, medical department) and Transversal services (General Secretariat, Communication Department, Legal Department, CISO). All the directions work together to develop the HDH and its services, but also to promote its activities at the national and international scale.
Health-RI	Health-RI internal organisation is constituted by 4 “action lines” that have specific objectives: the Action line 0 is dedicated to management, administration and finance, the Action line 1 is committed to carry the interactions with stakeholders and government, strategic networking, the Action line 2 takes care of the infrastructure and health data community, the Action line 3 is working on the health data one-stop-shop development, services and tools. Each activity is carried out in a federated way: deployment of a small central coordinating hub and 8 “regional nodes”, most of them centred around a university medical centre. Across the 4 action lines listed above there are four themes that have specific focus: 1) data architecture, 2) ELSI (Ethical, Legal, Societal Impact), 3) FAIR Data Implementation, and 4) Biobanking and Cohorts.
IACS/BIGAN	BIGAN is an infrastructure supported by the IACS Biocomputing Unit (a Scientific & Technical Unit) integrated within the Knowledge Production Area in close functional relation with the Projects Management Unit and the Ethical Committee, and acts under the executive management of the Innovation and Knowledge Production Area ExecutiveManager/Director and IACS Executive Manager/Director.

4.2 Data access components

Introductive Note
This part outlines this report’s core subject: the detailed steps to access health data in the five selected institutions, including key findings for the following: • Data types and Sources • Access request • Process review • Access permit • Effective Data Sharing • Technological Capabilities

- Pricing model

Key Takeaways

- ❖ Selected health data platforms federate myriad of individual-level data sources, including EHRs, medico-administrative data, hospital registries, and even biobank data (in the case of Health-RI)
- ❖ National researchers are unanimously eligible to access health data in the four selected countries/regions, EU and international researchers are also free to request access to health data in four out of the five selected structures. While private actors are unanimously allowed to request access to health data, they are subject to different processes
- ❖ Health data access procedures take place exclusively online, an ad hoc upfront feasibility assessment of the study can be carried out by the staff of the selected structures.
- ❖ The committees identified as directly involved in the review process are the following: 1) Ethical/ scientific committees; 2) Steering entity (a governing body which assesses the requests) 3) A data protection agency. Only Findata and IACS/BIGAN centralises completely the processes for two or more data source requests.
- ❖ The average time to access health data across the five structures is 1 to 6 months.
- ❖ A data use/access agreement has to be signed between the authorised user and the platform.
- ❖ Fees apply when it comes to one or all of these several specific services: review of the data permit request; authorisation of access (permit issue); data extraction services; additional fees applied by data holders; use of the virtual working environment; use of available technological capabilities.

4.2.1 Data types and sources

Three types of data have been emphasised in the questionnaire's framework: anonymous data, de-identified data and aggregated data.

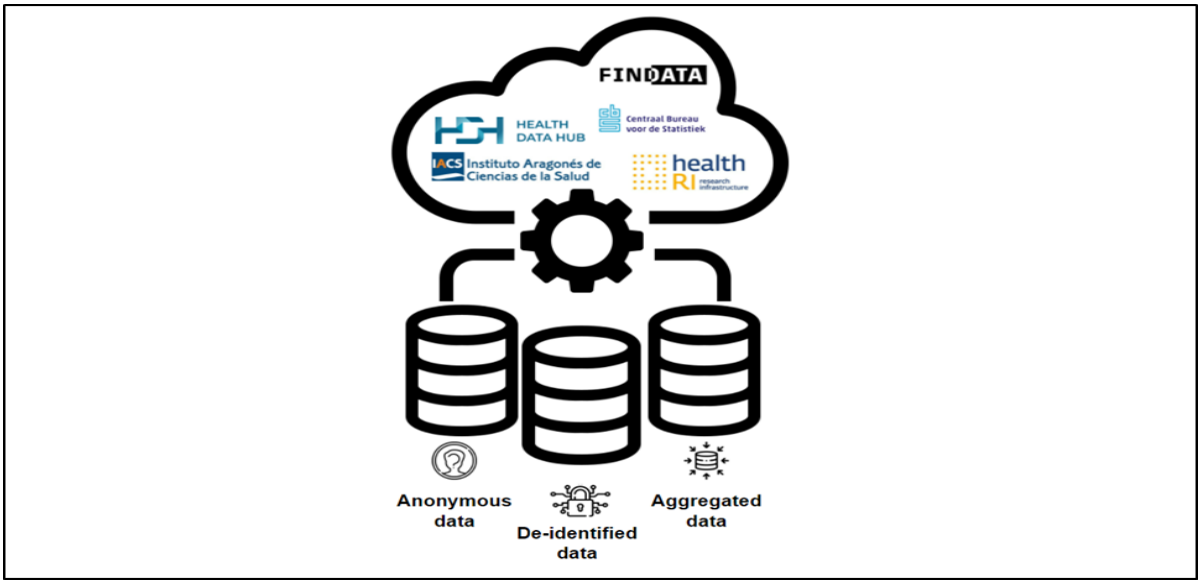
Four out of the 5 platforms store and provide access to all three types of data. Health-RI also federates institutions handling all mentioned types of data, while not being directly involved in the data handling process, and not being mandated to grant access to this data.

Individual-level data is being handled, mainly from public sources. The data is being systematically de-identified, either by a third party or by the platform itself. The data scopes may be different according to the institutions' legal mandates.

Table 5: Data types and sources per institution

Institution	Data types and sources
CBS (Statistics Netherlands)	In the case of CBS (Statistics Netherlands), the data sources are mainly public, including hospital discharge registers, primary care databases, causes of death, medical professions register, health interview survey. and patient records. The included databases are listed in the CBS questionnaire.
Findata	Findata handles primary care records, hospital records and information systems data, electronic health records (EHR), social welfare data, claims data.
Health Data Hub	The HDH mainly operates on the SNDS, which historically includes three databases: the SNIIRAM database (data linked to health insurance reimbursement), the PMSI (French hospital discharge database), and the Causes of death database. The HDH will also link other databases to the main SNDS database to build up its catalogue, which means that the list of databases will change over the years and the related decree listing these will be updated accordingly. The first list of databases is available in annex 4.
Health-RI	Health-RI is helping researchers to get access to the resources united through the BBMRI Netherlands Biobank network as well as the national COVID-19 initiatives.
IACS/BIGAN	For the IACS/BIGAN platform, the sources are public (primary care records, hospital records, Aragon EHR among other health information systems).

Figure 4: Categories of data handled by the institution



4.2.2 Data permit request procedure

A key interest of this document is the data access procedure, by summarising the different steps and process prerequisites. We were interested in identifying the end user eligibility between national researchers, European researchers, international researchers, national policy makers, European policy makers, international policy makers, individual citizens or other actors (e.g. private actors).

As an overall trend, the data can be accessed by researchers beyond the local/national level (EU/International) and this, unanimously across the selected countries. Private actors can submit a health data permit request that differs from the classic procedure (i.e., going through additional steps). The request procedure can be different if the actor is private or internationally based. There is a specificity regarding the French legal framework that implies that, in principle, any person or institution that obtains authorisation from the CNIL can access the data (individual citizens, private actors etc.).

Table 6: Eligible applicants to access health data per institution

Institution	**End-user categories**							
	National researchers	European research-ers	International researchers	National policy makers	European policy makers	Internatio-nal policy makers	Individual citizens	Other actors (private actors)
CBS (Statistics Netherlands)	X	X	X For microdata	X[7]				
Findata	X	X	X	X			X[8]	X
HDH	X	X	X	X	X	X	X	X
Health-RI	X	X	X					X
IACS/BI GAN	X	X	X	X	X	X	X	X

Second, to receive these requests, the four platforms use an electronic request system. Either the candidate has to go through an electronic fit-for purpose form, or an integral electronic process for registration and request, or both. The process is different for Statistics Netherlands, which requires the institution the project coordinator is affiliated to, to be fully authorised by Statistics Netherlands for micro-data access. Only once that pre-registration is obtained, researchers can request access to the specific project data.

Health-RI also stands out by having developed a health data request centralising platform named Podium, which is basically a health data request management tool, used by health data holders and applicants across the country without costs or just handling costs. Larger

[7] Academic research, planning offices established by or by virtue of the law, and only the research departments of ministries and other departments, organisations and institutions. On European level: A Community or national statistical authority of a Member State of the European Union.

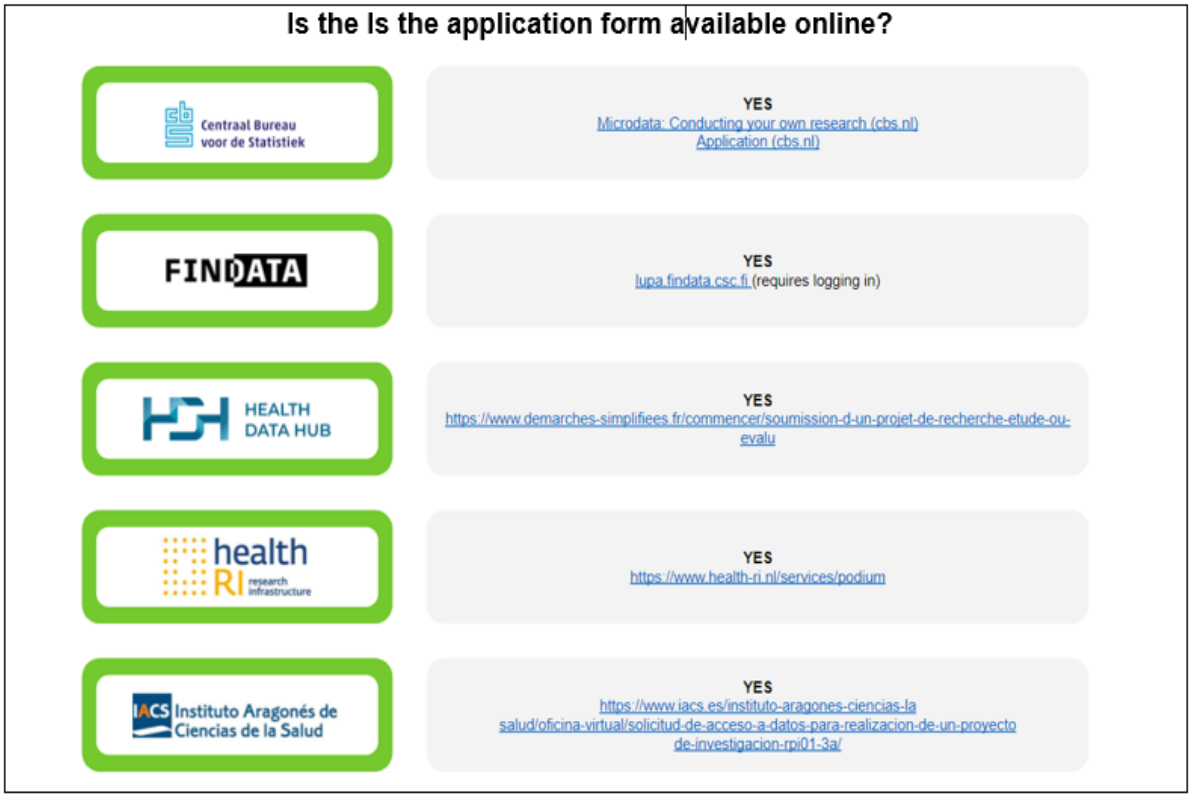
[8] In specific cases (i.e, students or independent researchers working with grants)

data holders have their own request form, others have an informal process through e-mail, etc. Researchers that know the data source usually directly reach out to the data holder; Health-RI provides a portal for researchers new to the arena.

Plus, candidates are expected to provide specific additional documentation (e.g., research protocol and/or beforehand ethical approvals if applicable), other dispositions are mandatory, such as specifying the scope of the data needed for the study.

