Business case for the Distributed Infrastructure on Population Health DIPoH

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DIPoH
Distributed Infrastructure
on **Population Health**

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This document contains the business case for the establishment of a sustainable Infrastructure for Health Information: the Distributed Infrastructure on Population Health (DIPoH). It is the fulfilment of deliverable number 7.2 of work package 7 of the Joint Action on Health Information (hereinafter referred to as InfAct) with project number project 801553.

The following business case consists of three main parts addressing:

1. The need for the infrastructure and its contextual embedding;

2. The organisational structure and governance; and

3. The finances.

More detailed information and backgrounds are provided in 13 Annexes.

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Glossary

Comparative population health research: Domain of science focusing on population's health status and population's exposure to health determinants as life styles, environment or health systems. The comparative nature lays on DIPoH's scope related to the use of Pan-European data, for cross-country comparisons including analyses by gender, age groups, and over time (secular trends), or other appropriate stratified variables.

Data: Discrete observations of attributes or events that carry little meaning when considered alone.

Data hub: an entity that is part of a hub-and-spoke system for data integration in which data from multiple sources and with various requirements is reconfigured for efficient (distributed) storage, access and delivery of information / a data exchange with frictionless data flow at its core.

Data model: In a distributed research infrastructure, data models are a formal description of data sources (entities, their attributes and their relationships) and metadata specific to a scientific study, that are the basis for semantic interoperability, thus allowing reliable comparative research.

Data reuse: Data collected by public institutions as part of their health information systems (population- and disease-based registries, surveys and health examination surveys, electronic health records, administrative data, claims data, etc.) are gathered for purposes different to research. Reusing the wealth of data is a paramount opportunity for population health research.

Distributed Research Infrastructure: A distributed RI consisting of a central facility and interlinked nodes and networks. As opposed to centralised research infrastructures, the distribution of resources and services are devoted to a common goal and coordinated by an overarching level.

European Free Trade Association (EFTA): an intergovernmental organisation established in 1960 to promote free trade and economic integration to the benefit of its Member States with currently 4 members: Iceland, Lichtenstein, Norway and Switzerland. The European Economic Area (EEA) includes the European Union and the EFTA countries except for Switzerland.

European Union Associated Countries (EU AC): the territories and countries where Articles 81(1) and 82 of the EU Treaty apply or competition provisions similar thereto apply pursuant to bilateral or multilateral agreements between the European Union and such territories and countries.

European Union Member States (EU MS): Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

FAIR principles: following the rule that data and information must be Findable, Accessible, Interoperable and Reusable.

Federated data infrastructure: an infrastructure facilitating data sharing with individual institutions gaining access to resources in other institutions in a secure and trusted way.

Health information: All organised and contextualised data on (public) health and health service activities and performance that is fit-for-use and contributes to health promotion, prevention, care and policy-making.

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Health information systems: All activities and resources related to public health monitoring, reporting and knowledge translation, importantly including structured data collection systems and analysis of knowledge gaps to feed research. Operating a health information system requires governance mechanisms and legal frameworks, inter-institutional relationships, principles and values.

Information: Data which is contextualised, i.e. reduced, summarized and adjusted for variations such as the age and sex of the population so that comparison over time and place are possible.

Intelligence: the product of information being transformed through integration and processing with experience and perceptions based on social and political values.

Interoperability: Following the European Interoperability Framework, interoperability refers to a) a full compliance with the **legal** and ethical provisions in each constituent node; b) an **organisation** that supports knowledge exchange and software transference across nodes; c) a compatible **technological** environment that supports the communication between nodes and allows the deployment of the computational tasks; and d) the existence of common data models that enables **semantic** standardisation across data sources. In a distributed research infrastructure, interoperability is a key feature for its governance and achievements.

Knowledge translation: The appropriate exchange, synthesis and ethically sound application of knowledge to interventions that strengthen the healthcare system and improve health.

National Node on health information: an organisational entity, often linked to a national institution or governmental unit that functions as a national liaison and brings together relevant national stakeholders in the country in a systematic way. Its exact role in DIPoH and nationally depends on the needs, wishes and (legal) organisation of each country.

Population health data: data related to the health of specific groups of people.

Research: process employing both quantitative and qualitative methodologies and covering a broad range of topics and aims, from more fundamental to more applied.

Researcher: a professional engaged in the conception or creation of new knowledge, products, processes, methods and systems, as well as in the management of the projects concerned.

Research Networks: a group of collaborating researchers (existing or newly developing communities) that collect, exchange, and harmonize research data and/or information on a particular health topic, linking national data for EU comparison .

Secondary use of data: see data reuse; Reuse is the preferred terminology, as 'secondary' may have an unwanted connotation of coming second in importance; without data there can be no progress in public health and health care.

User: an individual, a team, or an institution from any sector, including public and private sector, making use of the Research Infrastructure's facilities, services or data to enhance his level of expertise and improving methods and systems.

Executive summary

Framework for sustainable public health intelligence

'Data' is a highly valuable commodity, especially in the right environment where data can be taken further towards actual information and actionable knowledge. There is a great demand in public health intelligence for Europe, which the pandemic has highlighted further. A sustainable infrastructure where the data, the necessary domain-specific expertise and the right legal, operational, semantic and technical circumstances come together is lacking. This business plan describes the set-up of a sustainable infrastructure that combines just that. The infrastructure will take the shape of a Research Infrastructure (RI), which will ultimately attain the legal status of an European Research Infrastructure Consortium (ERIC). The goal of DIPoH is efficient and efficacious use of public health intelligence for the advancement of public and population health in Europe.

The challenges in population health and research in the European Union (EU)

Health and health care take up a fundamental position in all European countries. EU citizens list health as an important good and a healthy population is a prerequisite for economic sustainability. Yet, our societies are confronted with ageing populations, increasing burdens of chronic disease, persistent inequalities and growing pressure on health systems. Health care accounts for more than 8% of the GDP in most EU Member States (MS). To tackle these challenges countries need a timely and topical supply of high quality health intelligence.

Currently, the necessary type of research input is not structurally and sufficiently available within the European research landscape. Data on population health and health care are scattered over different databases, institutions, projects and networks, generally lack interoperability and are often difficult to find, access and re-use (un-FAIR). Many health information activities operate on a project base, lacking long-term sustainability and integration. There is little investment in translation of knowledge into society. Also, large disparities exist in health information systems and health research capacities in EU MS. Health researchers, MS, the European Commission (EC) and the European Parliament all have called structural action on health information for years, illustrating the need for action.

Why a Research Infrastructure for Population Health?

The health challenges Europe is facing require use of the full capacity of the European research community. The foundation for this lies in a sustainable and coherent supply of European comparative health data, research and international research networks to identify common challenges, best practices and new research insights. In other words: a solid European Structure for Health Information, entailing all activities and resources related to population health monitoring and health system assessment, including structured data collection and analysis of knowledge gaps for research. Pan-European comparative studies of population health problems are able to look into the underlying factors and point at possible solutions. Europe hosts a range of lifestyles and different health (care) systems providing a large natural experiment to be investigated. Re-use and linking public data from various sources allow researchers to generate larger, more powerful datasets. These will provide in-depth insights to the most important factors influencing health, health care and the safety, quality, effectiveness and costs of interventions. Through the participation of countries, an RI is in a better position to support the sharing of research data and results. An RI eventually has the potential to inform improvements to health and social sector policies, practices and technology, to increase national wellbeing through better health and/or lower health and social services costs. DIPoH will provide countries with access to high quality data and information on health, within a framework that allows for translation into usable knowledge and uptake into policies.

What are the main objectives of the Research Infrastructure?

DIPoH will ensure the best available health intelligence by providing support towards the development of large-scale, integrated and sustainable data services for population health and health services research. DIPoH will contribute to cataloguing, curating and integrating data, information and knowledge generated by a critical and growing mass of European researchers and their international networks. In this way, it will exploit the natural variation in health and healthcare in Europe. DIPoH will strengthen the synergy in the EU by facilitating comparative research, efforts at data linkage, pan-European use of data, methods, results and better involvement of national experts. DIPoH will help researchers ensure that research is findable, accessible, interoperable and reusable and create ever-stronger research networks.

What services will the Research Infrastructure provide?

In order to reach the above objectives DIPoH will provide large-scale, integrated and sustainable services to population health sciences through four main activities:

● A **one-stop shop**: DIPoH will function as a library providing the data catalogue on health and health care data, their meta-data, methods for collecting, curating, reporting and using them, as well as the people knowledgeable about this. It will facilitate access and (re-)use of European data for research on the health of populations and on health care systems and their outcomes.

● Investing in **innovation** in health information development for population health research to support health researchers use pan-European data in a distributed way, link different data sources and make their research FAIR and ELSI compliant. Population and patient health data and health care systems data will be available at individual and aggregated level from many sources, among others, disease registries, administrative health and non-health databases, surveys and health examinations, and cohorts of populations and patients

● Providing **capacity building** to promote interoperability and tackle health information inequalities: learning about management of data on population health and health care starting from the phase of designing data collections to analysis, reporting and preservation. Training of the health research community involves both the data producers and data users.

● Assisting the health research community in developing methods for **knowledge translation research** to support decision-making processes. This is the return of investment to society, improving the health of the European citizens and increasing the efficiency of our health care systems.

How will the Research Infrastructure be organised and who will be involved?

DIPoH will be a distributed effort with a central coordination office, national nodes across EU countries, pan-European domain specific research networks and their research communities and a structure for FAIR data exchange. The Central Office will coordinate governance and services. Research networks (existing and new) contribute their expertise. National nodes on health information (in development) are involved as national coordinating partners and liaisons to their national research institutes and ministries of health and research. Data hubs (in development) combine knowledge on FAIR data sharing and set up an infrastructure.

How will the Research Infrastructure develop and support itself?

There is widespread demand for DIPoH's services. Much has been done already to make the infrastructure a reality and the consortium will keep developing itself as a learning organisation. The momentum is there for investments to get formally organised. The set-up of DIPoH is being supported through in-kind contributions, investments from institutions and EU grants for development. When the legal entity is established, the Consortium will receive funding from MS through membership fees, in-kind contributions and the individual fees for services; The consortium is expected to be highly successful in acquiring research grants and to receive assignments from several stakeholders, including the EC, charities and commercial parties.

1. Defining the Health Information Research Infrastructure

The COVID-19 pandemic has very clearly shown the importance of well-functioning health systems, health information systems and international exchange of health information. It has shown the value of a healthy workforce, the relevance of population health risk factors and inequalities and the added value of gathering and using knowledge in terms of human value and efficiency.

In this business plan we make the case for a sustainable infrastructure for population health and show that this infrastructure will support researchers and policy makers on exactly these themes. In this section we cover the need for the infrastructure, its position in the landscape and added value to it, its users and services, potential hurdles and timeline.

1.1 Concepts and gap analysis

To support good population health, there is a need to generate and use health intelligence. For this, it is necessary to have data and the right infrastructure and expertise to make use of the data. It is important that data is collected in large population samples and compared with other regions or countries. However, there currently is no sustainable infrastructure for this, projects are short-lived and data is scattered.

Importance of health and health care
Health of populations and health care draw intense political and societal attention throughout the European Union (EU). A healthy population is a prerequisite for economic sustainability. EU citizens list health as an important good and health plays a fundamental role in all Member States (MS). The EU MS have committed themselves to ensure that human health is taken into consideration in all of its policies (Treaty on the Functioning of the European Union) as well as to the principles that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition" and that "Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures" (preamble to WHO constitution).

Challenges and gap analysis
Society is confronted with increasing health inequalities, substantial and increasing health expenditures, ageing populations, increasing burden of ill-health, growing pressure on health systems, strong technology drive and growing patient expectations. Health care accounts for almost 10% or more of the GDP in almost all EU MS. A large part of this is spent on treating NDCs. NCDs significantly affect patients' working and social environment which, considering their scale, greatly affect societal stability. A substantial proportion of the direct and indirect costs of NCDs in Europe could be saved through preventative policies and actions (Council 2011). Losses to health related to health inequalities have been estimated to account for 20% of the total costs of healthcare (Mackenbach, 2011).

The health information field has long been confronted with challenges (see figure 1.1). It is fragmented, with data being scattered over different databases and institutions, lacking interoperability, difficult to find and to access and incomplete. Large disparities exist in health information systems and health research capacities in EU MS. Many health information activities are operating on a project base lacking integration and long term sustainability. Data suffers from lack of reproducibility and (re)usability. There is little investment in translation of analysed population health data into society. "The existing gaps in the availability of relevant and comparable data remains a barrier to assessing the full implications of non-communicable diseases for individuals, communities, healthcare systems and economies. The lack of data prevents researchers and governments from assessing the impact and effectiveness of NCD policies, programmes and treatment on different population groups" (ECDA, EPHA & NCD Alliance, 2019).
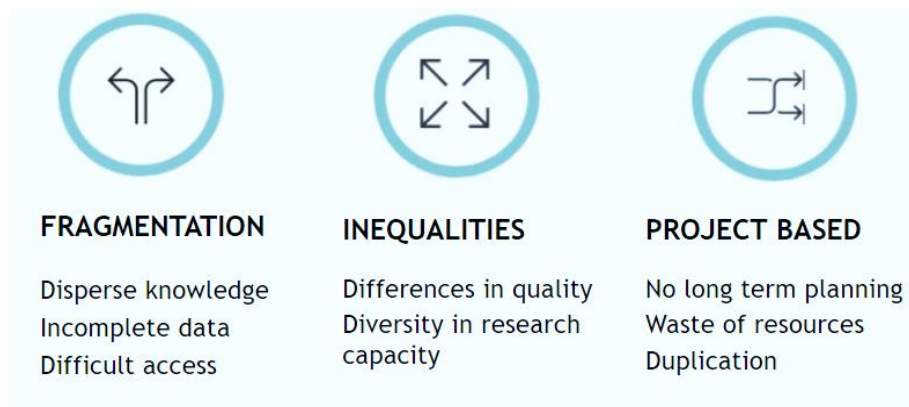
Figure 1.1: Current challenges of health information

In order to develop new ways of tackling the challenges, identify the most (cost-)effective way to address them and evaluate if and what information gaps exist, data, information and monitoring is needed. Formulated in terms of structure: Europe needs a well-functioning health information system (see box 1 and figure 1.1).

Opportunities for European health information and research

Pan-European comparative studies help to identify problems in population health (trends), investigating the explaining factors behind them as well as possible solutions. This means: learning from variations in health and care and from best practices in EU MS. They provide an opportunity to build a critical mass, by large-scale collaboration throughout Europe, to be competitive and have international impact and visibility. They generate more and better health data, growing potential for linkage of health and non-health data, data enrichment (big data) and artificial intelligence and IT-improvements (towards more timely and real time assessment).

DIPoH structures a concerted effort between national research experts together with research communities of pan-European research networks. DIPoH can provide the necessary type of research input that is currently not structurally and sufficiently available within the EU research landscape (see section 1.4). DIPoH can contribute to the effective translation of health knowledge towards citizens, policy makers and health system managers and into the development of interventions, guidelines and policies that will benefit society. In other words, DIPoH can contribute importantly to a European Health Information System.

Box 1: The importance of health intelligence as major building block for prosperity (based on Verschuuren et al, 2017)

- **Promoting health and delivering good care is only possible with good health intelligence.**
- **Good health intelligence is only possible with good data.**
- **Society can only prosper if well-functioning health information systems are in place.**

Health information systems are multi-layered systems, aimed at producing health intelligence. Health information systems include research activities related to data collection, analysis and contextualisation, health reporting, knowledge translation, and finally policy-making. New policies may lead to new health situations which may result in new relevant research questions thus re-initiating the process.

High-performing equitable health systems need guidance from high quality health information systems, requiring research at all levels.

Provided with societal context, research is made available for decision-makers (evidence-informed policies), improving health systems and ultimately the health of populations. In terms of outputs: from data to information, knowledge and wisdom.

DIPoH:
- Covers gaps in the health intelligence process currently not covered
- Adds value to existing national research infrastructures
- Connects national research communities with international research
- Pools resources and capacity
- Speeds up the process between data collection and wisdom
- Strives to be a new world class infrastructure
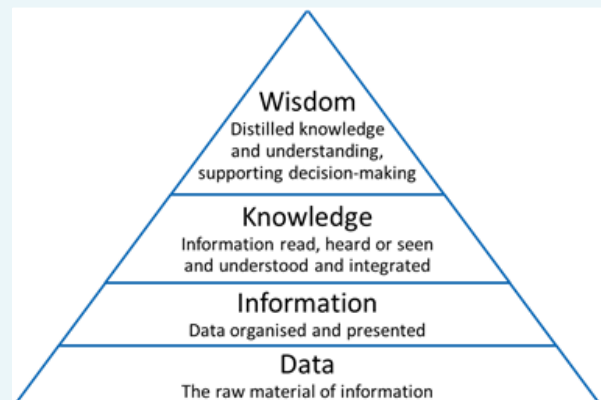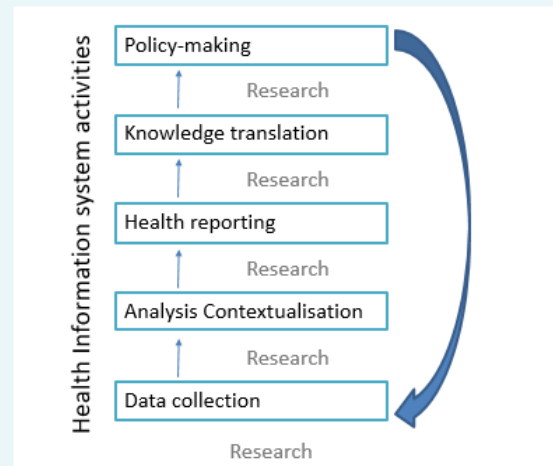
Time for joint effort

Action is required to organise European health information into a sustainable structure. If DIPoH will not come into existence, in the long term, this will lead to high costs to both health and economy. This is due to inefficient use of resources (e.g., because of duplication and discontinued websites), increasing knowledge gaps and an increasingly large part of the population that cannot live to its full potential, reflecting for example in a less capable workforce and more disease. The need for a health information infrastructure at European level has long been recognised and already prepared for in several international collaborations, see Annex 1 for a historical context. EU Members States and Associated Countries (MS/AC) now have a chance to organise themselves.

1.2 Business plan for a Research Infrastructure for population health

In light of historic and current (political) context, the set-up of a research infrastructure on the ESFRI road map and ultimately European Research Infrastructure Consortium (ERIC) is regarded as the way forward. Compared to the other options, the strongest argument to support the setup of an RI is its feasibility in the relatively short term (see Annex 2). It has the following advantages:

- Through the participation of countries it is in a better position to support the sharing of research results and data, and to support the adoption of methodologies by the research community and by operators of infrastructures at the national level.
- It is not project based and (therefore) can assure continuity, maintenance and sustainability of health information research.
- DIPoH offers the technical facilities, the agreements on standards and the organisational framework that are necessary to make the sharing of comparable health data possible at European scale. Only an entity operational at EU level can achieve this.
- It can apply for funding from European Commission (EC) programmes.
- Its internal structure is flexible and can be tailored to current needs and demands and thus has high usability for the MS' national health information infrastructures and EU institutions.
- In addition, an ERIC has authority and a strong legal base. It provides instant legal recognition at EU level.

1.3 Purpose, Vision and Mission of the Infrastructure

In order to more efficiently and effectively support the health of populations in Europe, DIPoH will:
- Connect stakeholders and population health information delivered by research communities;
- Improve stewardship for FAIR data for efficient (re)use and sharing of data;
- Invest in knowledge translation;
- Retain knowledge; and
- Invest in capacity building.

DIPoH's vision is a sustainable infrastructure for improving the health of populations in Europe.
The mission of DIPoH is to facilitate comparative research through identification, access, assessment and reuse of population health data within the EU and support evidence-informed policy-making.

1.4 Scope and landscaping

Scope: what does DIPoH cover?
The conceptual model under which DIPoH operates is shown in figure 1.2. This framework provides the overview of the different domains that are included in population health information. These together provide a larger picture of the health of populations as a whole:

1. Health status and well-being information: includes data of different disease states, the population quality of life indicators, life expectancy data, and different mortality statistics data.

2. Determinants of health: the information of the different factors that determine health. These are behavioural factors, risk factors and protective factors, socio-economic factors and environmental factors.

3. Health systems: including health information systems and healthcare systems. The performance, access, efficiency, and availability. These all impact the health of the population as well.
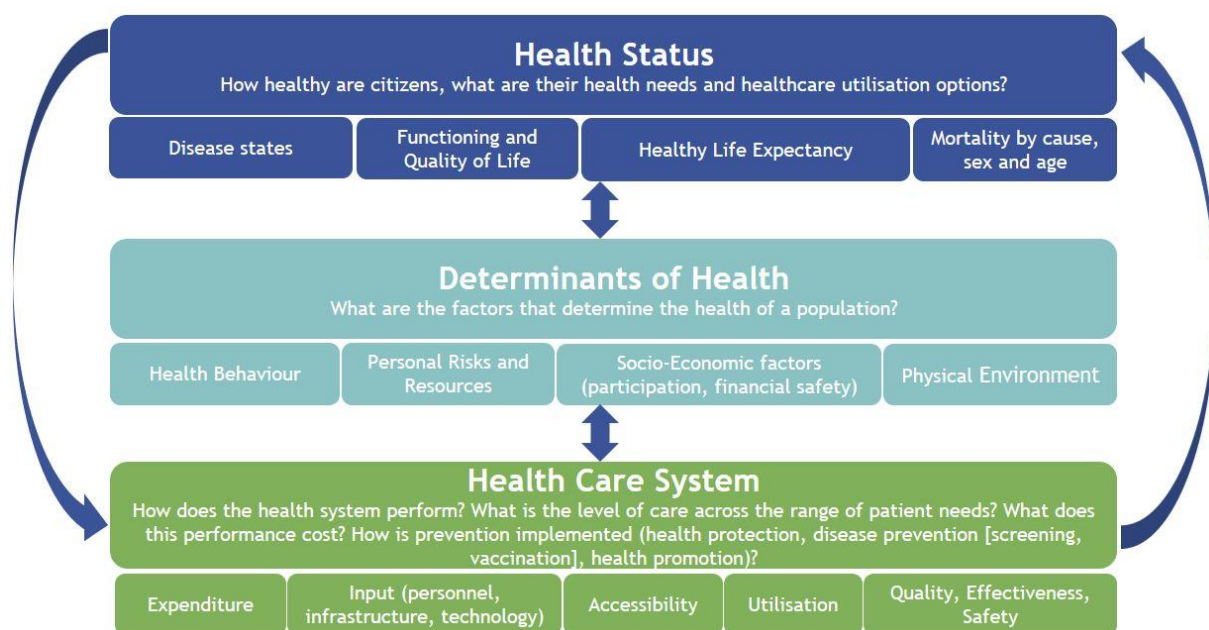
Figure 1.2: Schematic representation of (population) health framework