Three out of the five structures analysed provide exclusive data access (IACS/BIGAN, the HDH and Findata), which means that access to the regional (for IACS/BIGAN) or national (for Findata) health data is completely centralised and is only possible through these institutions. In France, projects requesting access to health data, are subject to authorization by CNIL before accessing the data through the HDH or alternative process. Besides, there is a specificity regarding the Finnish's policy, going through the Findata process is mandatory for project coordinators that are willing to access two or more data sources for the same research purpose, but if their request is about a single data source, they can use the data holder's process. For the 2 other platforms (Health-RI and Statistics Netherlands), the project coordinators can also formulate their query to the data holders directly.

Figure 5: Data permit request form in different institutions



4.2.3 Process review

The Assessment of the EU Member States' rules on health data in the light of GDPR report, issued by the European Commission (DG SANTE) early 2021[9], identifies three non-mutually

[9] Assessment of the EU Member States' rules on health data in the light of GDPR – Page 98

exclusive access mechanisms for the secondary use of health data among European Member-States:

1. The access is granted after authorisation by a research ethics committee (REC) or a data protection agency (DPA). An approach adopted by 22 Member-States in the EU.
2. There is no intermediary between the data holder and the project coordinator, the data holder directly provides access without consulting a REC or a DPA. This mechanism is observed in 7 Member-States.
3. A centralised governance body exists, which is the case in 13 Member-States.

From the questionnaire's results, the committees identified as directly involved in the process review are the following: 1) Ethical/ scientific committees; 2) Steering entity (a governing body which assesses the requests) 3) A personal data protection agency. Only Findata and IACS/BIGAN centralises completely the process for two or more data source requests.

An ethical approval is necessary in 3 out of 4 structures. Health-RI is still in the phase of implementing a single and centralised data access procedure, but an ethical approval by one of the Institutional Review Boards will be required. In the case of the HDH, an approval by the French Scientific and Ethical Committee for Research, Studies and Evaluations in the Health Sector is necessary to move forward with the data permit request only when a CNIL approval is required, otherwise, approval from the competent local ethics committee is required. IACS requires a Regional Committee for Ethics approval, as well as Statistics Netherlands.

In the case of the Finnish data, no need to go through an upfront ethical approval before requesting the data. But, on an ad-hoc basis, the following evaluations might be needed: evaluation by the Finnish Ethics Committee of the National Institution of Health and Welfare, and an evaluation from the Office of the Data Protection Ombudsman.

Regarding the process review itself, each structure has its own practices in terms of timing or technical considerations. See table 7.

Table 7: Average time to access health data per institution from time of request

Institution	**Average time to access health data**
CBS (Statistics Netherlands)	1-2 months
Findata	1-3 months
Health Data Hub	3-6 months to be granted authorisation by the DataProtection Agency
Health-RI	Varies depending on the data custodians (from fewweeks to a few months)
IACS/BIGAN	Varies depending on the complexity of the data request(1 week to 2 months)

The timing to render a decision upon data request depends on several criteria:

- The completeness of the application
- The feasibility of the study itself
- The timing for upfront or other ad hoc required approvals (from an Ethics committee for instance).

4.2.4 Permit issuance and data use agreement

Among the different structures, it has been observed as a general practice that an agreement is signed between the project coordinator - end user - and the health data access platform.

Plus, the data is made available under specific rules to be followed by project coordinators. For instance, Statistics Netherlands limits access to a small number of researchers during the time of the study, data has to stay at Statistics Netherlands with remote access only, and a non-disclosure agreement has to be signed beforehand.

Findata differentiates access to data through the platform based on the type of data. When the institution provides aggregated-level data ensuring its anonymity, the data is handed to the applicant with unlimited access. In the case of individual-level data: the permit has always a defined time limit, the remote environment and there is no pre-defined limit for the number of users. The projects can add new users with an amendment application. The permit holders only are able to process the data. The data will be removed within 6 months from the remote environment of Findata.

In the case of the French HDH, the access duration is limited to the time of carrying out the study and is defined by the CNIL. Project leaders have to accept Terms and Conditions, sign an agreement, and HDH provides them with awareness and training on how to use health data.

Health-RI does not have a homogeneous process; data processing requirements depend on data custodians' own practices.

IACS/BIGAN provides access that is limited per “blocks”, which means that users can request access to a specific block of data identified specified as necessary, within the temporal range of the study, and with a clear definition of the case study for the identification of the cohort of patients to be studied according to the BIGAN Research portal catalogue.

4.2.5 Effective data sharing and technological capabilities

Another area of focus is the access environment, through which the data is made accessible to project leaders (data provision): either remote project spaces (virtual working environments), that usually include different tools for processing and analysis are accessible to project leaders, or the data is directly handed to the user, after security dispositions of the latter have been checked.

Two sorts of procedures are identified: data is either transferred as data files to the user in the case of IACS or made available through a secure remote environment (Findata, HDH, Statistics Netherlands and Health-RI).

Health data platforms make sure that the individual-data, that has been either anonymised or pseudonymised, cannot be re-identified, and that it is impossible to trace back to individuals, institutions or any other entities whose data is concerned.

Table 8: Authorisation of access practices and technological capabilities per institution

Institution	Authorisation of access practices
CBS (Statistics Netherlands)	The Statistics Netherlands team takes care of the data preprocessing, cleaning, and pseudonymisation. Pseudonymised data is generated within one unit at Statistics Netherlands, so the datasets can be linked within Statistics Netherlands only, (e.g., demographic data, health data, social, economic). Results must then be screened by Statistics Netherlands to ensure no individual data could be re-identified or exposed in the project's results. If in accordance with GDPR and WGBO (Medical Treatment Agreement Act), researchers can upload datasets which will be pseudonymised and can be linked to the other microdatasets. Tools available in the secure remote access IT-environment are SPSS, STATA, R, Python. SAS etc.
Findata	Data is shared in an agreed-upon secure operating environment: Findata's secure remote access environment - these packages are described per size (S, M, L and XL) and include tools for data analysis (SAS, R, Stata, Python) that are made available on the project environment. There will soon be other remote access environments available in Finland, too.
Health Data Hub	The required data will be made available directly on a tailored secure project space. The HDH provides through its technological platform state-of-art tools to project coordinators, including the following: • integrated development environments (IDE), such as JupyterLab or RStudio, working respectively - with programming languages Python and R, • effective tools for interfacing with large datasets, such as PySpark or Sparklyr, • data visualisation tools, such as Superset, • database management systems, such as PostgreSQl or MySQL, • applications for image visualisation and annotation, such as Cytomine, • tools fostering collaboration, such as Git and Gitlab.
Health-RI	Currently, data holders mostly manage the preparation of data and the provision of analytical or visualisation tools. Health-RI provides a number of tools. The institution also ensures that the different tools are interoperable. Health-RI is also investing in federated analysis. For instance, Podium has been developed by Health-RI, which is a data request management tool, data holders can freely use it. Other services are available, among them the Personal Health Train, cBioPortal, XNAT[10]. Depending on the data custodian practices, the data can be handed to the project coordinator as data sheets or made available in secure data environments. The objective is moving towards the prioritisation of a single

[10] "Services & Tools | Health-RI." Accessed January 21, 2022. https://www.health-ri.nl/services

	virtual secure environment, which is the purpose of the AnDREa project[11].
IACS/BIGAN	Data is pseudonymised at the BIGAN Platform and ad hoc ETL Processes based on Apache Cassandra database are being processed by the BIGAN staff. Data is transferred as data files or structured database access, depending on the requester capabilities. Regarding the IACS/BIGAN general technological capabilities offered to the project coordinators, limited access to Zeppelin (Spark), R and Python servers is available, and an analytical platform is under development. BIGAN serves under a specific security policy based on ISO 27001, security audits are taking place (continuous impact assessment).

4.2.6 Pricing model

Two policies have been observed: 1) fees are differentiated per actor requesting access to data and: 2) different services that are charged to the project coordinator, see Table 9.

The fees differ whether the project coordinators are affiliated with public or private institutions, i.e. IACS/BIGAN charges lower prices for public bodies, and also the HDH plans to grant access and deploy its technological capabilities for free to public institutions. In certain cases (e.g. Findata, IACS/BIGAN) a difference is made based on the project coordinator's nationality: whether they are national, European or international. However, Health-RI does not apply any price differentiation model according to the project coordinator's type but grants free access to governmental bodies. Statistics Netherlands does not apply any differentiation.

In the case of Findata, the fees for the services provided by Findata, in accordance with data holders, are laid down in a specific decree issued by the Finnish Ministry of Health and Welfare, that states the rates per year[12]. In the case of IACS/BIGAN the pricing model distinguish tariffs according to type of user, providing lower fees for public bodies.

The ranges of prices to access health data for each institution are described in Table 10.

Table 9: Charged services among the institutions

Institution	**Charged services**				
	Reviewing the data permit request	**Authorisation ofaccess (permit issue)**	**Data extraction services**	**Data holders apply additional fees**	**Use of the Virtual working environment/ Use ofavailable technological capabilities**
CBS (Statistics		X	X	X[13]	X

[11] "anDREa consortium." Accessed January 21, 2022. http://www.andrea-cloud.eu/.

[12] "FINLEX ® - Säädökset alkuperäisinä: Sosiaali- ja terveysministeriön ministeriön… 1168/2020." Oikeusministeriö. Accessed January 18, 2022. https://finlex.fi/fi/laki/alkup/2020/20201168.

[13] Some types of individual-level data can be charged by the data holders in specific cases, but this is not the standard practice.

Netherlands)					
Findata		X	X	X	X
HDH	To be determined				
Health-RI			X	X	X
IACS/BIGAN			X		X

Table 10: Range of prices to access health data per institution

Institution	**Range of prices to access health data**
CBS ((Statistics Netherlands)	Authorisation of access: 200€ to 375€ Importing external microdata (simple to complex encryption): 250€ to 1,300€Use of available technological capabilities (software): 40€ to 560€ Services during an ongoing project (per month) from 18€ to 500€Services after project completion: 50€ to 750€
Findata	Decision on a data request: 2500€ Data permit for an applicant based in Finland or another EU or EEA country: 1000€ Data permit for an applicant based outside an EU or EEA country: 3000€ Data permit and request related to a thesis (national researcher): 250€ Remote access environment fees (per month): from 187.50€ to 460.42€ (depending on the remote access environment package size) *Price list : https://findata.fi/en/pricing/*
Health Data Hub	Determination of prices still ongoing
Health-RI	Only access to the data analytics environments is charged, which ranges from 1560€ to 6220€ (depending on the datasets complexity and size)
IACS/BIGAN	32.72€ to 52.80€ per hour of service

4.3 Business model and Sustainability

The five institutions are mainly publicly funded, but part of their sustainability is ensured by the data access fees that cover their running costs, an exception made for the HDH and Health-RI which are still in the process of designing its access fee-for-services policy.

4.4 Scientific Research Impact

Introductive Note
After being granted access, and carrying out the study, the project coordinators may also be supported afterwards. Another area of interest focuses on the follow-up on the research after its completion, specifically how the platform is involved in scientific value-making. Indeed, it has been observed that there are specific guidelines for disseminating health-data-based research.

Key Takeaways
❖ We note several levels of engagement with the ecosystem and ways to engage with different spheres of the society (target audience: researchers, general public (citizens), other national key players, international stakeholders, acting in the health data promotion). ❖ Inclusion of citizens in the institution's governance is rather an ad-hoc practice, but is observed for the HDH, CBS and IACS/BIGAN structures. ❖ HDH/ IACS/BIGAN have national/regional plans fostering the building of a trustworthy relationship with citizens, raising awareness, and even furtherly creating a common culture of health data.

4.4.1 Scientific Activity and Outreach

The mentioning of the platform in the publication is mandatory. Open science is largely encouraged, especially when it comes to making health-data-based research freely available to the general public. More information per institution is available in Table 11.

Table 11: Involvement of the institutions in scientific value-making

Institution	Obligation to publish results after data use	The publications must be publicly accessible	The resulting publication has to comply with the research protocolthat has been initially submitted torequest the data
CBS	X	X	X
Findata	X		
HDH	X[14]	X	X

[14] Once the research has been carried out, the project coordinator must send the results to the HDH, as well as the methodology and means required for assessment purposes. These results as well as the methodology are released on the HDH online public projects directory.