Through this framework it is clear that DIPoH will include multiple domains. However, it is important to note that DIPoH will not interfere with domains already covered sufficiently well by specific institutions or specialised networks, but will rather investigate how to create synergy (this is further explained in the following sections). Considering the framework above, DIPoH focuses on Non Communicable Diseases (NCDs) and may include the wider impact of infectious diseases on population health (for example the long term impacts of COVID-19 on the health of populations).
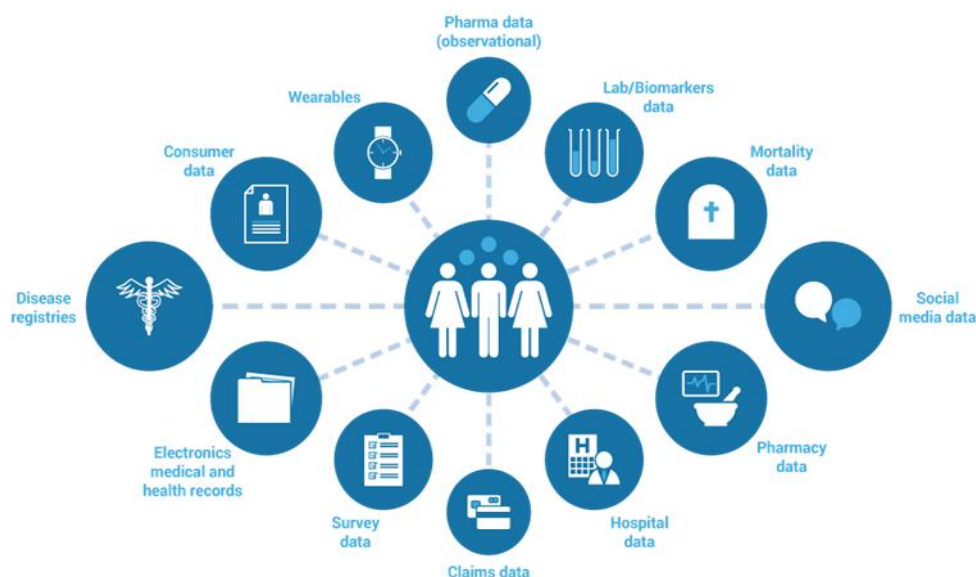
Figure 1.3: Population health information sources

A uniqueness of DIPoH is that it includes information regarding the full population (healthy and non-healthy population) and is not focused on patient data only. Additionally, DIPoH will include routinely collected data, surveillance data, and project-based data and outputs. DIPoH will not include clinical

and experimental research. Furthermore, DIPoH aims to include both aggregated as well as individual level data relevant for assessment of specific domains in the framework of population health.

DIPoH's position in the European health information landscape

Wider European Region

There are three main players in the wider European health information landscape: The World Health Organization Regional Office for Europe (WHO-Europe) the Organisation for Economic Co-operation and Development (OECD) and the EC, its different directorates and agencies. These three main players coordinate a selection of statistical data collections and (overlapping) indicator sets, have different geo-coverage and have different mandates. The international organisations do not yet collaborate optimally and gaps and deficiencies persist. As a research infrastructure on population health DIPoH will not duplicate the work of the international institutions, rather ensure synergies and collaborations (see table 1 for summary).

European Union

In the EU, different health information areas are not systematically covered. There is no common health information strategy or reporting agenda. Projects and initiatives are scattered and there is no clear overview of the activities at EU level. There is a need for continued effort to generate better coherence of health information activities in the EU, for example harmonisation of health indicators and monitoring tools across Europe and hosting health related-databases and their metadata on the full domain of health. DIPoH is tailored to serve the needs of the MS/AC and provide its users with an overview of the initiatives and networks that are already active in health information and related fields in Europe. DIPoH interacts with the broader landscape of public health by closely collaborating with the International Association of National Public Health Institutes (IANPHI), The Association of Schools of Public Health in the European Region (ASPHER), and The European Public Health Association (EUPHA). In addition to close interactions with the other research infrastructure of the ESFRI landscape (see next section), DIPoH will serve as a cornerstone for the implementation of the future European Health Data Space. The DIPoH consortium is active in the new Joint Action for the European Health Data Space (TEHDAS), and European Open Science Cloud (EOSC) projects.
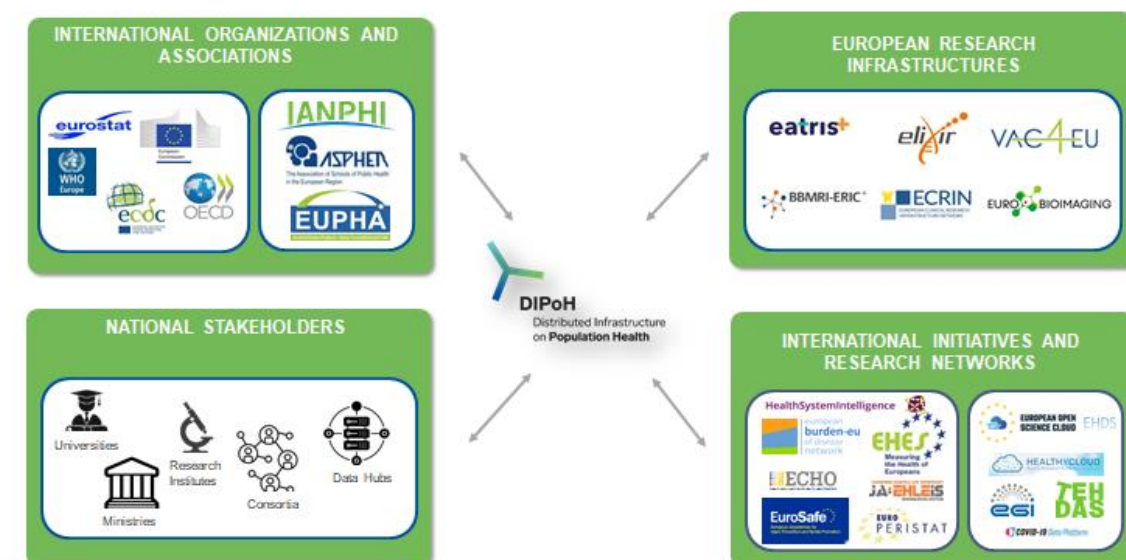

Figure 1.4: European and global interactions of DIPoH

European Union Research Infrastructures

Recent initiatives in Europe have encouraged the formalisation of Research Infrastructures (RIs) to unify and integrate fragmented facilities, resources, and services, and to facilitate world-class research addressing complex public and population health challenges. The European Strategy Forum on Research Infrastructures (ESFRI) consolidates Research Infrastructures in the European Research Area (ERA), covering a vast remit of topics of health, agri-food and bio economy. However, what is lacking is the holistic view throughout human lifetime on the effect of lifestyle, the environment and health services on health and disease in the population, as well as the impact of health on society.

The scope of DIPoH fills in an important research gap, addressing the challenges in the provision of sustainable information, data sharing, and expertise on population health in the EU (see figure 1.5). DIPoH services support and strengthen research networks in the area of comparative population health research and comparative health system research within the EU as well as data curators in MS/AC. This will improve the quality of data and research, reduce research inequalities by encouraging and enhancing comparative research approaches across MS/AC and work towards the sustainability of population health research networks. DIPoH strengthens the ERA by providing joint access to better and comparable data, tools and methods.

More specifically, within the RIs in the Health & Food ESFRI domain, synergies can be created with DIPoH when it comes to, for example, translation of knowledge in medicine (EATRIS), use of samples (BBMRI), use of multicenter cohorts for clinical research (ECRIN), use of bioinformatics (ELIXIR), as well as with the other fields which all share a link to health.
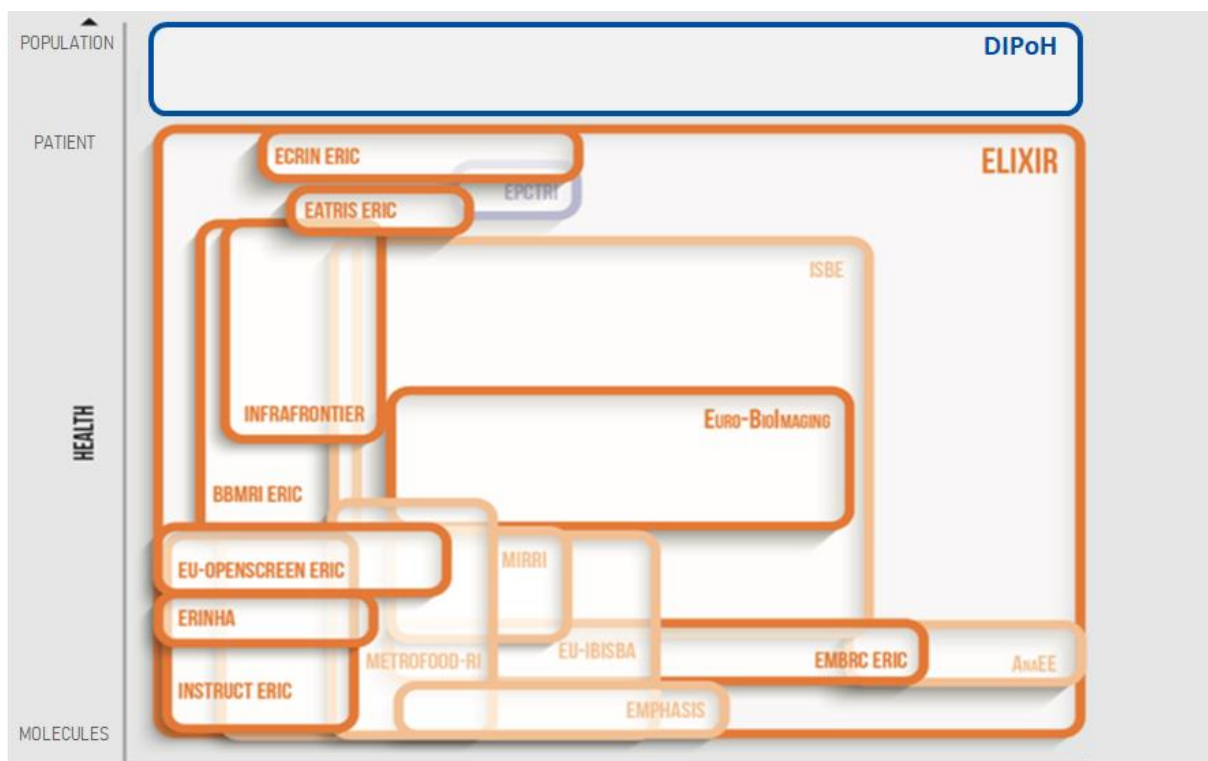

Figure 1.5: The position of DIPoH in the Research Infrastructure landscape (adapted from ESFRI landscape analysis 2018)

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Table 1: Summary of summary of DIPoH's position in relation to other RI's and the major Health Information players

	DIPoH	ESFRI RIs	EC and its directorates and initiatives	WHO Europe	OECD
Mission	To offer a compilation of data, tools, reports, training materials and expertise on population health information sources across Europe.	To offer highly evaluated research infrastructures and specific services to European researchers.	To assess needs, finance investments and evaluate the results from a long-term EU perspective.	To provide global leadership in public health	To promote policies that will improve the economic and social well-being of people around the world.
Content/ Scope	Overview of course modules overview of population health related data sources, reports, experts in countries across Europe. Tailored specifically to MS/AC needs. Coverage of a wide range of stakeholders (ministries of health, National Institute of Public Health or Research or Disease Control, Ministries) in the country representing a diverse set of types of data sources (e.g. survey/interview data, administrative data, population data, registry data, biobank/sample/specimen data, customer record data, observational study data).	European scope. Areas cover life sciences, genomics, biobanks, translational research, clinical trains and surveys. The current compilation of ESFRI RIs does not include any RI on population health. Public health is missing as well. Computing services and training on FAIR and ELSI. Most of these RIs do not deal with personal individual sensitive health data. Linkage between data sources in these RIs is limited.	Only a selected set of indicators for example in Eurostat. Relatively limited in health. Provide funding to different initiatives and projects. Many investments are put in population health projects in the past Health Programmes but continuity is not assured leading to fragmentation and ad hoc projects. None of the agencies focus on population health or chronic diseases (ECDC Focus on infectious diseases). Their initiatives are fragmented and project based, no structured compilation of what already exists across all directorates and initiatives.	Provide a centralised dataset on selected indicators. The scope of EU countries is different to OECD and EC covering a vast geographical region from the Atlantic to the Pacific oceans Their mission and vision are not fully aligned with needs of EU MS/AC	Serves a wide region (including for example Japan, Mexico and Israel) and is focused on social and economic development provide a centralised dataset on selected indicators Focus on an economic perspective on health. Their mission and vision are not fully aligned with the needs of EU MS/AC.