Health-RI	X	X	X
IACS/BIGAN	X	X	X

Another aspect is the scientific activity in the national/regional health ecosystem. First, the activity covers a wide range of health data sources. The institutions answered unanimously that they have no specific and defined research scope for granting health data access. Second, every structure demonstrates various practices to promote the secondary use of health data, within the health data ecosystem and beyond, with citizens and policymakers (see Table 12). Table 13 summarises the current number of projects on the platform.

Table 12: Outreach of scientific activities

Institution	**Outreach scientific activities**
CBS (Statistics Netherlands)	Statistics Netherlands works closely with the Dutch Archive of national datasets "Microdata user day" is organised once a year, involving health data users, holders and citizens.
Findata	Findata organises and participates in both working and expert groups on health data re-use (e.g. the Collaboration Group of the data controllers and customers; the Ecosystem Group of secondary use of social and health data; the Expert Group on data protection of secondary use of social and health data).
HDH	The HDH offers to bring together researchers from all specialities and from over the world through a network gathering as of today around 187 researchers. The HDH has also launched a postdoctoral fellowship program. The Health Data Hub has also initiated several ecosystem unifying events beyond the first two calls for projects in 2019 and 2020 (e.g. call for tenders with Unicancer, the National Federation of Cancer Centres in France; Call for projects "Data and associated technologies applies to health" with DataLab Normandie; partnerships offering to healthcare facilities interested in developing their data strategy; AI and medicine symposium co-organised with the MIT in May 2021; a world class winter school on AI for Health…).
Health-RI	Health-RI interacts through collaborative conferences, webinars, workshops, and cross-communication through websites, social media and the various newsletters prepared by the organisation.
IACS/BIGAN	Within Spain, IACS participates in the IMPaCT-Data initiative, promoted by the MoH and the Ministry of Economy, to create a federated infrastructure to support research projects that integrate real world clinical data with medical images and genomic data among different regions and national institutions. BIGAN experience serves as a reference in the integration of structured clinical data. At the EU level, among others, IACS participates in the PHIRI project in WP6 (Research use cases measuring the impact of COVID-19 on

	population health) integrating data from the BIGAN platform to nurture 4 use cases) and leading WP7 (Building a federated research infrastructure for a rapid policy response) for rapid policy relevant research response to the evolving pandemic. It also coordinates HealthyCloud project to define the strategic agenda for the European Health Research and Innovation Cloud.

Table 13: Number of scientific projects ongoing per institution (2021)

Institution	Number of running projects in 2021
CBS (Statistics Netherlands)	28; Remote Access 769 research projects, about 75 on Health research
Findata	262
HDH	55
Health-RI	No info (100's through participating biobanks and cohorts)
IACS/BIGAN	30

Scientific activity was not bound to the national scale exclusively, it is also internationally oriented. All the platforms included in this report are either running or participating in international health data organizations' federating efforts.

Moreover, selected institutions are involved in the TEHDAS project. While Statistics Netherlands and Health-RI are entities affiliated to the Dutch Ministry of Health, Welfare and Sports (VWS) for this joint action; IACS/BIGAN, Findata and the HDH are involved either as leaders of a work package WP or a subtask.

4.4.2 Going further: citizens' involvement

Several reviews revealed that as an overall trend, European citizens tend to have a positive attitude towards individual-level data sharing, while regretting the lack of awareness raising regarding health data reuse purposes, such as research, and effective scientific outreach[15].

As the selected institutions are part of EU Member-States, the institutions fully comply with GDPR, which means that general dispositions on citizens' rights are guaranteed and made publicly available for the individuals to be well informed.

Moreover, the importance of building a trustworthy relationship with citizens is highlighted.

Each one of the structures engages with citizens through different types of initiatives. Including the citizens in the governance is an ad-hoc practice, which has been observed for only 2 structures (HDH, IACS/BIGAN) out of 5.

[15] Skovgaard, Lea L., Sarah Wadmann, and Klaus Hoeyer. "A Review of Attitudes towards the Reuse of Health Data among People inthe European Union: The Primacy of Purpose and the Common Good." *Health Policy* 123, no. 6 (juin 2019): 564–71. https://doi.org/10.1016/j.healthpol.2019.03.012.

Table 14: Institution practices towards citizen engagement

Institution	Engagement with citizens highlights
CBS (Statistics Netherlands)	Statistics Netherlands provides data to the Archive of national datasets for public consultation. There is also some ongoing collaboration and coordination.
Findata	Findata does not engage directly citizens through citizens targeting initiatives but is engaged to make individual-level data-based research available to the general public through a project directory.
HDH	According to the law of July 24th 2019 on the organisation and transformation of the healthcare system, the Health Data Hub has a mission in article 41 (V) to "inform patients, promote and facilitate their rights", which stands as the first manifestation of the Health Data Hub's engagement with civil society. The Health Data Hub has chosen to create a citizen's direction to address the needs ofthe different citizen representatives with whom it interacts. Regarding the information towards citizens, a public directory has been modified with the purpose of being more user-friendly as well as more exhaustive to meet the general public's expectations: e.g., people who wish to be more informed about their own health condition by learning about a specific pathology. Citizens can also easily find clear information to contact the Data Protection Officer (DPO), in order to be fully informed of their rights. The catalogue web page also provides information about the data hosted by the Health Data Hub, besides the DPO contact information. The website explains and makes the rights of individuals regarding their personal health data more accessible and understandable and presents the HDH commitments to the citizens. These commitmentsconcern the general interest character of the projects carried out within the Health Data Hub, data security, transparency and respect for rights. These commitments are also available in an "easy to read and understand" format, and their translation to English is in progress. The citizen is also a patient, who is meant to benefit from the results of health data relatedresearch. In this perspective, the Health Data Hub brings together patient associations and pilot project partners. The challenge of keeping the citizens well informed lies also in training and disseminatinga culture of health data. To this end, a list of frequently asked questions is available on the website, as well as a training program, co-constructed with patient associations and specifically targeting civil society. The Health Data Hub is also building concrete partnerships with patient associations willing to go even further in their involvement, such as several associations around the study ""Vivre COVID-19" led by France Assos Santé (FAS) with the support of the Health Data Hub, the partnership with the French Federation of Diabetics that wants to submit its own researchproject, or the implementation of the on-demand query service that aims to carry out simple treatments on behalf of associations that will not have the means to invest in research but that

	need the figures for their advocacy for example; Open resources allow interested citizens to take part in the exploitation of health data aswell as data challenge type events (one organised last year and seven in preparation for2021/2022). To contribute to the construction of the Health Data Hub, the Citizens' Direction is keen to listen to the people concerned and is therefore carrying out perception studies and a consultation, notably with the United Kingdom and Belgium, as part of the TEHDAS jointaction. The HDH also contributes to the Interministerial Directorate for Transformation's Open Government Partnership (OGP), through 5 commitments: • Building a health data culture • Promote open science • Ensure transparency of data use and facilitate the exercise of right • Foster open data practices • Support the creation of a citizens advocacy program
Health-RI	The main targets in the health data ecosystem for Health-RI are researchers, and occasionally policy makers and/or citizens are involved in Health-RI activities. The highest advisory board includes representatives from patients and citizens organisations to strengthen the link with the civil society; Health-RI is also incubating a Societal Council, dedicated to the matter.
IACS/BIGAN	The Aragon Government is engaging with citizens on health issues through the Plan Salud 2030, the Aragonese citizens can provide direct feedback on the secondary use of health data-based research. Additionally, the regional government deploys an Aragon Health Council, which is the highest body on citizens' participation in public health issues. The BIGAN model itself is based on the patients' empowerment, by making research on individual-level data widely available, and by guaranteeing the citizen's right to opt-out from the BIGAN database infrastructure.

4.5 COVID-19 highlights

Introductive Note
Which was also interesting to look at, is how granting access to health data among the five selected structures evolved during the COVID-19 outbreak. This part includes the COVID-19 health data related effort per institution, at both national and international levels, with a specific focus on data centralisation initiatives.

Key Takeaways
❖ All institutions mobilised efforts toward tackling COVID-19 related health crisis

- ❖ Prioritisation of COVID-19 related research on data, access has been accelerated
- ❖ Multiple COVID-19 health data related research has been published

The institutions interviewed have been working on COVID-19 related data monitoring and gathering COVID-19 related health data.

More specifically, another general trend is that COVID-19 research has been prioritised, by means of accelerating the health data access procedure when it came to this topic in some cases.

Table 15: COVID-19 Health data related effort per institution

Institution	**COVID-19 Health data related effort**
CBS (Statistics Netherlands)	Statistics Netherlands does not hold permanent COVID-19 data, but the institution receives COVID-19 testing data from municipal health centres (almost 20-25 centres in the country). It took approximately 9 months to gather this type of data, which was published last June 2021. This is linkable to other social and economic data for research.
Findata	Findata grants permission for health and social data when data is collected from multiple data controllers listed in the Act on Secondary Use of health and social data (except for internal research by National Institution for Health and Welfare). Findata has given data permits since April 2020. There are six COVID-19 related research cases that mention COVID-19 in the title[16].
HDH	In April 2020, the HDH was tasked with exploring how data could be better mobilised to support the COVID-19 crisis management. Thus, to facilitate the sharing of data for research purposes, the HDH came up with the first version of its technologic platform and obtained the authorization to gather data related to the epidemic. As of May 6th, 2020, teams from the Ministry of Solidarity and Health were able to process data on the platform to study the decrease in emergency departments during the first lockdown. The data available in the COVID-19 data warehouse are currently those of the OSCOUR database (summaries of emergency room visits), the SNDS Fast Track database (for patients hospitalised for COVID-19). SI-VIC (hospital data for the COVID-19 pandemic), SI-DEP (COVID-19 virological test results (RT-PCR) and SI-VAC (COVID-19 vaccination follow-up). Fifteen COVID-19 related projects have been identified and are now being supported by the HDH. Their purpose is to improve models for monitoring the epidemic, to study healthcare pathways and, to identify predictive factors, to help with screening and diagnosing diseases.

[16] Findata. “Päätökset.” Accessed January 16, 2022. https://findata.fi/tietoa-meista/paatokset/.

Health-RI	Health-RI has developed a Dutch COVID-19 Data Support Programme[17] and COVID-19 projects portal, to support researchers and healthcare professionals in understanding the pandemic main features and finding sustainable solutions. Moreover, Health-RI is providing the technical infrastructure and data governance for a national COVID-19 observational data register in collaboration with the Dutch University Medical Centres (under the name COVID-NL)
IACS/BIGAN	BIGAN has provided significant support in centralising COVID-19 related data at the Aragonese regional level and worked on increasing health data research in the COVID-19 pandemic, by specifically, facilitated the creation of a COVID-19 dashboard to monitor this sanitary crisis trends in an efficient way.

[17] "Dutch COVID-19 Data Support Programme | Health-RI." Accessed January 21, 2022. https://www.health-ri.nl/initiatives/dutch-covid-19-data-support-programme.

5 Synthesis

Key Takeaways
❖ A myriad of health data sources exists among each one of the countries included but remain scattered: the selected institutions were created with the objective of centralising, facilitating the researcher's journey, and accelerating data access procedures to foster health data-related research. ❖ Notwithstanding differences in the entity's legal form and minor differences (whether the data permit review process is delegated to third-parties or not), the process of reviewing and granting access is quite homogeneous. ❖ The institutional differences (whether centralised/decentralised) also explain some of the differences in engaging and collaborating with data holders. ❖ In order to allow multilateral conversation and action between the institutions, training activities, workshops, joint information sessions and many other collaborative initiatives have been encouraged for moving towards a data complementarity and standardization-oriented approach at first national level and then EU level. ❖ The assessment of the comparability of the five entities highlights the need to further strengthen **peer-to-peer cross-border collaboration,** promote bi- or multilateral partnerships with specific focuses (i.e., data quality, data standardisation, metadata, building a common health data culture while engaging citizens…).