1.5 Added value

Countries face similar health and care problems, as illustrated by increasing incidence of diseases related to lifestyle, changing demography and increasing health care costs (see section 1.1).

DIPoH adds a world class population health research community to the EU. This community will be able to contribute to new EU public health policies and initiatives, such as the Mission on Cancer[1] and the European Health Data Space[2], as well as to the upkeep of initiatives from the past, such as the European Core Health Indicators[3].

As defined by its members, DIPoH can set clear targets and objectives to focus efforts on priority research questions and make better usage of existing health information sources. The natural variation in Europe can and should be used for research and policy purposes on national and international level. These purposes are interconnected. Through a research-policy cycle, DIPoH can provide the necessary tools for research, the relevant information for decision-makers and bring different actors in health information together to strengthen health information in the EU and nationally. DIPoH will provide a structure of exchange where policy-makers can feed their own expertise back into the research community and can facilitate knowledge gaps being filled.

Willingness of institutes within the MS, i.e. national public health institutes, to contribute to the setup of an initiative such as DIPoH is an important added value as in general these institutions are bridging research and policy. More and better research collaborations between national researchers in the EU/EFTA MS, enhanced exchange of best practices among them, increased harmonization of data and definitions, indicators, tools, guidelines and methods are benefits for both the EU and its MS. A large increase in well-accessible, comparable health data and a decline in health information and research inequalities among the MS will be important outcomes. European harmonisation, standardisation and collaboration in the area of interoperability and secondary use of health data is crucial for the future of European health research. EU MS will benefit by having their researchers and experts participate in ever stronger international health research networks, and have a broader and more sustainable flow of research data for benchmarking, policy evaluation and implementation research. For MS, it will be beneficial to have the so-called National Node function operational in their country. The result will be a more complete overview of their health information systems and of their relation to international health information exchanges. More detailed expected impacts can be found in Annex 3.

Some more quantitative information is available to support the set-up of an infrastructure for population health such as DIPoH envisions. An Australian analysis estimated that investing in public health data linkage will deliver considerable return on investment, i.e. a benefit to cost ratio increasing from 12.7 to about 16.5 to 1 for data linkage organised by the Public Health Research Network, or strong net benefits of between 1.2 - 17 billion dollars (Lateral Economics, 2017). A report commissioned by the EC (PWC EU services, 2018) estimated that the minimum cost for the EU of not having FAIR data is €10.2 billion per year, which will increase over the years if no action is taken . The monetary value of health inequality related welfare losses in the EU has been estimated to be €980 billion per year or 9.4% of GDP (Mackenbach, 2011). A systematic literature review into the return on investment of public health interventions in high-income countries (covering health protection, health promotion, legislative, healthcare and wider determinants interventions on both local and national level) showed a median return on investment being 14 to 1 (Masters et al, 2017). The authors concluded that public health budget cuts represent a false economy, as in the longer term they are likely to generate billions of pounds of additional costs to health services and the wider economy.

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[1] https://ec.europa.eu/info/publications/conquering-cancer-mission-possible_en
[2] https://ec.europa.eu/health/ehealth/dataspace_en
[3] https://ec.europa.eu/health/indicators/echi/list_en
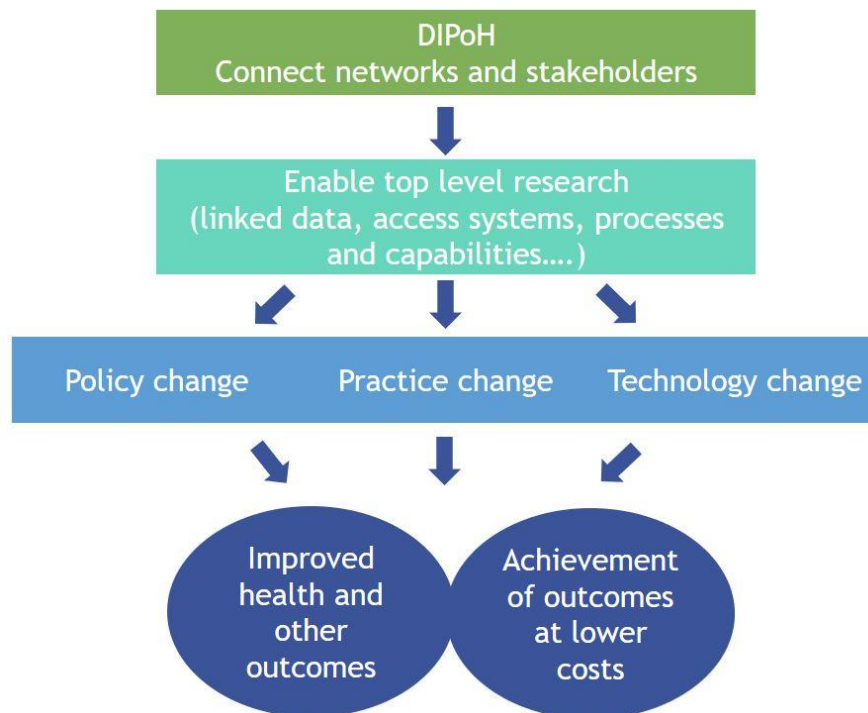
Figure 1.6: Value chain of the health information RI impacts (adapted from Lateral Economics, 2017)

DIPoH will be the sustainable backbone to support researchers and policy makers in the fields of population health, population health monitoring and health systems performance monitoring and assessment. The ultimate results of an improved health information system will be improved health and wellbeing, reduced health inequalities and reduced costs (see figure 1.6). DIPoH's ultimate beneficiaries will be citizens and society.

1.6 Users and Services

This section describes the user communities of DIPoH and the services DIPoH provides for them. The services will be accessible in a one-stop-shop manner, via the European Health Information Portal, www.healthinformationportal.eu. Part of the Health Information Portal will be publicly available, part will be accessible to formal users only.

User groups, needs, access & strategy

DIPoH has a potentially wide-spread user community, both in terms of those working directly with the data, those in need of its results, and those empowered by it. DIPoH strives to be a successful and performant RI and therefore to provide services, resources and tools in line with the demands and needs of its user communities. The most important user groups and their needs have been identified through direct interactions with stakeholders since 2015 (in the context of 2 projects: BRIDGE Health and InfAct) and are discussed below. Annex 4 presents an overview of the user groups and their expected market size.

The most direct users are European **researchers** involved in public health and population sciences, e.g. epidemiologists, statisticians, health economists, data scientists, ethicists, sociologists, other allied health professionals, as well as data providers. Researchers will want to use the RI, because of the increased opportunity for:

- Identification of population health data sources, access to data sources and reuse of the data
- Access to existing knowledge and expertise
- Structured scientific exchange and agenda-setting
- Tackling population health information inequality
- Cross-country exchange and analysis

Researchers may be users on an individual basis or they may be users as part of a network. These European Research Networks can roughly be of 2 types:

- larger, more established pan-European networks with a long time record and ongoing research activity indicating sustainability based on the quality of the network, of the research and on the ability to find project funding . These networks have remained active and productive for many years. These networks need forms of support through a RI to optimise their growth, and ensure the sustainability of their data collections and research activities in order to advance research methodologies, increase the multidisciplinarity and the interactions with other population health research domains. The more established networks will fulfil a dual role of both using DIPoH and providing services, see section 2.2..

- Research networks that are promising, but would need capacity building support through DIPoH to become optimally effective and productive in terms of research efforts and output.

Another main category of users are **policy and decision makers**. DIPoH will enable national and regional decision makers to make use of a well organised network of health research expert networks and knowledge repositories, to support evidence-informed decisions, priority setting and programme evaluation. They are beneficiaries of DIPoH as users of the outcomes of the infrastructure, both in national and international, governmental or non-governmental in the health (care) field or related fields. Also, their use and knowledge may feed back into the research process.

Other users include: other European RIs linked to health and data sciences; the healthcare sector; data providers/data owners and developers in various health information domains; students and educational organisations; the media; EU citizens and patients organisations; non-governmental organisations and charities; industry and private sector; EU institutions such as Eurostat, DG SANTE, Joint Research Center, European Centre for Disease Prevention and Control, European Monitoring Centre for Drugs and Drug Addiction, European Medicines Agency and others and non-EU organisations such as WHO, OECD and other.

The user does not need to be solely a beneficiary of services, but can be fully involved in the conception and creation of new knowledge, products, processes, methods and systems. This applies to both research networks and national nodes on health information (see section 2.2).

Services

DIPoH will provide large-scale, integrated and sustainable services to population health sciences through four main activities (see figure 1.7):

1. A **Health Information Portal** that serves as a one-stop shop with remote access to newly developed catalogues of (meta)data, guidelines, methods, tools and connections for population health information research. Pooling EU expertise stimulates creativity that supports the development of cutting edge research and enhances the development of new technologies.

2. **Innovative methodological developments** for broad scale use of existing data generated by MS and EU research networks; enabling data linkage and advanced data analysis techniques on different sources; advancing technical standards on interoperability of health data by producing and promoting common health data models enabling syntactic and semantic consistencies among health and healthcare data sources; and promoting FAIR data principles and research that is compliant with ethical, legal and social implications (ELSI).

3. **Capacity building activities** that enhance the use of innovative methodologies for population health research. Promoting skills development in data management from designing data collections to analysis, reporting and preservation. Capacity building is made available through state-of-the-art communication channels and digital tools.

4. Strengthening the health research community in developing **knowledge translation methodologies** to support decision-making processes, such as the HI-impact index, horizon scanning and foresight exercises.

Figure 1.7: The four pillars representing the activities of DIPoH

The one-stop shop approach, supported by the Health Information Portal, will facilitate collaboration processes between actors within and between knowledge domains and networks. The Health Information Portal offers both policy-supportive and more fundamental researchers the possibility to create a user account, to become a member, to access a restricted area for members and to access a services area and the possibility to store a certain amount of data supported by a web-team and services support unit. DIPoH will follow the European Charter for Access to Research Infrastructures and offer different access modes and levels.

First, all open source software and information on the Health Information Portal will be widely accessible to all. Thus ensuring open, interconnected, data- driven research across Europe.

For the members of DIPoH, there will be specific benefits directed at facilitating the establishment of new research projects in synergy with each other and having instant access to each other's expertise. This includes dialogues and seminars on key health information-related issues, connecting

researchers, stakeholders and policymakers and different forms of knowledge and information. The members of DIPoH will also benefit from special reduced costs for DIPoH's services- for example, training programmes and workshops.

Finally, DIPoH will also coordinate several services that are offered for a fee. This will thus be market driven and will refer to specific commission services, expert support, access to catalogues and training programmes.

Thus, from a user perspective, the following services with different ways of acquiring them are envisioned: (See also Annex 5 for elaborated services and their mode of access).

- Basic services: available to anyone
- Membership services: available to paying members
- Contract services: available for a fee, upon request

User strategy to accommodate future needs

DIPoH's user strategy takes account of the user dimension and user requirements and identifies potential gaps between the user needs and its services offered, both in the short and long term. As needs may change, DIPoH strives to continuously develop further and update the strategy and aim for widening its use base. This will be done based on a solid knowledge of its user community and stakeholder awareness, taking into account the category of users, their origin, size, and purpose of use. Ways to do this are focus groups, surveys and keeping track of user statistics from the HIP measuring Key Performance Indicators (KPIs, see also Annex 8) as well the set-up of a stakeholder and user forum/consultation platform (see section on Governance).

1.7 Risk analysis

A number of risks may threaten the feasibility and sustainability of DIPoH and require attention.