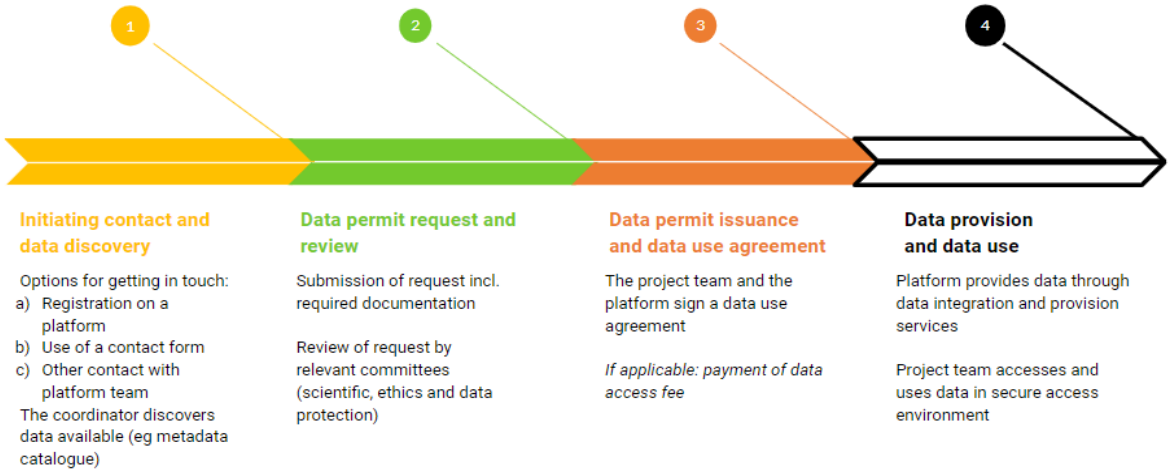
This report provides an overall assessment of the steps required to obtain access to health data in a number of centralized and decentralized systems based on a comparative approach, highlighting a number of similarities but also some key differences.

This report highlights different approaches around governance and access to health data due to different legal and political frameworks across the selected countries. Two national nodes for health data have been developed in Finland and France with an intent to centralise health data requests and health data permit granting delivery. On the other hand, the three other selected institutions evolve in different contexts and are subject to various legal and political frameworks: Health-RI is a public-private partnership with the purpose of reuniting the different health data institutions in order to facilitate the researcher journey, however this structure is not mandated by law, and demonstrates a bottom-up approach of acting towards fostering secondary use of health data. The Spanish example, IACS and the BIGAN platform, is also quite different: the Spanish political system is decentralised, but IACS itself centralises the Aragonese public health data storage and centralises the data access process at the strictly regional level. As a common objective to these platforms can be cited the respect of FAIR principles.

According to the general tendencies observed in the process of receiving and processing the health data access requests in four national/regional settings, general practices have been

observed and paved the way to elaborate a generic health data access procedure. See Figure 6.

Figure 6: Overview of a generic data access approval process



While the above proposal of a generic data permit request procedure appears to be a valid approach, one should also highlight certain limitations with regards to the comparability of the five structures included, which have very different legal and institutional frameworks. The cost in time and human resources, for instance, maybe different according to the responsibility for authorisation and data access. In the case of Findata, both data permit authority and data provision are delegated to the same entity, as for IACS/BIGAN at the regional level, while the process is decentralised for the HDH. Similarly, the metadata catalogue descriptions are provided by individual data holders in the case of Findata, versus being developed by a single national initiative such as Health-RI. Questions arise around the effect on the granularity of the data and on the emergence of international standards for data descriptors and the impact on findability of data, particularly for international researchers? In the four countries represented, there are several ways in which the selected institutions collaborate with data holders. First, Statistics Netherlands organises the “Microdata user day” for every stakeholder concerned in the ecosystem, starting with end-users to data holders themselves. Findata and Finnish data holders have a close collaboration, the latter providing descriptions of the extracted data for the users willing to apply for a data permit by Findata. The HDH has also a very interesting practice, as there is a Data Controller Agreement (“Convention des Responsables de Données”) in place, outlining the HDH technical, human and financial support. The Dutch partnership Health-RI has been included as an initiative to encourage data holders to share the data itself, by emphasising a bottom-up approach. In the case of IACS/BIGAN, the main data controllers are the Aragón Regional Health Authority (Department of Health) and the Aragon Health Service (SALUD), with whom a Data Controller Agreement has been established. Data controllers are also involved in governance, such as BIGAN Oversight Committee which controls and follows up BIGAN activities includes representatives of the above public bodies.

This initial benchmarking report paves the way for comparing further aspects such as database content and interoperability, e.g. claims and DRG metadata at the HDH and Statistics Netherlands. Both entities are working with national claims databases that are comprehensive and well-established, therefore experience sharing in the future can allow for future EU health economics studies of quality and unbiased comparability. Complementarity of data bases can add value at the international level. This is the case of clinical and omics data available through Health-RI and demographic and healthcare financial data available through CBS Netherlands.

The report also invites reflections on how to improve the process' sustainability and should encourage follow up activities to be conducted in areas of importance (ex. metadata description, cross-referencing with databases from various data holders, data security compliance, …). This can include observing training activities, workshops, joint information sessions, and any other collaborative initiatives, at national and broader levels.

Finally, all the interested institutions were created based on the same observation: there exists a myriad of health sources across a wide range of European countries, data gathered but scattered until then. It explains, inter alia, the need to develop health data centralising initiatives, or specifically in decentralised settings.

The results of this report outline the need to further advance this work, through a European conversation, thanks to projects like TEHDAS and the EHDS pilot project. Other EU/ International initiatives with at the core, promoting and implementing peer to peer bi- and multilateral partnerships to allow the exchange of best practice are also growing. In addition, collaborative work on common data standards (e.g. EHDEN) are also required to broaden research scope.

References

1. Hansen, Written Johan, Petra Wilson, Eline Verhoeven, Madelon Kroneman, Robert Verheij, and Evert-Ben van Veen. “Assessment of the EU Member States’ Rules on Health Data in the Light of GDPR,” 2021, 262.
2. Health Data Hub. “Les pratiques de gouvernance et d’accès aux données de santé dans le monde." Accessed January 22, 2022. https://www.health-data-hub.fr/actualites/benchmark-international.
3. Skovgaard, Lea L., Sarah Wadmann, and Klaus Hoeyer. “A Review of Attitudes towards the Reuse of Health Data among People in the European Union: The Primacy of Purpose and the Common Good.” *Health Policy* 123, no. 6 (June 2019): 564–71. https://doi.org/10.1016/j.healthpol.2019.03.012.

Annex 1 Questionnaire template

Questionnaire on Health Data Access Steps

The **purpose** of this questionnaire is to **understand the health data access process across a range of data custodians in 4 countries: Spain, France, Finland, the Netherlands.** The benchmarking of accesssteps is part of **task 5.3** which will contribute to the objective of identifying best practices of cross-border data sharing in Europe.

All Questions are mandatory unless otherwise stated.

1. General Information

1.1 Name of institution

1.2 Country of institution

1.3 Contact person for the purpose of this survey

1.4 Email address

2. Institutional Governance and Structure

2.1 Institutional function

- ☐ Data permit authority
  (an institution responsible for providing permission to access health data)
- ☐ Data holder
  (an institution that stores and manages health data)
- ☐ Both

2.2 Institution type

u

- ☐ Public
- ☐ Private
- ☐ Non-for-profit
- ☐ Public-Private Partnership
- ☐ Other (please describe) _____

2.3 When was the institution established?

DD.MM.YYYY

2.4 Legal basis of the institution

Describe any laws and regulations that govern the establishment and/or the operation of the institution. Please include any hyperlinks to legal text where available.

2.5 Institutional strategy

Describe the main objectives of the institution. Include hyperlinks to the institution's strategic plan or roadmap, if available.

2.6 Decision-making

Briefly describe the roles and responsibilities of the executive management (executive board, steering committee, director, chief)

2.7 Organisational structure

What are the main functions/departments and how do they interact?

2.6 Does the institution require an independent ethical approval for data access?

- ☐ Yes. There is a single national ethical review committee/agency.
- ☐ Yes. There are several authorised independent ethical review committees.
- ☐ No. Ethical review is done within our institution.
- ☐ No. There is no need for ethical approval.

2.7 Does the institution's governance structure involve citizens? If yes, in which roles?

3. Data Types and Sources

3.1 Categories of data handled by the institution (You can select multiple options).

☐ Anonymous data ☐ De-identified data ☐ Aggregate data

3.2 Please list the databases that are accessible through the entity. Include hyperlinks of data sources and supporting material if available.

Database name	Description	Data holder/Data Source
ex. National Cancer Registry (NCR)	*A database of all cancer cases diagnosed between 2003-2021 in the regions of xxxx.*	*National Cancer Institute of xxxx*

3.3 List any databases that will be added in the near future.

Database name	Description	Data holder/Data Source

3.4 Are there any national rules/initiatives to encourage data holders to share data? If yes, please give examples.

3.5 Does your institution provide exclusive access to the databases, or can the data holder also provide access?

- ☐ Yes. Access is exclusively provided via this institution.
- ☐ No. Data is accessible through multiple sources including _____

3.6 Does your institution have a metadata catalogue? Is it comprehensive?Please provide hyperlink if available.

- ☐ Yes. Add link here
- ☐ No.

3.7 Is metadata described by your institution or other entities (ex. data holders).

- ☐ Yes. Metadata is described by this institution.
- ☐ No. Metadata is described by/ in collaboration with _____

4. Data Access Process

4.1 End user categories (Check all that applies).

- ☐ National researchers
- ☐ European researchers
- ☐ International researcher
- ☐ National policy makers
- ☐ European policy makers
- ☐ International policy makers
- ☐ Individual citizens
- ☐ Others (please specify) _____

4.2 Is there an application form/request for data access?

- ☐ Yes
- ☐ No

4.3 Is the application form available online? Please add the hyperlink if available.

- ☐ Yes. Add link here _____
- ☐ No.

4.4 Is the application process managed exclusively by your institution? Please list other stakeholders, if applicable.

- ☐ Yes
- ☐ No. Stakeholders are: _____

4.5 Is the data access process for international entities and European entities the same as for local entities?

- ☐ Yes
- ☐ No

4.6 Is data access granted to private sector users? If yes, please state the eligibility criteria?

- ☐ Yes. Eligibility criteria: _____
- ☐ No

4.7 Are there any requirements or restrictions regarding publication of scientific research resulting from data accessed via your institution?

You can provide examples including but not limited to co-authorship regulations, open science initiatives, public interest concerns, etc…

For questions 4.8 - 4.11 please include access steps for international and national users, if processed differently.

4.8 Part 1: Access Request

In this section, describe the steps for submitting a request for health data access by end users. Please include details of any prerequisites, application forms, ethical review requests, and other administrative steps to submit a formal request for health data access to your institution.

4.9 Part 2: Review Process

Explain the review process from submission to approval, including:

a. stakeholders for ethical, scientific, or administrative approval
b. internal process and follow up by your institution
c. average timeline for various scenarios (ex. international project, expedited review, full review, etc...)

4.10 Part 3: Access Permit

Describe the types of access available (include limitations on number of users, time, viewing versus processing of data, etc.):

a. limited duration access
b. access to aggregates of project data

c. access to individual-level project data
d. unlimited duration of access
e. other (please specify)

4.11 Part 4: Effective Data Sharing

Describe steps for preparing and enabling data sharing. Include hosting solutions, pre-processing, and storing steps.

5. Technological Capabilities

5.1 Describe the technological platform for data access.

5.2 List technological offerings, including data analytics tools, if available.

5.3 Describe data security measures for the storage and sharing of health data.

5.4 Does the institution foster open data and open-source initiatives? Please indicate, if any.

- ☐ Yes. Initiatives are _____
- ☐ No

5.5 Briefly explain data quality practices implemented in your institution or in collaboration with data holders.

6. Business Model and Sustainability

6.1 Sources of funding. Please select one.

- ☐ Public funding
- ☐ Industrial funding
- ☐ Mixed public and private funds
- ☐ Other (please specify)_____

6.2 Pricing Model

Describe the pricing model

- by category of end user (public sector, private sector, researcher, policymaker, etc.)
- by type of service (flat rate per project, differential prices per database, packaged analytical tools, etc...)

6.3 Is there a subscription mechanism for users requiring multi-access?

☐ Yes ☐ No

6.4 Sustainability

Does the institutional operation (services offered) cover the costs to maintain the service? (ex. Does the fee cover the running costs and any data controller charges?)

7. Scientific Activity and Outreach

7.1 Does the institution work with a broad range of public health data or is there a special focus on a particular research domain? *(optional)*

7.2 Briefly explain how the institution engages with data holders, data sources, and other

entities within the health data ecosystem? Include any joint activities or communications. *(optional)*

7.3 Briefly describe any outreach activities to the following categories *(optional)*

- Researchers (local, international)
- Citizens
- Policy makers

Questions 7.4 and 7.5 concern response to the current COVID-19 pandemic

7.4 - Indicate any special measures to encourage data utilisation (ex. expedited review, fast-track processing, waiving of fees, etc...).

7.5 - Indicate any data centralization initiatives (regional, national, European) your institution leads or participates in. Include hyperlinks if available.

Annex 2 Databases that are accessible through the entity

	Database name	Description	Data holder/Data Source
Statistics Netherlands	Microdata catalogue (cbs.nl)		
	Hospital discharge register, primary care db, causes of death, medical professions register, health interview survey.		
	Gezondheid en welzijn (cbs.nl)	Complete list of 88 datasets covering 12 (health and social care) themes with links to descriptions in Dutch (incl. metadata)	
	Gebruikershandleiding Zorgregisters: Informatie gebruik (cbs.nl)	Link to document with a description in Dutch of the 12 themes, and which datasets are to be found within each theme.	
Findata *Finland*	Several databases, does not apply to data collected for statistical purposes		Finnish Institute for Health and Welfare
	Benefits and prescriptions		Social Insurance Institution of Finland
	Data saved in Kanta services		Social Insurance Institution of Finland (data processor)
	Work and earnings data, benefits and the bases for them		Finnish Centre for Pensions
			Finnish Medicines Agency Fimea
	Occupational illnesses, exposure tests and patient registers		Finnish Institute of Occupational Health
	Matters relating to social welfare and health care		Regional state administrative agencies
	Individual's basic details, family relations, place of domicile and building details		Population Register Centre
	To the extent that access is required to data covered by the act on the investigation of the causes of death		Statistics Finland
			Public and private service providers of social welfare and health care
	NB! Findata does not issue permits for the data of all controllers. More details on these data restrictions can be found in the Act on the Secondary Use of Health and Social Data.		
Health Data Hub *France*	OSCOUR	Emergency log	Santé Publique France
	SI-VIC	Information system for all victims of attacks and exceptional sanitary situations (e.g, COVID-19)	Direction Générale de la Santé (French Ministry of Health)
	SNDS Fast Track	SNDS for patients suffering from COVID-19 only	CNAM
Health RI *Netherlands*	see https://catalogue.bbmri.nl/menu/main/app-molgenis-app-biobank-exp	Catalogue with many (not all) data and samples collections in NL	as listed in the catalogue

	lorer/biobankexplorer#/		
	see https://covid19initiatives.health-ri.nl/p/InitiativeOverview	Catalogue with covid-19 initiatives in NL	as listed
IACS/BIGAN *Spain*	User Database (BDU)	Demographic, administrative and insurance covering data on insured population	Health Department (Government of Aragón)
	Hospital Discharge Records in the National Health System (CMBD-H)	Hospitalization statistics and Specialized Out-Patient Care of the hospitals of the National Health System	Health Department (Government of Aragón)
	Primary Care medical records database (OMI-AP)	Data on primary care: appointments, episodes, vaccinations, medical prescription, DPG's (primary care medical history)	Aragon Health Service (SALUD)
	Computerized History of Emergency (PCH Urgencias)	Hospital Emergency service Dataset	Aragon Health Service (SALUD)
	Electronic Prescription (REC)	Prescription of medication, etc.	Aragon Health Service (SALUD)
	Hospital Information System (HIS)	Appointment data for specialty care and scheduled surgery (also known as a surgical waiting list)	Aragon Health Service (SALUD)
	Laboratory Information Systems (LIS)	Biochemistry, Hematology and Microbiology analytical tests requests and results	Aragon Health Service (SALUD)
	Electronic Health Record (partial)	Discharge reports and structured clinical data from specific clinical processes (COVID-19, stroke, pregnancy and newborns…)	Aragon Health Service (SALUD)

Annex 3 Databases that will be added in the near future

	Database name	Description	Data holder/Data Source
Statistics Netherlands	COVID-19 vaccination		
	COVID-19 testing		
Health Data Hub ***France***	I-Share	Tracking the health and consumption habits of 21k students	Université de Bordeaux
	MEMENTO	Follow-up every 6 months with the objective of better understanding the natural history of Alzheimer's disease	Bordeaux University Hospital
	Hepather	Cohort of patients with hepatitis B or C matched to the main SNDS database	Inserm
	Canto	Cohort of patients treated for breast cancer	Unicancer
	ESME	Metastatic breast cancer patients treated in the 18 CLCCs	Unicancer
	BNA	Memory consultations on Alzheimer's disease and related disorders	DGOS
	BNDMR	Records of more than 500k patients with 4,700 rare diseases	AP-HP
	e-SIS	Breast cancer screening in the Gard and Lozère departments	CRDC Occitanie
	Oscour	Summary of individual emergency room visits	SPF
	MDO	33 notifiable diseases	SPF
	STOIC	Chest scans of suspected Covid-19 patients and follow-up data	AP-HP
	E-must	Prospective collection of information concerning Myocardial Infarction (MI) managed by EMS/EMR in Île-de-France since 2000	ARS Île de France
	ATU	Clinical studies on bronchial cancer	Roche
	UroCCR	Clinical, biological and radiological data for all newly diagnosed kidney cancer patients diagnosed with kidney cancer	Université de Bordeaux
	EPICOV	Covid-19 France database, survey of 135,000 people selected at random by INSEE and who answered a questionnaire	Inserm - DREES

Health RI ***Netherlands***	(Radio-)Diagnosis Imagine System (RIS)	Diagnosis medical imaging and reporting system	Aragon Health Service (SALUD)
	Pathological Anatomy	Results and diagnostic from Pathological Anatomy Laboratories	Aragon Health Service (SALUD)
IACS/BIGAN ***Spain***	Hospital Pharmacy	Drug prescriptions and administration to inpatients	Aragon Health Service (SALUD)
	61	Urgent home care and urgent medical transport. Out-of-hospital hyperacute care	Aragon Health Service (SALUD)

Annex 4 Figures of consolidated results from the questionnaires

Figure 1: Institutional function

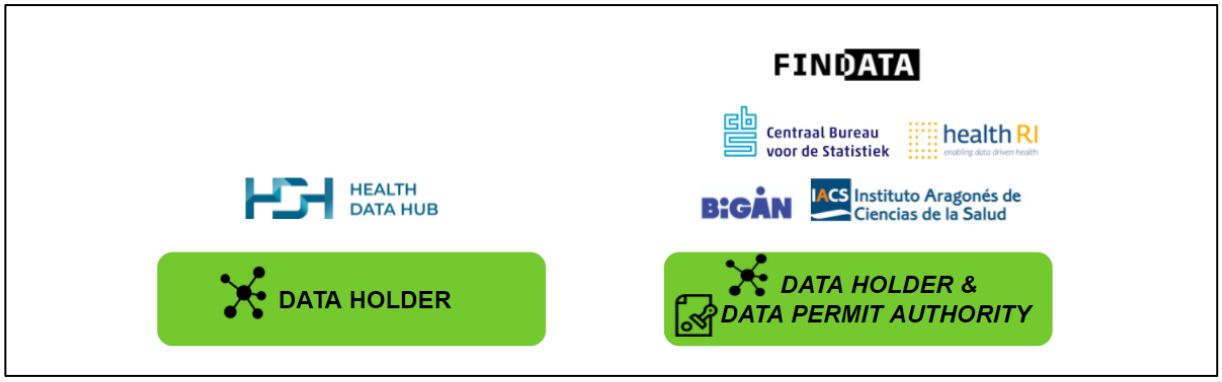


Figure 2: Institution type

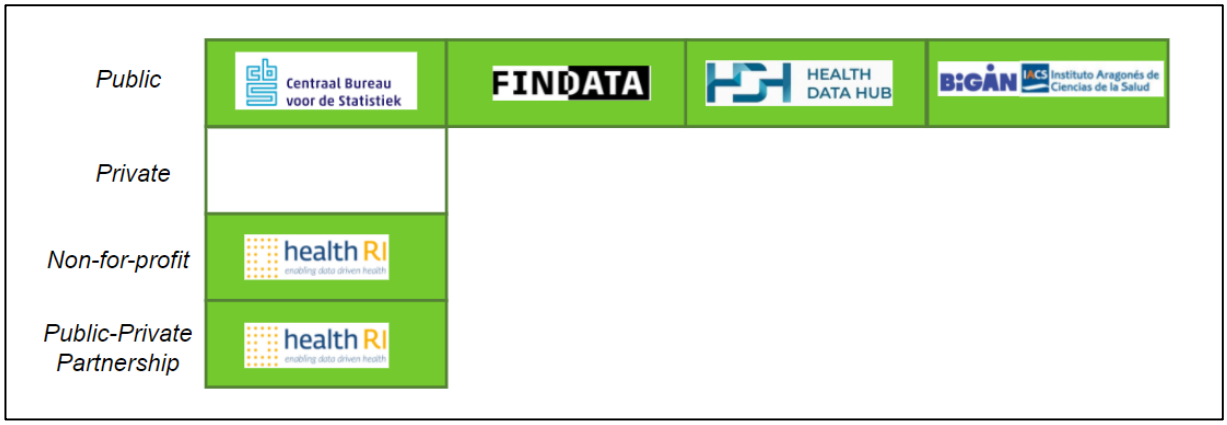


Figure 3: Does the institution require an independent ethical approval for data access?