First of all, DIPoH needs support and commitment from governmental structures responsible for health research as well as those responsible for health policies. However, tunnel vision lies in wait and bridging this may be difficult. For improvements in health and health care to become reality, it is necessary to convince research and policy that the two need each other.

Furthermore, although health is rated as one of the most important issues in peoples' lives, relatively little funding is available for population health research, including prevention, health promotion and knowledge translation. Whereas this infrastructure can pull forces together to attract funding and COVID-19 has increased demand and opened doors, it may still prove difficult to get MS governments to fund basic structures needed for DIPoH to function. Financial viability is something to think through well in advance. Good landscape and market analysis (do not supply what is not demanded), as well as good insight into funding resources will increase chances of survival.

For many MS public health is a "national" matter, where there should be no "interference" from the EU. Considering the commonalities in the problems countries face, it seems remarkable that health ministries still hide behind the subsidiarity principle to keep their eyes turned mainly inwards. The pandemic may have changed some of this perspective, but despite COVID-19, it will require continued effort to convince MS that European collaboration in the field of Health Information is effective and that international collaboration adds value to the national health system. A prerequisite to this is that DIPoH will actually solve the lack of sustainability of collecting data and make them available.

A point of attention is that DIPoH will not have a mandate to exercise any control over the (lack of) coordination with and between EU and other international organisations that play a role in health information. This lack of power may affect its efficiency in harmonising the European landscape.

Also, selected technological solutions may not fully support planned/emerging services, or new emerging technologies fit better for the needs causing delay in establishing planned services, requiring new, unplanned investments on technology upgrades. Technology procurement processes are complex and could lead to some delays.

Other possible points of attention are the timeframe needed to set up DIPoH (shaping the governance structure and services, etc) and the time needed to show the benefits DIPoH delivers, in order to convince funders.

Potential risks and possible mitigation strategies are summarised in the below table 2. An overview summarizing strengths, weaknesses, opportunities and threats are presented in Annex 6.

Table 2: Potential risks and mitigation strategies

Risk	Likelihood	Mitigation strategy
People: 1. High pressure workload 2. Slow recruitment of suitable personnel or expertise required that is not available	1. Medium 2. Low	1. Plan ahead, build and make use of network 2. Make use of network
Consortium: 1. Too little political and other support 2. 2021 ESFRI roadmap application not successful 3. Length of finding agreement on statutes	1. Medium 2. Medium 3. Medium	1. Active engagement strategy, towards MS (ministries of health and research; political support); research networks (letter of intent) and public health institutes (MoU) 2. Explore alternatives (see 1.8) 3. Organize open and transparent communication
Legislation: GDPR causes problems	Medium	Multiple initiatives liaised to DIPoH are working on this issue (e.g. TEHDAS)
Product/service delivery: 1. No users or users do not find services useful 2. Users/data owners not convinced that sharing of data is safe and do not want to participate in the process 3. Issues with data interoperability / federated structure takes longer time to develop than expected 4. EU MSs are sceptical of the return of investment 5. Health and health sector benefits will need time to become visible	1. Low 2. Low 3. Medium 4. Medium 5. Medium	1. Ongoing market analysis, promotion by national nodes on health information, use of research networks as sounding boards, collection of user feedback 2. Provide proof of concept 3. Learning from the experience and expertise of consortium partners who already have established similar services nationally, monitoring technological developments and collaborating with other RIs working with similar services. 4. Organize open and transparent communication, 5. Present (multi)-annual work plan
Market: 1. Competing initiatives 2. Too much time before being active and generating funds	1. Low 2. Low	1. Invest in uniqueness and market share 2. Continued investment in consortium reputation; PHIRI is already in action

Financial:		
1. Not enough direct funding (either through MS budgetary restrictions or lack of interest and commitment)	1. Medium	1. Apply for H2020 funding (e.g. Design study) in parallel with Road Map
2. No workable solutions for a viable funding model on the long term can be found	2. Medium	2. The consortium has applied for external funding through several EU calls and will actively monitor new funding calls. Upon establishment of ERIC and services, fees can be expected.
3. Technological solutions turn out to be fragile, not fully suitable for requirements of the platform and planned services, or are outdated delaying the establishment of the DIPoH services and leading to unplanned investments	3. Medium	3. Good collaboration with other, likeminded, technological initiatives (in context European Health Data Space)
Reputation: Unable to build solid reputation and attract members	Low	There is proof of a good reputation already and the upkeep of this will be invested in
Game changer: EC reorganisation disestablishing relevant DG	Low	DIPoH will keep warm the increased attention for European Health

1.8 Timeline and 5-year road map

Timeline: phased approach

DIPoH is successfully engaging with stakeholders such as national public health institutes (via MoU), Ministries of Health and Research (via EoS), Research Networks (via criteria and LoS) and organisations in the international landscape (via collaboration), via the setting up of national nodes (NN), the European Health Information Portal and through developing services. The DIPoH concept has been submitted to the ESFRI road map and is already being implemented in project PHIRI. Among other things, this includes the set-up of data hubs as a tangible infrastructure for federated data exchange and expanding the other organisational elements (see section 2.2).

The next 5 or 6 years, DIPoH will learn by doing and will focus on further developing and implementing the Infrastructure. This will include further development of the Health Information Portal; engaging with users and implementing services; finalising the organisational, financial and legal frameworks to achieve the legal entity and realising a sustainable management plan and funding for operation. From 2028 onwards DIPoH will serve as a fully operational research infrastructure.
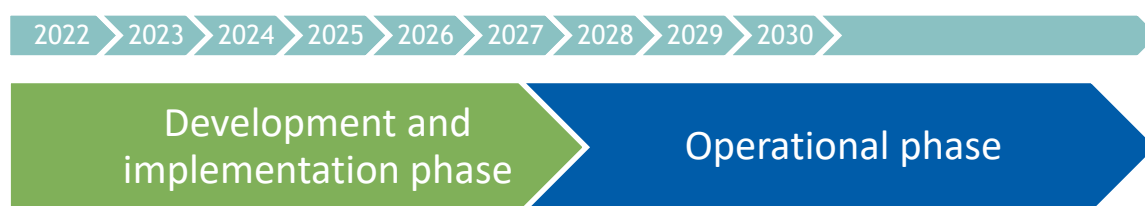
Figure 1.8: DIPoH timeline

Development and implementation stage

DIPoH's development and implementation phase prepares for the implementation and establishment of the legal entity and finalises all aspects for the deployment of the legal entity of the operational RI. This is summarised in table 3 and described in more detail in Annex 7.

The operational phase

Once the legal entity and organisation management have been deployed and DIPoH is functioning and delivering services, DIPoH enters its operational phase (2028 onwards). In this phase, DIPoH delivers its full range of services to its users. DIPoH will continue reaching out, collaborating and networking with new and upcoming RIs, international organisations and EU bodies. Regular and annual reports are produced (research results, outreach, accounting, and progress). Finally, during this time preparations for upgrade take place, or if not achievable, decommissioning actions are identified.

Table 3: Summary of planned phases of DIPoH to become operational

Phase	Description
Development and implementation phase **2021-2027**	**Research Development & Technical Construction** ● Health Information Portal construction/and implementing pilots ● Data sharing and linking models development and implementing data capture ● Hubs/networks functions with DIPoH (NN and DSN) implemented ● Scientific needs framework
	Organisational Agreements ● Communication strategy developed and implemented ● Governance and management structures updated and finalised ● Business plan and budget update and finalised ● Agreements signed with experts and networks ● Stakeholders and user engagement strategy developed and implemented ● Collaboration discussions with other RIs ongoing ● Connection to EOSC achieved ● Legal entity identification and preparation of statutes

Development and implementation phase **2021-2027**	**Central Facilities and Specifications** ● Site selection and preparation for Central Office ● Services support unit set up ● Capacity building programmes plans set and implemented ● Data management framework developed and implemented ● Data and user access policy and code of conduct set ● Data library inventory set up
	Deployment towards operation ● Deployment of organisational structure and implementation of legal entity ● Sustainable funding for operation secured ● Central Office set up ● Staff recruitment and training for Central Office and services support unit ● e-infrastructure including the Health Information Portal are up and running ● Common data models updated and ready for scale-up ● Services either operational or being piloted ● Collaborating agreements implemented with other RIs, EOSC, international organisations, and EU bodies.
Operational phase **2028+**	● Provision of content and services to DIPoH different user communities ● Political and financial support obtained for long term operation ● Outreach activities ongoing and communication plan update regularly ● Regular and annual reporting (including auditing for accounting and budget systems) ● Preparation for possible upgrade ● Detailed and approved plan for upgrade ● Institutional and political agreements prepared for upgrade ● Funding for upgrade secured

KPI for monitoring progress

DIPoH will use Key Performance Indicators (KPI) for monitoring progress in accordance with the RACER principle, to develop a set of KPI that are relevant, accepted, credible, easy, and robust. KPIs are based on user, operational, financial and strategic metrics are further described in Annex 8.

Alternative scenarios in case access to ESFRI 2021 road map is not granted

In the current status InfAct has submitted the concept of DIPoH to join the European Research Infrastructures landscape by applying to the ESFRI roadmap 2021. The roadmap for implementation is as specified above.

In the situation that DIPoH will not be accepted to the ESFRI 2021 roadmap. The following alternative scenarios are planned:

1. The consortium will reassess the possibility to join the ESFRI landscape through an application to the 2025 roadmap. Phasing will need to continue through external projects and funding to bridge the time gap between 2021-2025. Currently, an ongoing project is the Population Health Information Research Infrastructure (PHIRI) for COVID-19 which is a rollout of DIPoH in the area of COVID-19 (2020-2023). Therefore, additional funding would be needed between 2024-2025.

2. Direct application for an European Research Infrastructure Consortium (ERIC) by developing statutes and establishing DIPoH as a legal entity through an external process to ESFRI. An ERIC application requires a request to EC, statutes, a technical & scientific description, a declaration by the foreseen host MS, as well as requirements relating to infrastructure. The ESFRI application and this document already make a good basis for this. The trajectory could be finished within the PHIRI project or in parallel with some increased effort to mobilise MS/AC.

2. Organising the Health Information Research Infrastructure

DIPoH will have a distributed structure connecting national nodes in EU countries and pan-European research networks through a central coordination office. In this section, we summarise the tasks and roles of the operational elements, the profile of the people working in them and ways to ensure stakeholder commitment to the infrastructure. We start with the governing mechanism foreseen for the Research Infrastructure.

2.1 Governance and accountability

Legal status: the ERIC

The current preferred legal entity of DIPoH is a European Research Infrastructure Consortium (ERIC)[4], based on the stakeholder consultation carried out in BRIDGE Health[5]. The ERIC is a specific legal form that facilitates the establishment and operation of Research Infrastructures with European interest. This allows for the establishment and operation of new or existing Research Infrastructures on a non-economic basis, although an ERIC can carry out some limited economic activities related to its task. It becomes a legal entity from the date the Commission decision setting up the ERIC takes effect. An ERIC is a legal capacity recognised in all EU countries, has flexibility to adapt to specific requirements of each infrastructure, has a faster process than creating an international organisation, has exemptions from VAT and excise duty and may adopt its own procurement procedures which have to respect the principles of transparency, non-discrimination and competition.

A State may decide to be represented by one or more public entities or private entities with a public-service mission, e.g. research organisations or research councils, to exercise specified rights or fulfil specific obligations on its behalf. To become an ERIC, it is necessary to put in a request to the European Commision, to provide a declaration by host MS and to have statutes. Draft statutes have already been prepared by a core set of countries, and will be further expanded in the following phases of DIPoH.