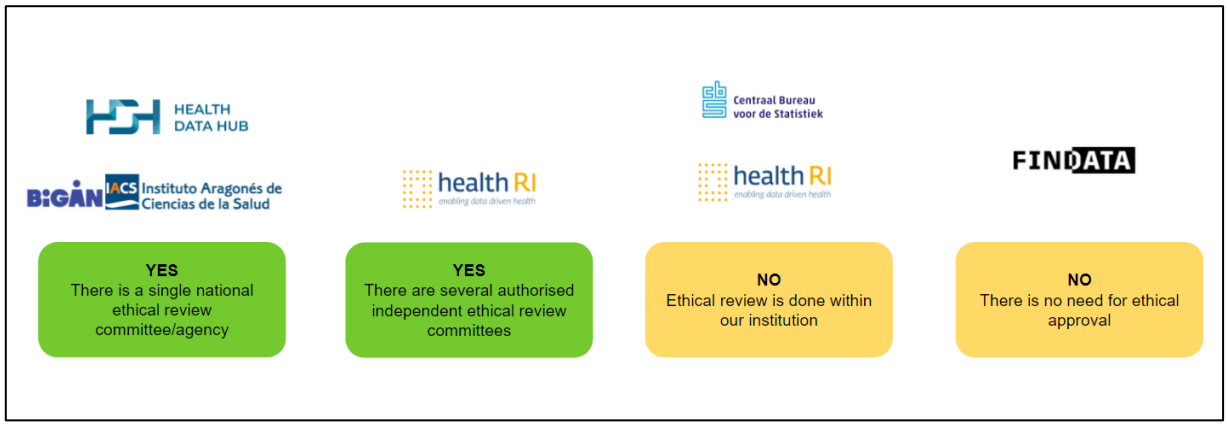
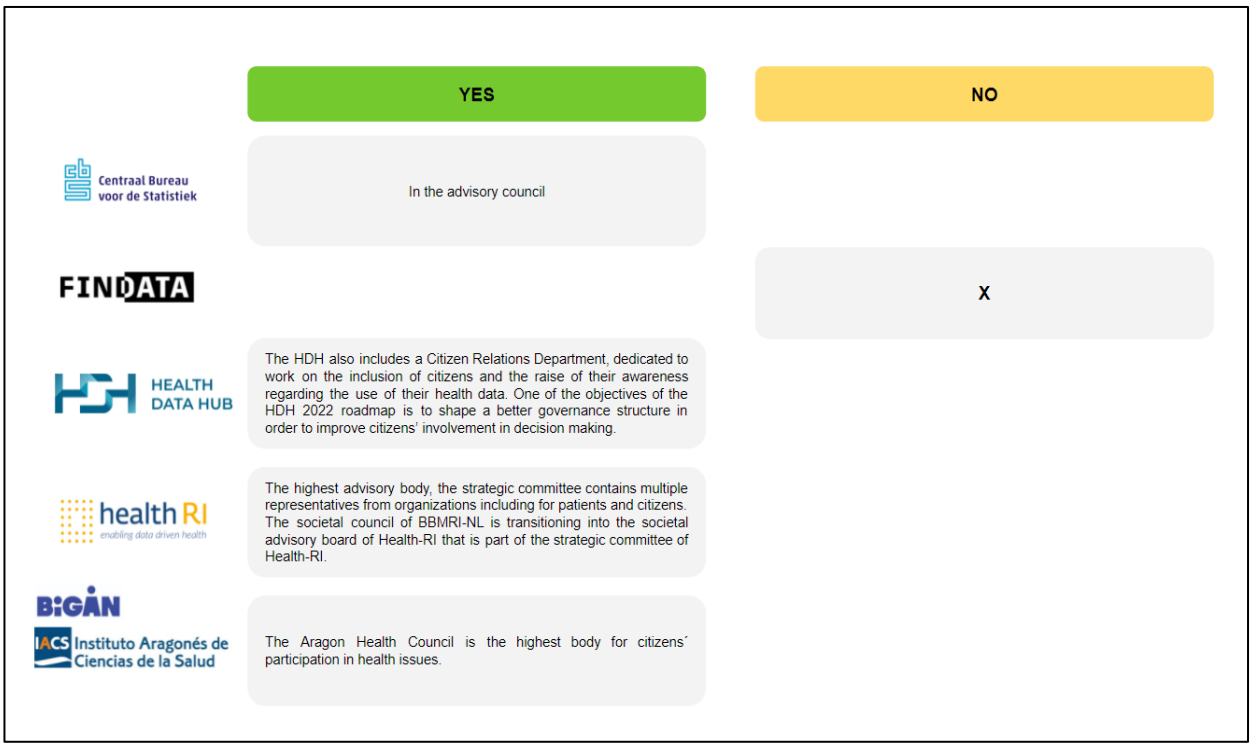


Figure 4: Does the institution's governance structure involve citizens?



	YES	NO
Centraal Bureau voor de Statistiek	In the advisory council	
FINDATA		X
HEALTH DATA HUB	The HDH also includes a Citizen Relations Department, dedicated to work on the inclusion of citizens and the raise of their awareness regarding the use of their health data. One of the objectives of the HDH 2022 roadmap is to shape a better governance structure in order to improve citizens' involvement in decision making.	
health RI	The highest advisory body, the strategic committee contains multiple representatives from organizations including for patients and citizens. The societal council of BBMRI-NL is transitioning into the societal advisory board of Health-RI that is part of the strategic committee of Health-RI.	
BIGAN / IACS Instituto Aragonés de Ciencias de la Salud	The Aragon Health Council is the highest body for citizens´ participation in health issues.	

Figure 5: Categories of data handled by the institution

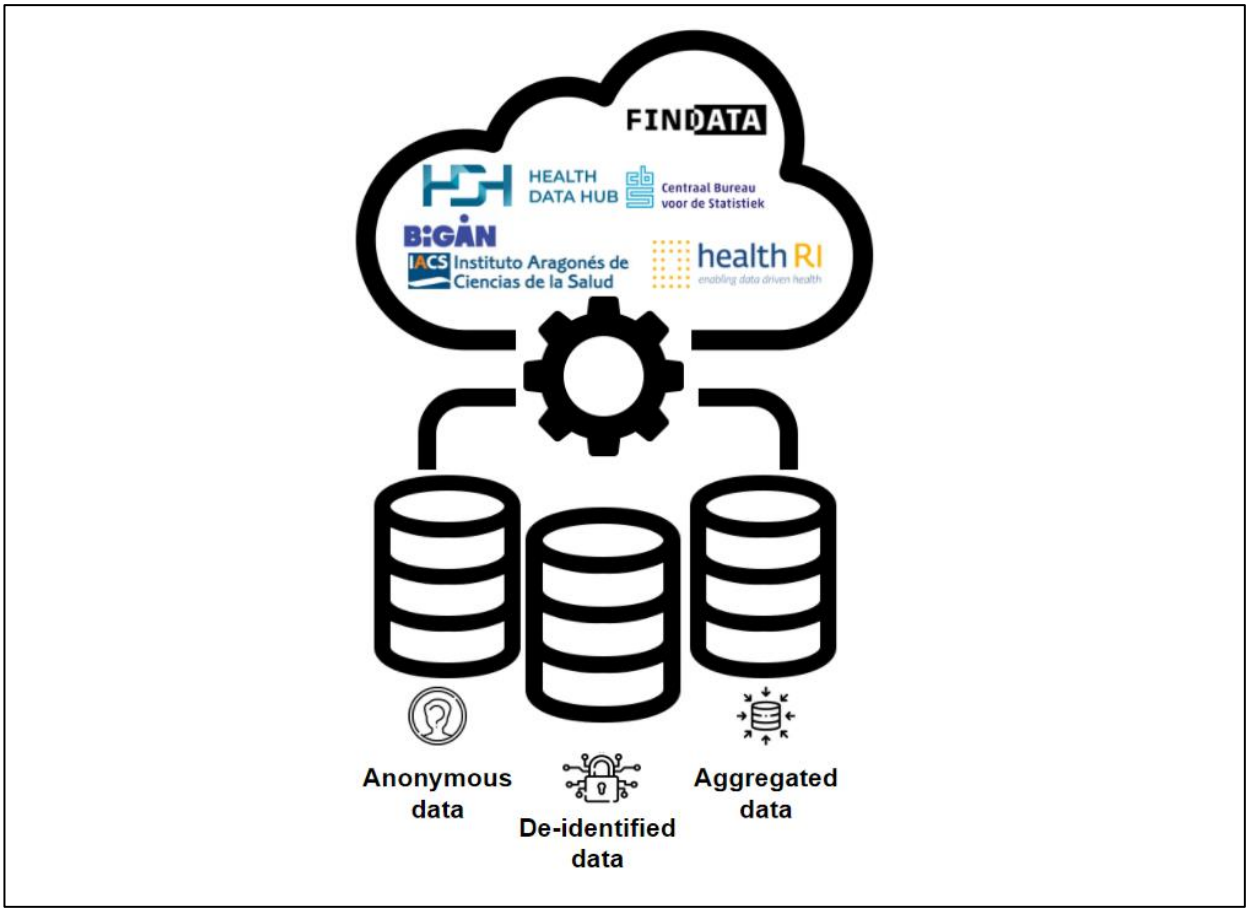


Figure 6: Does your institution provide exclusive access to the databases, or can the data holder also provide access?

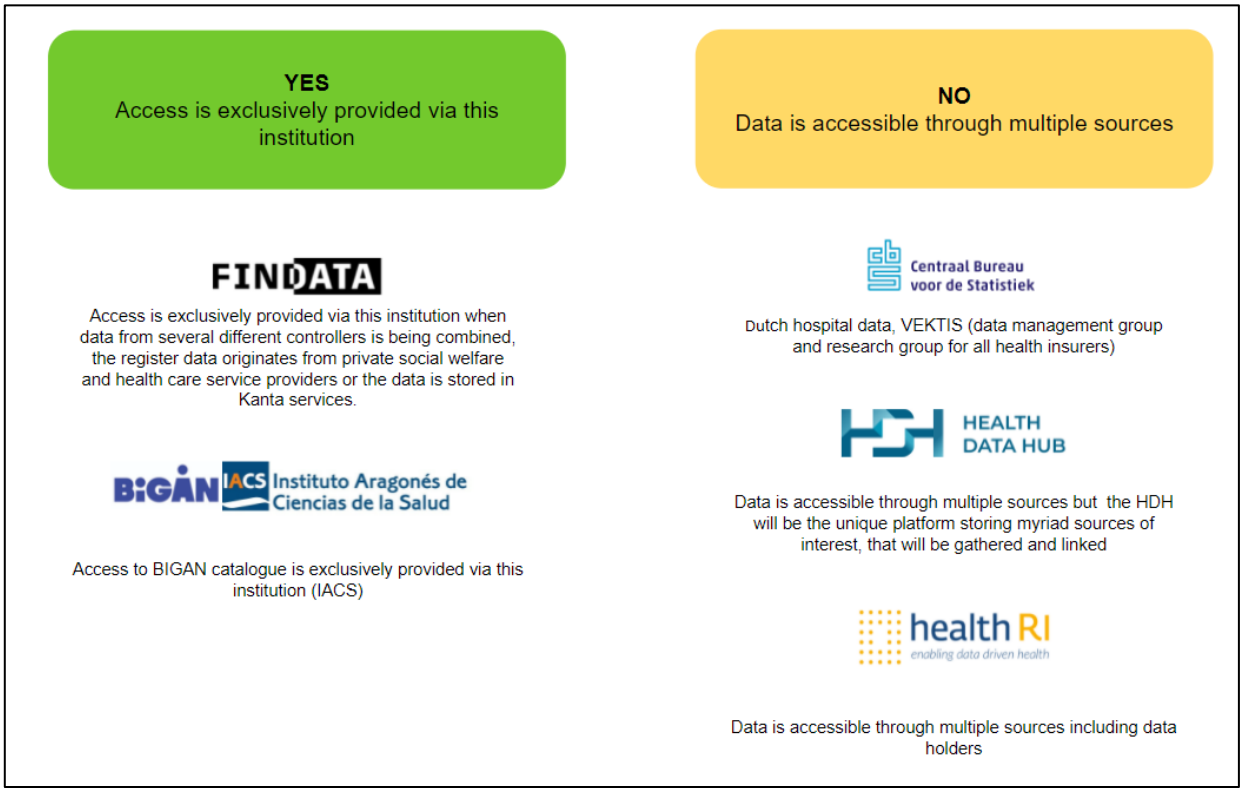


Figure 7: Does your institution have a metadata catalogue? Is it comprehensive?