Governance during transition towards the ERIC

This business plan is oriented towards governance as an operational structure under ERIC status. Until that status is reached, a fluid transition period with interim governance will be ensured (see table 4). During the transition, the General Assembly (GA) is, and continues to be, the highest decision-making body securing the stakeholder commitments and making strategic decisions that set the scene for the operation of DIPoH RI and its legal entity. The interim coordination office (ICO) will propose adoption of new RI arrangements (technical, administrative, governing and financial aspects) that will need approval and adoption by the GA. This also includes preparations for the recruitment of the Director General for the legal entity and the Core Team staff. Once approved, new terms will operate under the new adopted operational governance and management model.

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[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R1261&from=EN
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5244564

Table 4: Governance structures of DIPoH

	DIPoH interim phase	**DIPoH legal entity**
Ultimate decision-making body	The General Assembly	The Assembly of Members
Central office executive body	The Interim Coordination Office	The Central Executive Management Office
	Project Coordinator	General Director
	Support team	Core team
External support bodies	Scientific Advisory Board	Scientific Advisory Board
	Ethics and Privacy Board	Ethics and Privacy Board
	Technical Advisory Board	*
Stakeholders body	Stakeholder and user forum	Consultation platform
Internal support bodies	The General Assembly	Network Committee

*In contrast to the interim governing structure, in the DIPoH governance as a legal entity there is no Technical Advisory Board. This is because the e-infrastructure will already be in place, and the technical expertise for the running of DIPoH will be part of the Central Office personnel.

DIPoH governance and management model

The governance structure of DIPoH ERIC is shown in figure 2.1 and is composed of an Assembly of Members, a Scientific Advisory Board, an Ethics and Privacy Board, a Central Executive Management Office, a Consultation Platform and a Network Committee. The strategic decisions are taken by the Assembly of Members with support from the Scientific Advisory Board. The executive activities are carried out by the Central Executive Management Office, which includes the Director General and the Core Team. The operating activities are carried out by the Network Committee and networks which are represented in the Network Committee. Further elaboration on the governing bodies is available in Annex 9.

Figure 2.1: DIPoH ERIC governance bodies
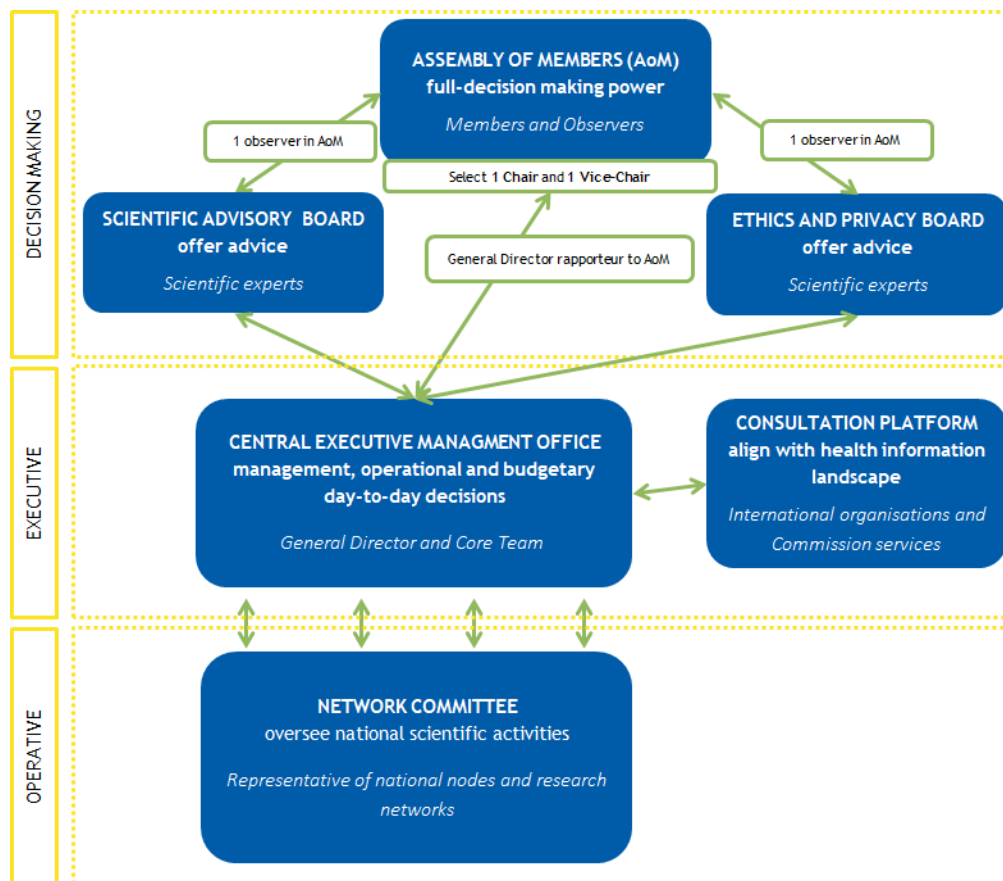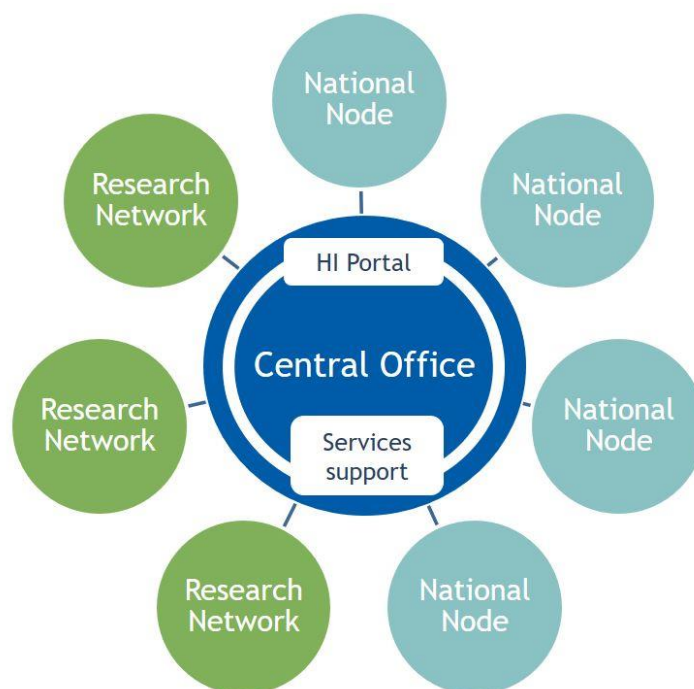
2.2 Operational elements

DIPoH exists of the following operational elements (see figure 2.2):

- A **Central Office**, including
  - A **web based platform** that delivers services and
  - A **services support** unit
- **National Node** (NN) units within MS/AC, that may require support
- A growing number of participating **Research Networks** (RN)
- A federated data infrastructure

Figure 2.2: Operational elements of the infrastructure

Central Office: roles and tasks

The Central Office (CO) represents the coordinating element of DIPoH across the different phases of its construction. The main role of the CO is to provide coordination, administrative and management support, strategic development and evaluation.

During the development and implementation phase, the CO will oversee the set-up of the Health Information Portal and development of DIPoH's services. It will lead and coordinate activities relevant to the development and expansion of the consortium. The CO will support countries in establishing and developing their NNs and organise and support meetings between nodes.

In all DIPoH phases, the CO is the connecting pin between the DIPoH operational elements and the governing bodies, and with external stakeholders. It will take care of progress reports and evaluations, implement advocacy and communication and fulfil an important role in liaising with national and international stakeholders. It sets out the broader strategic lines and priorities that underpin R&D plans, programmes and projects. It will liaise with EC Directorates and agencies, OECD, WHO and other international institutions and organisations. It will oversee DIPoH's personnel that develops and manages the web based services platform.

Web based platform: the Health Information Portal

Within the InfAct project, a first version of the web based platform was set up: the Health Information Portal (www.healthinformationportal.eu). It is further developed in the PHIRI project as a one-stop shop facilitating access to population health and health care data, information and expertise in Europe. It includes or will include catalogues of meta-data, libraries and repositories for tools, methods, standards and guidelines, discussion fora, health information related news, information on important networks and efforts by international organisations, research output and other knowledge products (see also the section on Services). It communicates and advocates the scientific work of projects and programmes developed under the flag of DIPoH. It offers the services and tools necessary for researchers to access and link different data sources and to use Pan-European data in a GDPR compliant, federated way.
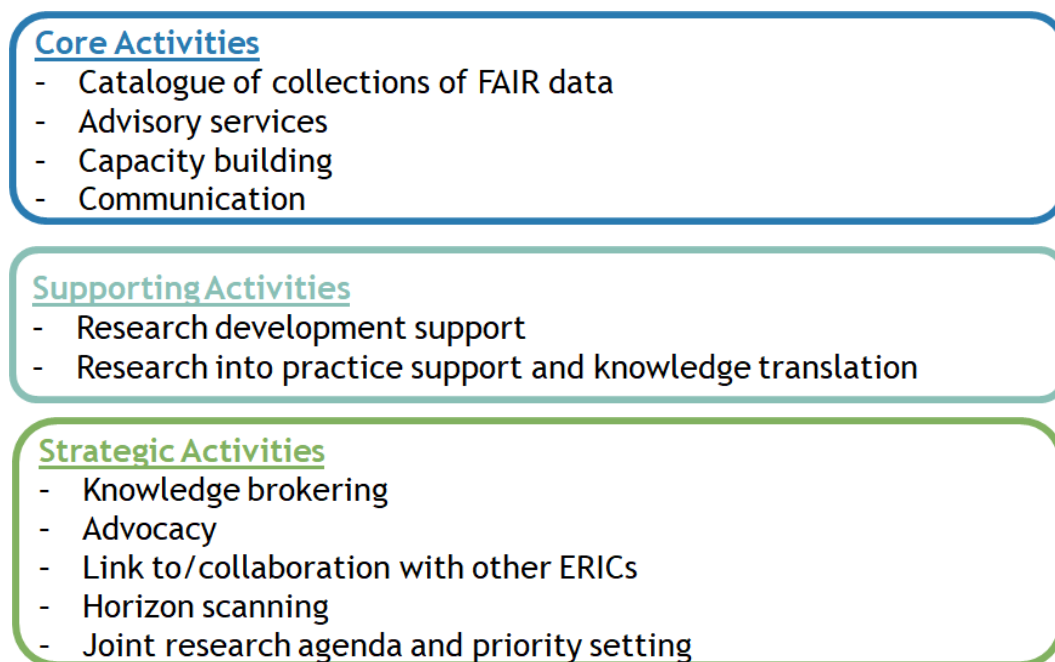
RI Services support

Services support is a small support unit within the CO providing central coordination, development and evaluation to the services DIPoH delivers, in liaison with the Web platform. This applies to any services - for the general public, for members or by contract - where central coordination is desired (some of the projects and activities may fall under the responsibility of a research network or a national node). It will support project submission, finance, administration, coordination, dissemination and strategy and execute R&D plans, being a knowledge broker.

DIPoH will perform 3 types of activities to deliver the services:

- Core activities: the basic and main activities that the research infrastructure contributes to bring together the data, networks, experts on health information across Europe.

- Supporting activities: the activities that the research infrastructure will undertake to provide added value to research by its members.

- Strategic activities: the activities that are part of the research infrastructure and link to the stakeholders beyond the research communities.

See figure 2.3 for a summary of activities and Annex 10 for detailed description.

Core Activities
- Catalogue of collections of FAIR data
- Advisory services
- Capacity building
- Communication

Supporting Activities
- Research development support
- Research into practice support and knowledge translation

Strategic Activities
- Knowledge brokering
- Advocacy
- Link to/collaboration with other ERICs
- Horizon scanning
- Joint research agenda and priority setting

Figure 2.3: DIPoH activity types

National Nodes on Health Information

The National Node (NN) is an organisational entity, often linked to a national institution or governmental unit that functions as a national liaison and brings together relevant national stakeholders in the country in a systematic way. The relevant stakeholders may include, for example, the national statistical office, the national public health institutes, representatives from ministries of health, research and/or science, and others. In addition, the NN may function as a discussion and advisory forum in matters of health data and information both for national or international matters. Examples include aspects of the governance of data, indicators and health reporting at the international level and health information stakeholders at national level. The exact role(s) of the NN

in DIPoH and nationally depends on the needs, wishes and (legal) organisation of each country. They are not exclusive to one entity and can be performed by multiple entities within the country. In general, the NN strengthens the national health system both by connecting the relevant national actors and by exchanging expertise in the international arena. DIPoH supports countries who wish so in setting up the NN function.