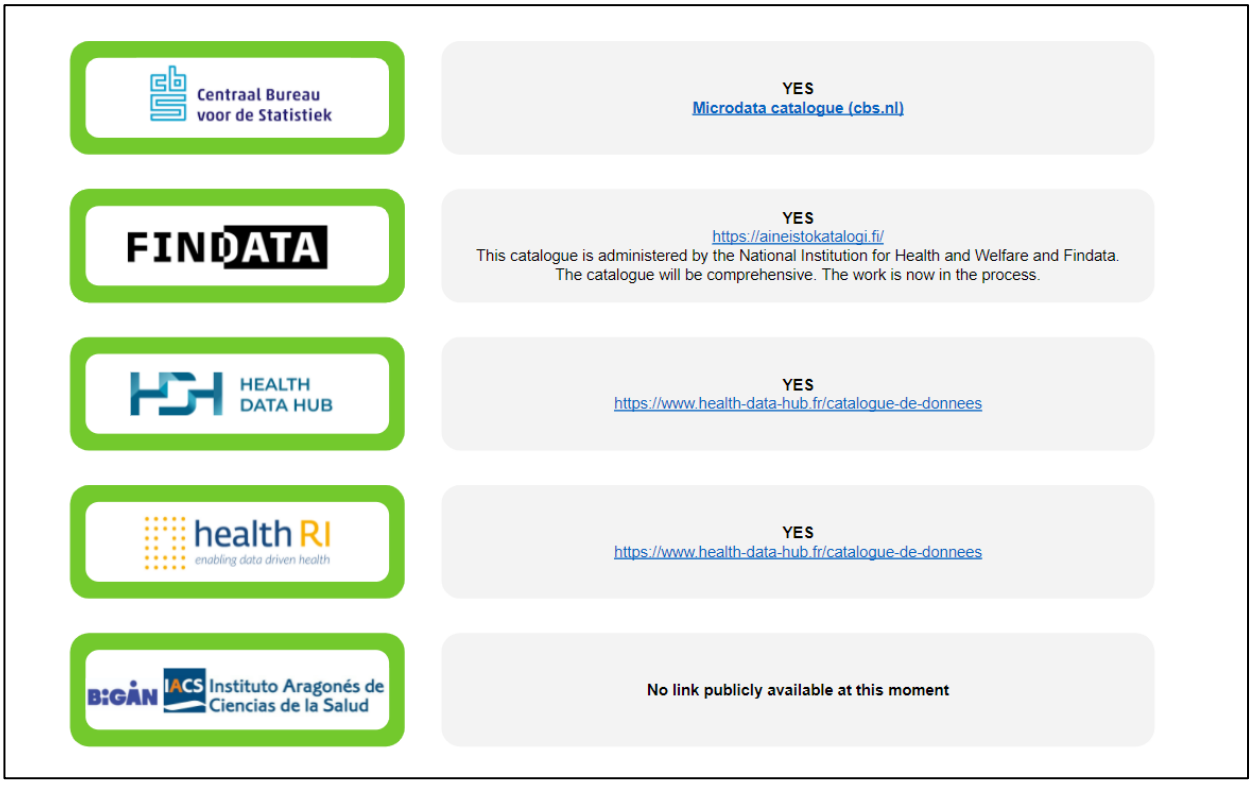


Figure 8: Is metadata described by your institution or other entities (ex. data holders)?

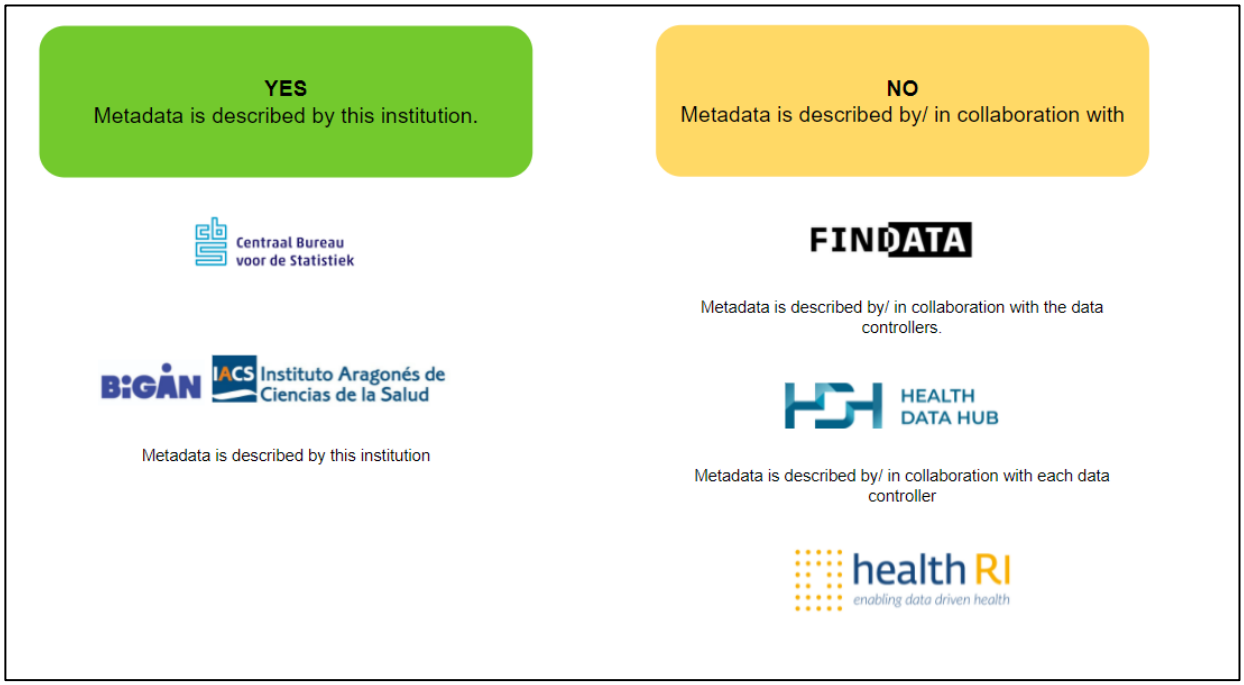


Figure 9: End user categories

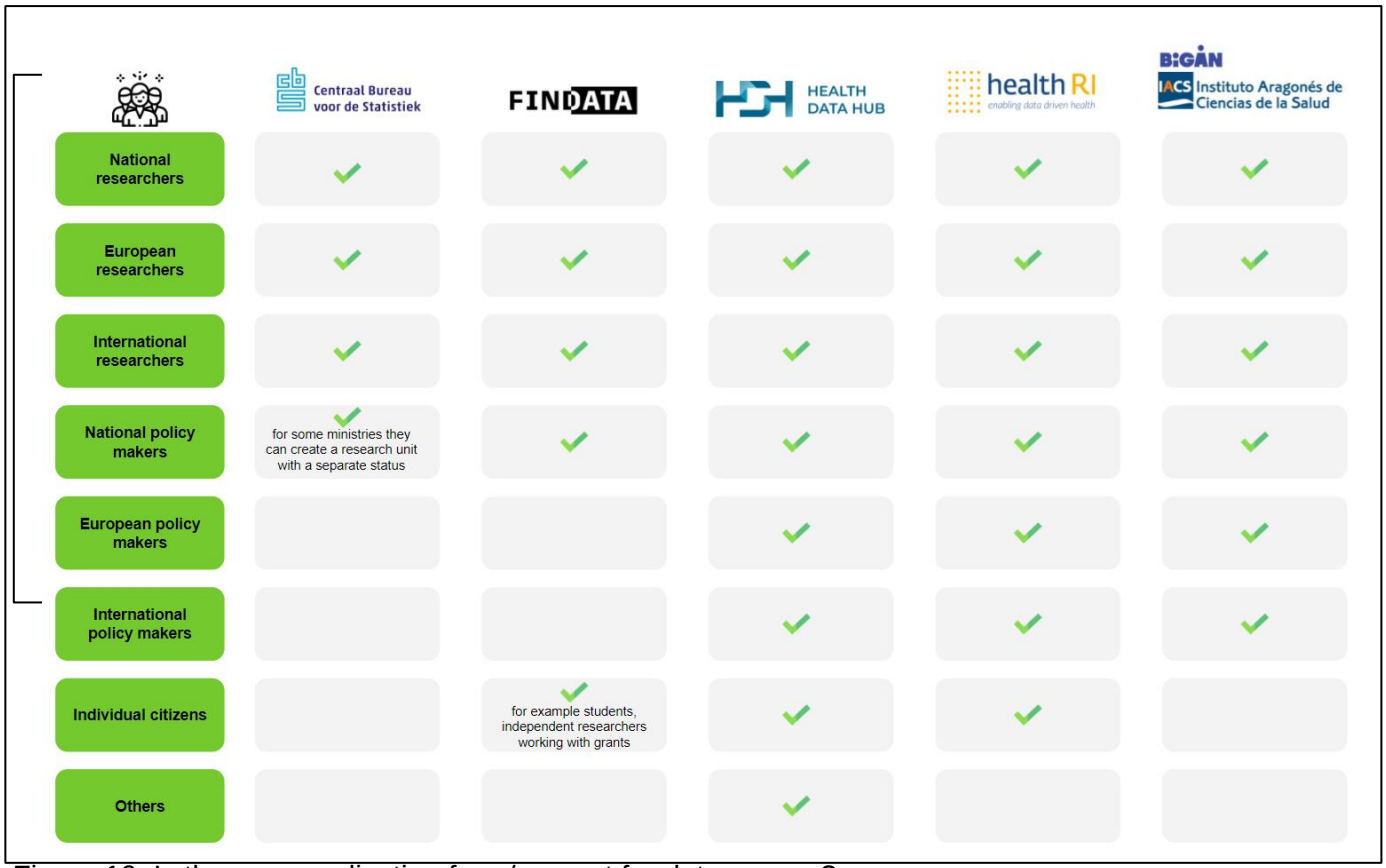


Figure 10: Is there an application form/request for data access?

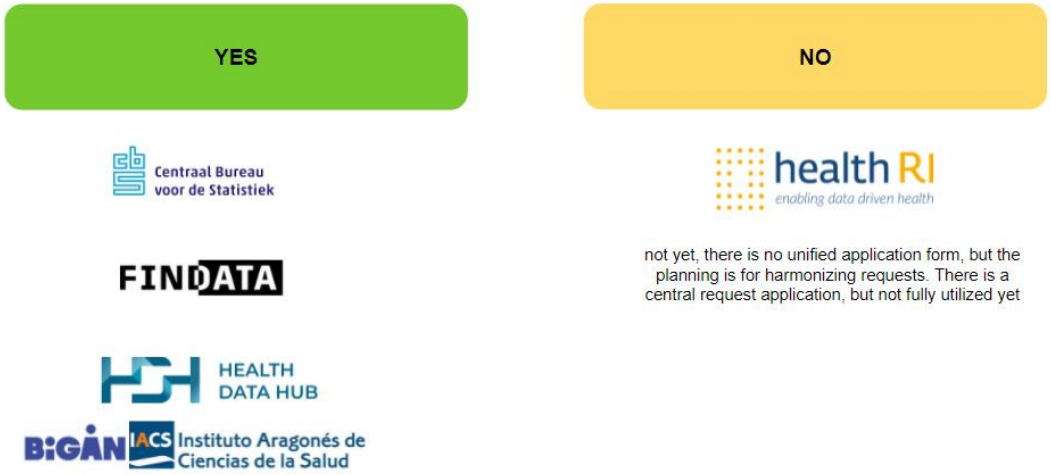


Figure 11: Is the application form available online? Please add the hyperlink if available.

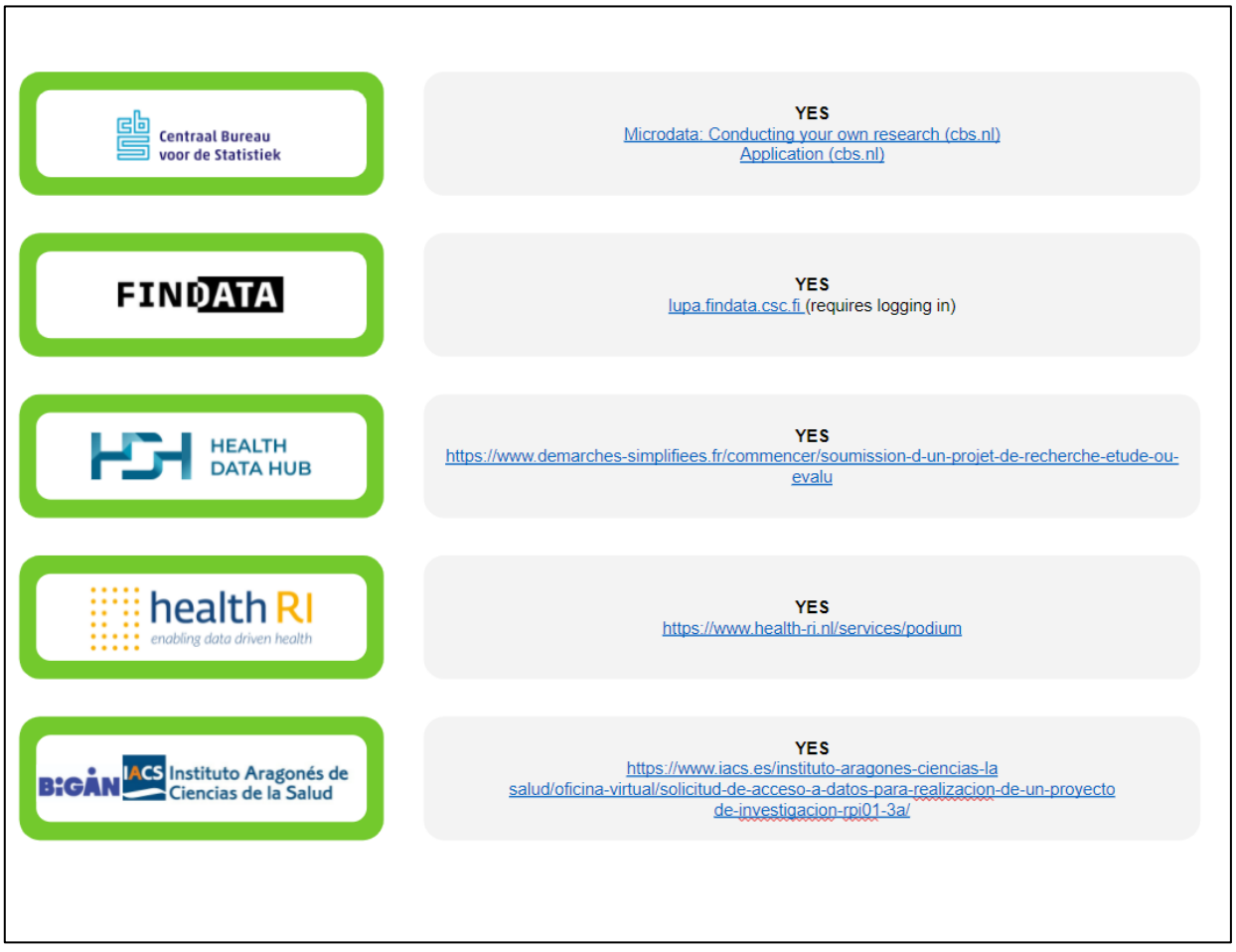


Figure 12: Is the application process managed exclusively by your institution? Please list other authorities, if applicable.

Figure 13: Is the data access process for international entities and European entities the same as for local entities?

Figure 14: Is data access granted to private sector users? If yes, please state the eligibility criteria?

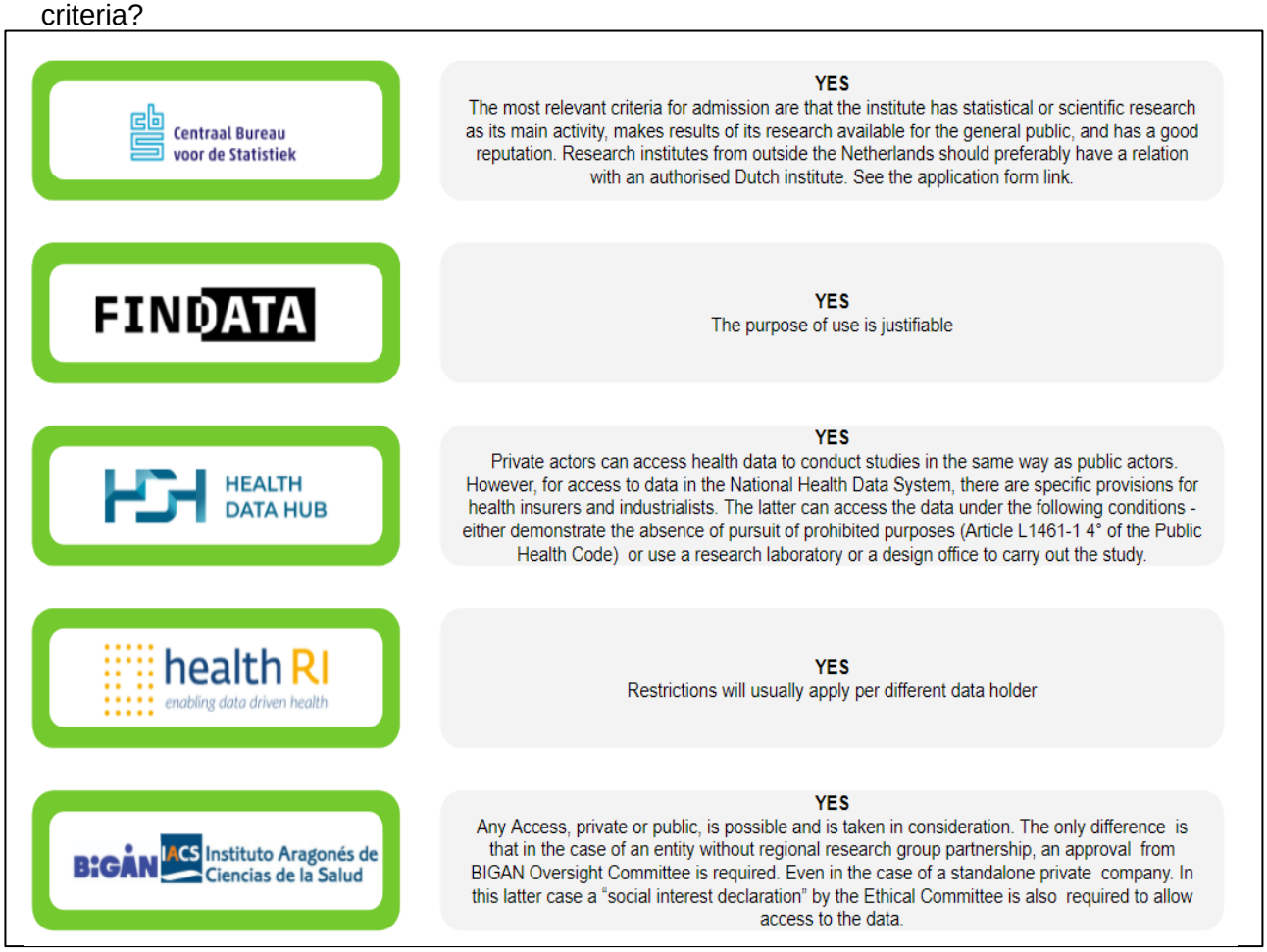


Figure 15: Does the institution foster open data and open-source initiatives?

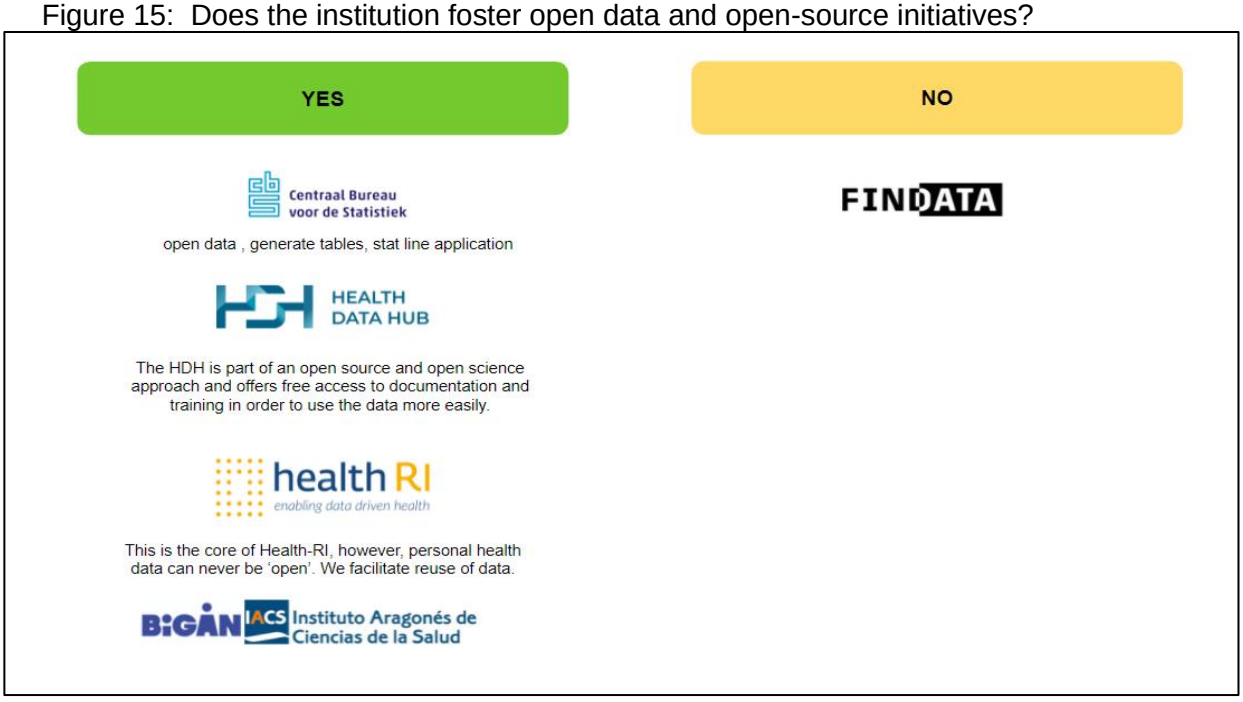


Figure 16: Sources of funding

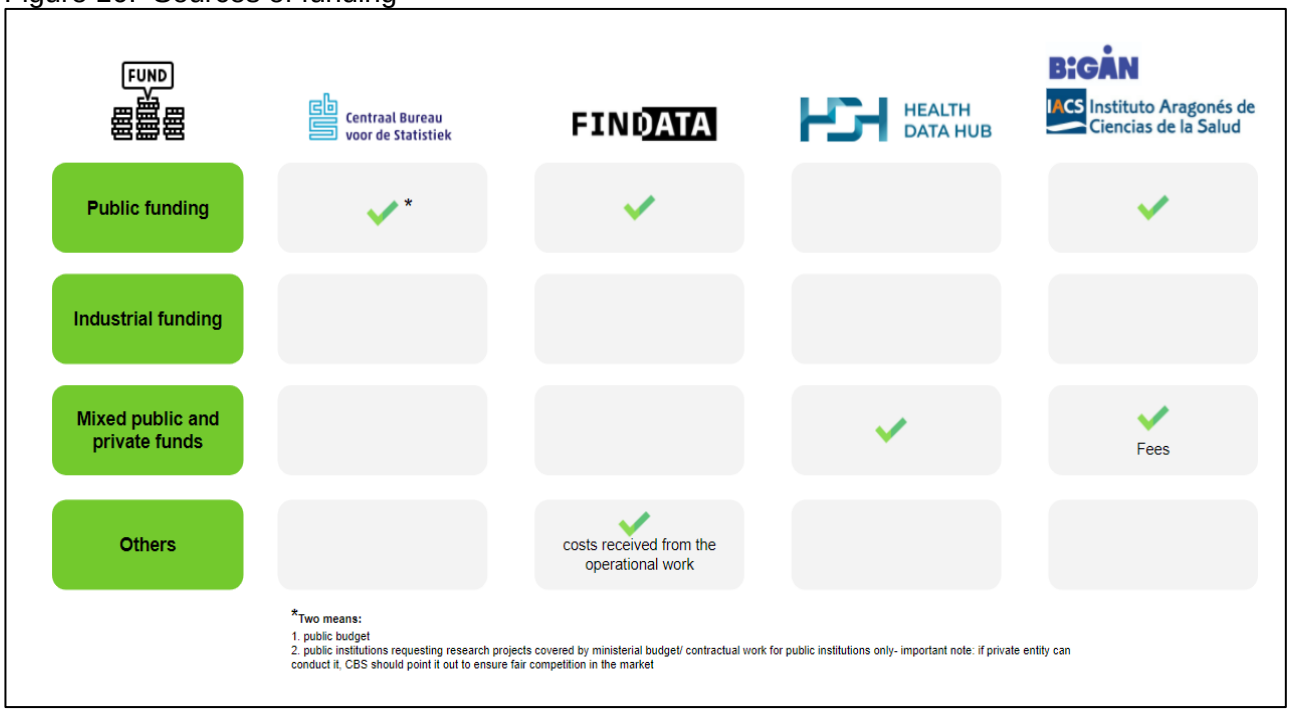


Figure 17: Is there a subscription mechanism for users requiring multi-access?