The NN functions as the national liaison to DIPoH and is responsible for the representation of their country in the board and its committees. The representatives have a good overview of the national and regional health information system(s) as well as the population health research programs and projects (know who has the data, what the data are like in general or know whom to contact). NN's should be in close contact with the Health and Science Authorities, to link and exchange with national policy priorities for the international health arena. The NN's have adequate knowledge of what is going on in the European health information arena (WHO, OECD, Eurostat and other EU Directorates such as SANTE and RTD) in terms of their work and research initiatives on health information, data delivery, indicator development and policy relevant reporting. Through this, the NN's will have a good grasp of the needs and priorities for improvement.

Another role of the NNs seeks to elicit and gather the knowledge of institutions and experts whose foundational business is the collection, curation and maintenance of national or regional data in MSs. These institutions and experts are in charge of providing the metadata, making data FAIR and ensuring interoperability of national or regional data, and defining the modality for reuse of data connected to the DIPoH Health Information Portal. These institutions and experts will also have good knowledge on the strengths and weaknesses of the different data sources in their country. They will guide DIPoH users on how to access the national or regional data, provide options of data linkages between different data sources, and provide access to data for reuse in certain formats, upon request from DIPoH-users.

Research Networks

Research Networks (RN) represent a group of collaborating researchers (existing or newly developing communities) that collect, exchange, and harmonize research data and/or information on a particular health topic. These RN often work on the setting up, improvement and reporting of population health research methodologies, the validation and reporting of tools (such as, indicators, software for analysis, data visualization tools, reporting, and translational research methods), exchange of expertise or engagement in capacity building activities, and on methods to have their research results integrated in the public management and policies.

RN will be individually linked to the CO through a collaboration agreement. If desired, RN with similar focus can join into a domain-specific node, coordinated by a self-appointed network partner. This will be up to the sovereignty of the networks themselves.

The RN (will) each have a nucleus to take care of harmonization and quality control of data, organising exchange of expertise, processing of data and coordinating research and reporting efforts. The strengths of a number of such networks have been analysed to provide a proof of concept and quality criteria for participation (see Annex 11). These should not be seen as admission requirements, but as the ambition to strive for during further development of the RN.

For example: Euro Peristat is a research network focusing on pregnancy and infancy, benchmarking on a set of 30 indicators. Its results are used in many countries to underpin policy changes. EHLEIS is a research network addressing the increasing societal urgency to assess whether life years gained are healthy. It produces yearly country reports in a format that is usable for decision makers.

The role of the RN will be to:

- Establish a **critical mass** in their thematic area via networking of researchers, joining expertise, undertaking **common research efforts**, sharing research facilities and contributing to capacity building

- Maintain, increase and exchange their scientific and technological **excellence**

- Generate **new data and methods** and strengthen their research capacity

- Facilitate and expand **data access and sharing**

- Develop a long lasting **strong** research base and **regular** data collection

- Facilitate the integration and transfer of **new knowledge**

- Deliver knowledge for policy making, anticipate scientific and technological needs and provide efficient scientific support for **strategic decision-making** in the specific field

- Enhance **communication and visibility** at the European and international level

Research Networks ensure that Europe has comparative data on topical health domains at its disposal, support a coordinated action in population health research, getting the most out of the existing national and regional health data repositories, and feed relevant information to policy makers.

Federated data infrastructure of data hubs

As opposed to a centralized architecture, DIPoH computational infrastructure is envisaged as a federated architecture (see figure 2.4) where the motion of raw data between the data hubs and a central repository no longer exists, so that only the analytical techniques (scripts) move (step 1 in figure 2.4). In the hubs, partial results are computed (step 2) and then gathered in a coordination hub (step 3) that combines them to get an overall solution to the research questions (step 4).
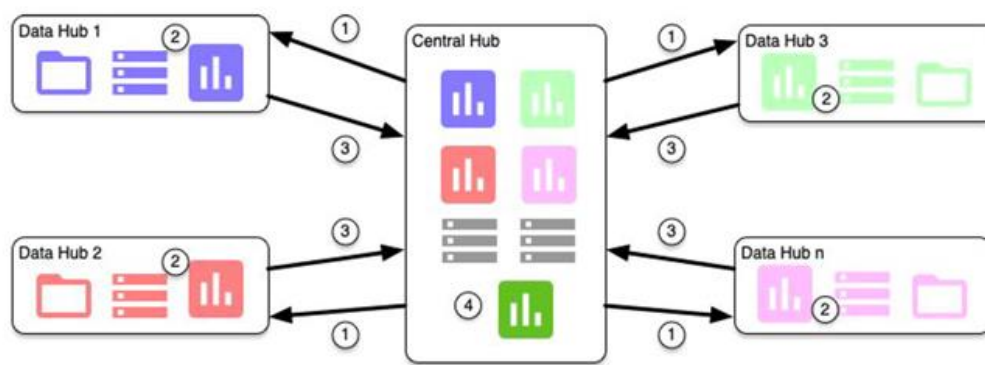
Figure 2.4: schematic representation of the federated data infrastructure

A major advantage of this approach lies in the fact that all the analyses with individual-level data are performed in the data hub premises following their own governance rules and regulatory restrictions and avoiding the potential security risks of having sensible data in a single point and the legal restrictions of moving massive data outside regions or countries. In addition, due to the distribution of the analyses into federated data hubs, the magnitude of the potential is larger as the computing capacities multiply. Three main challenges arise when using this type of distributed architecture.

- Firstly, a **common data model** is required to ensure interoperability across data sources and data hubs;

- Secondly, the level of complexity of the **analytical pipeline** is bigger than in a traditional approach as the techniques and algorithms should support the distributed schema; and,

- Thirdly, the amount of data accessed may erode trust in data holders and Data Protection Officers (DPO).

These challenges should and can be addressed by DIPoH. In order to guarantee the interoperability between the data hubs a common data model (CDM) is required. A natural option for DIPoH will be building upon an existing CDM structure, such as the OMOP Common Data Model[6]. In order to allow the implementation of techniques and algorithms in a distributed manner while addressing DPO security and privacy concerns, DIPoH will resort to consolidated open access libraries; so, for example, *dislib* library that would allow privacy by design full distribution of statistical techniques; or, *dataClay* library that would allow uniform data management procedures among data hubs. Finally, the DIPoH infrastructure is being developed according to the FAIR principles (e.g., all the code, including data model, the analytical pipeline and the presentation of results, will be developed in open source programming languages and published open access in Zenodo and GitHub repositories) allowing not just the easy access to interoperable products but also the transferability of the methods and procedures to other research domains.

2.3 Human Resources

A diverse infrastructure such as DIPoH requires a diversity in human resources (HR) in order to function. Table 5 lists the HR profiles that are required for operating DIoH. All relevant HR management procedures will be followed in appointing the highest international quality personnel.

Table 5: Human Resources profiles

Central Office	
1. Management/Coordination	Coordinator
	General director
	Project Manager (public health background)
	Administrative support
	Financial officer
	Business manager
	Business analyst
	Legal and Ethical Officer
	Data Protection Officer
	Communication specialist (website, social media, events)
2. Services Support	National Node liaison Officer
	Research Networks liaison Officer
	Services support Officer (public health specialist)
	Teacher/Trainer/Organiser Capacity building

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[6] https://github.com/OHDSI/CommonDataModel/blob/master/OMOP_CDM_v6_0.pdf

3.Health Information web portal front-end and back-end of distributed infrastructure	Health Information web platform officer
	Web designer/IT expert (implementation and maintenance)
	IT expert support (helpdesk)
	Infrastructure Network Systems Administrator
	Infrastructure Network Architect
	Software Developer
	Data Scientist - Analyst
Institute serving as Data Hub to connect with e-infrastructure (NN and RNs that own data)	
	System administrator (in contact with Health Information Portal officer in the Central Office)
National Nodes	
	MS Focal point/general health information generalist
Research Networks	
	Type of personnel depending on need (Project manager, data manager, data scientist, domain expert, capacity builder)

In addition, DIPoH will foster cooperation with national health authorities by encouraging national public health officials to participate in DIPoH as seconded national experts, bringing their expertise in specialised population health areas. Additionally, DIPoH will establish a researcher-visiting programme allowing staff members to spend time in different organisations across Europe. Also, a mentoring programme will be implemented providing a learning environment for junior staff members to work side-by-side with senior staff. Finally, DIPoH will train staff and users through its European Health Information Training Programme. Thereby it builds an educational community of practice leveraging the experience of DIPoH's members.

2.4 Commitment

DIPoH builds on a well-established stakeholder community. For sustainability of the infrastructure it is important to invest in the continued commitment of its stakeholders and expand this to a wider range of stakeholders.

The commitment strategy focuses on (1) raising awareness about DIPoH and the relevance of research on population health and its essential position in evidence informed guidelines and policy practice, (2) informing the community about the challenges in EU health information and the solutions DIPoH can bring, (3) engaging and involving the research community in health information activities of DIPoH, (4) promoting and supporting the use of the research evidence generated by DIPoH, (5) engaging and involving MS, (6) Partners in InfAct and PHIRI will be further engaged and involved in the deployment of DIPoH.

Some practical mechanism are:

- Institutions that did not manage to sign the MoU before submission are actively contacted. Additionally, national health information stakeholders are engaged through NN, raising interest in DIPoH among a wider network at national level.

- Assemblies of Members, complemented by bilateral meetings, are organised for/with Ministries of Health and Research that could join the initiative. Easy to read materials are disseminated to secure commitment.

- DIPoH reaches out to these different research networks across Europe. Data collected by the research networks will be investigated and evaluated on how it can be added to the Health Information Portal of DIPoH. DIPoH works through a network of networks and will organise Stakeholder and user forms that will highlight the added benefit for the research stakeholder community.

- DIPoH engages with several of the existing RIs and key players in the European health information landscape including international organisations and international initiatives. The consortium is also well known among key actors at European and international level (e.g. ECDC, EFSA, OECD, WHO, Eurostat, JRC, EEA, European Observatory on Health Systems and Policies, IANPHI, EUPHA, ASPHER). This connectivity has strengthened (inter)national credibility and support and this is used to familiarise and involve prospective member countries or entities.

3. Financing the Health Information Research Infrastructure

This section provides the cost structure and revenue streams of DIPOH. In short, we distinguish two phases: 1) a phase of development and implementation and 2) the phase in which DIPoH is in full action (operating). In the operating phase, DIPoH will be an ERIC. The ERIC has legal status and is eligible as a sole beneficiary for several EU funding mechanisms including Horizon Europe. Members provide cash or in-kind contributions as determined in the agreements or statutes. It must carry out its principal task on a non-economic basis, but may carry out limited economic activities, provided they are closely related to its principal task. These activities can support the sustainability of DIPoH.

3.1 Financial Overview

In terms of costs the distinction is made between costs for development and implementation and operating costs. Previous European projects have already contributed to the development and implementation of this Research Infrastructure. **Development and implementation costs** include: all resources needed to further design, prepare and implement DIPoH. As of November 2021, the PHIRI project is an active contributor to this. **Operating costs** include: housing and equipment costs, personnel; consumables and maintenance. The cost estimation elements consist of: human resources, technological resources, and others and overhead (incl building, equipment). In the calculations, cost estimations have been considered for the Central Office, the National Nodes and the Research Networks, including the data hubs. For these estimations taxes, interest, and other financial charges are not considered.

Revenues include: **funding for the development and implementation phase**, and **funding for the operational phase**. A mixed funding model is considered, which throughout time variably builds on grants, in-kind contributions and membership contributions.

The following sections present the estimated costs, focusing mostly on the phase in which DIPoH is fully operational. More details can be found in Annex 12.

3.2 Estimated costs

The estimated costs are presented in table 6 and table 7 for the two phases. The costs included in each phase are the sum of: human resources (for the Central Office, the National Nodes, the Research Networks, the data hubs), technological resources needed mainly for the setup of the e-infrastructure of DIPoH, travel and other costs, and an overhead of 20%[7].

Table 6: DIPoH cost estimates for development and implementation phase

DIPoH development and implementation costs (2021-2027):	Total
Human Resources	32.918.400€
Technological resources	1.925.000€
Travel and other (including conference costs, scientific publications, and outreach activities)	1.356.800€
Overhead 20%	7.240.040€
Total	43.440.240 €

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[7] Calculation was based on ESFRI instructions: https://www.esfri.eu/sites/default/files/20190626_StR-ESFRI2_STUDY_RIs_COST_ESTIMATION.pdf

Table 7: DIPoH cost estimates for the operational phase

Yearly DIPoH operating costs	Total
Human Resources	7.804.800 €
Technological resources	305.000 €
Travel and other (including conference costs, scientific publications, and outreach activities)	241.600 €
Overhead 20%	1.670.280 €
Total	10.021.680 €

Costs for human and technological resources were based on input from partners who work with the technology and who know which types of functions are needed. They are further described below. More detailed cost estimates can be found in Annex 12.

Human resource costs

The cost estimation for human resources takes into account the identified DIPoH elements (see section 2.2) and personnel profiles (see section 2.3) and differentiates between the different DIPoH phases. For the purpose of this estimation, an average cost of 8000 € per month per person is considered. The following specifications are made:

1. The Central Office (CO). The aim of the CO is reaching out and keeping in contact with both internal and external elements in the RI. Costs consist of **i) Coordination:** costs for daily management, finance, administration, HR, dissemination, strategy and liaising with relevant actors in the field, **ii) Services support:** costs for developing, managing, supporting and evaluating services that DIPoH is offering, also ensuring the connection with the DIPoH elements and linking to the services they will offer through DIPoH and **iii) Health Information Portal:** costs for developing, hosting, maintaining the platform and providing content.

2. National Nodes (NN). These are represented by the MS/AC. Their aim is to connect with the national health information situation, reaching out to other NN in DIPoH and other health information (research) structures in the country. DIPoH aims to have as many countries on board as possible, including their political engagement. NN will have different shapes and budgets in different countries. Costs presented are specifically related to DIPoH. For each NN, a focal point/general health information generalist (0,5 FTE) is considered. DIPoH estimates to scale up starting from 10 active nodes in 2024, to 20 in 2027, to 25 in 2030. Costs are estimated for an active focal point in each country provided by the CO. Otherwise, the NN will be responsible for their final design and the funding of their day-to-day business.

3. Research Networks (RN). They work towards linking national data for EU comparison. Some RN are data owners/curators, while others work towards mediating between data owners and data users. RN will have different budgets. Costs presented are specifically related to DIPoH. For each network, 1 FTE is foreseen for personnel depending on need (project manager, data manager, data scientist, domain expert, capacity building organizer or trainer). DIPoH estimates to scale up starting from 5 service-providing networks in 2024, to 10 in 2027, to 15 in 2030. The CO will support integration of RN by providing funding for the coordinator of the network to link with DIPoH, ensure quality of the data and adequate use of standards, set-up of a services portfolio and exchange of services.

4. Data Hubs. These are organisations or institutions that have data collections for population health. They ensure semantic and technological interoperability and allow rapid reuse of data in accordance with FAIR principles. NN and RN can both fulfil the role of data hub. They need funding to connect with DIPoH, including personnel costs. The data infrastructure follows the preparation and implementation process to prepare for operational linking to the DIPoH Health Information Portal. This can then be scaled to more hubs once DIPoH is operational (in a shorter time frame). DIPoH estimates to scale up starting from 5 data hubs in 2022, 10 are added in 2023, another 15 are added (total 30) in 2024, and finally to reach 35 data hubs ready for operation by 2027. As the Data Hubs are either NN or RN that own data, an assumption here is that the maximum number cannot be more than the sum of the NN and RN included in DIPoH at each specific phase.

Technological resources

In addition to the cost of human resources, cost estimates for the necessary technological resources are made for the different DIPoH phases. These mostly apply to the data infrastructure and include the costs for materials, licenses, subcontracting, and services. These costs are estimated in accordance with the cost of hybrid infrastructure under IaaS (Infrastructure-As-A-Service) scalable on demand by EU wide used institutions (EUDAT, EGI). Running costs for the CO include costs for communication and meetings (travel and subsistence), maintaining servers, software applications, protective measures, etc. DIPoH plans to host the CO coordination at Sciensano and use its existing web-infrastructure. DIPoH also plans to build on existing e-infrastructures and use open access software.

An assumption is implemented for this cost estimation: the rate of the increase in the technological capacity that is being built for the e-infrastructure of DIPoH throughout the phases. It is estimated to start from a 60% capacity in the beginning of the preparatory phase, and to build up to a 100% capacity during the implementation phase. The capacity is directly related to the IaaS service provision on demand that will be utilized.

Other costs and overhead

The main costs estimated for the development of DIPoH are the previously mentioned human and technological resources costs. For the budget estimation additional costs are added. These include travel costs for the different meetings that will take place, for example for assembly of members meeting, different advisory board meetings, and consultation platforms and forums. For travel, an average cost of 800 € per travel was considered.

In addition to travel, cost estimates are also considered for including yearly conference costs (50.000,00 €), scientific publications (25.000,00 €), and outreach activities (25.000,00 €). These are added to all the phases. Finally, the overhead is calculated as 20% of the total. This also includes building and equipment costs for the CO of DIPoH.

3.3 Revenue streams

Figure 3.1 presents the possible sources of income of DIPoH. Throughout time, the funding mechanism will build variably on direct contributions including membership fees and direct EC funding, income in terms of fee for services, and in-kind contributions for the functioning of DIPoH and its services.
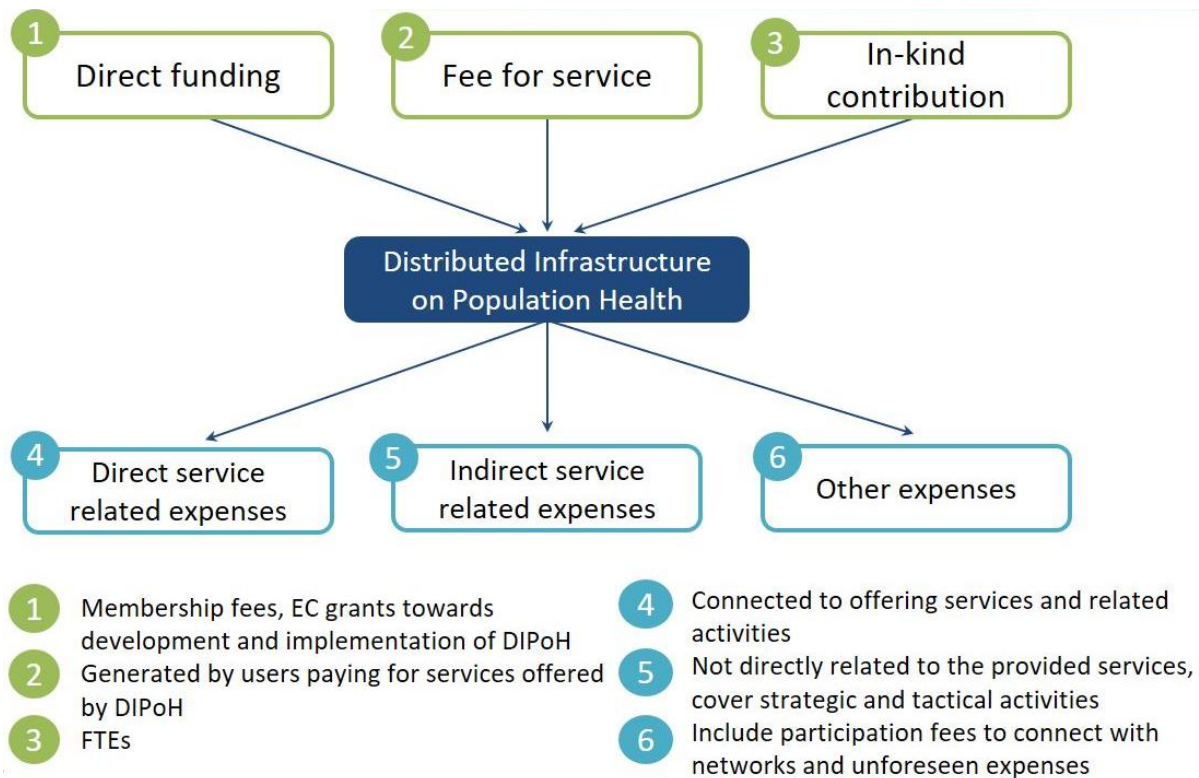
Figure 3.1: Revenue streams and expenses of DIPoH

It is important that the CO can rely on structural funding, for efficient coordination of development and maintenance of the structure. During the preparatory phase CO will be supported by financial support from the host country and in-kind contributions by the organisational elements. In addition to the lead country's financial commitment, which is foreseen to cover the management and coordination costs of the CO, the DIPoH partners who have signed the MoU have committed to some form of in-kind contribution for the preparation and construction of DIPoH. On a smaller scale, DIPoH will apply to EC grants (e.g. Horizon Europe Research Infrastructure Funding) to further develop DIPoH pushing European knowledge and data-driven economy. PHIRI has already been established as a roll out of DIPoH, enabling further development and implementation of the CO and the DIPoH services. For the current development and implementation phase, funding has already been secured through the following:

- EC-funding:
  - PHIRI (www.phiri.eu)
  - HealthyCloud (ww.healthycloud.eu)
- Financial contribution by coordinating and partner countries: Belgium, Spain, France.
- In-kind contribution by 16 supporting partner organisations

Once a legal entity is established, a special role for the MS/AC in supporting the CO is foreseen as this element requires a stable supply to support the RI's basic operation, complemented by fees from services. Thus, DIPoH will have a mixed funding model:

1. Membership fees are paid annually by members of DIPoH (MS/AC), to maintain the basic functions of the RI.

2. EU grants are competed for collectively by DIPoH partners, nodes and networks.

3. Service fees are paid by DIPoH users who require specific services (with discount for members).

4. National-level investments, in kind contributions by supporting national institutions and organisations are used to support focal points in the national nodes, research networks and their data hubs.

The income from membership contributions will depend on the final structure of committed partners and types of memberships. A precise contribution model still has to be developed. For MS, a direct financing structure will be developed based on: a fixed fee and a variable fee (possibly based on GDP, see Annex 13. In addition to country membership, it can be expected that a contribution model for organisations may also be developed.

Contributions will depend on the estimated costs of the services and functions and the de facto net revenues of the services. Beside the possible income as contributions from membership fees, there are possibilities for income from contracts (projects) by, for example: the EC, charities and the private sector. These are continuously being developed into a services portfolio, and need to be based on a thorough market analysis, lobbying and advocacy towards relevant stakeholders and potential customers. Users from different DIPoH members will receive a discount on payable services organised by DIPoH's CO.

The NNs and RNs will participate through mostly public institutions with dedicated budgets and expertise, part of which can be devoted to DIPoH for various tasks. DIPoH will invest in engaging with MS/AC and RNs to achieve full geographic coverage, as well as, cover the most relevant population health topics, thereby handling central costs efficiently and creating further commitment.

Additionally, MS already invest substantially in-kind by supporting and financing national data collections and researchers to collect, handle and report national data to international organizations. The costs of those numerous data collections for all EU MS cannot be easily estimated, but they form the underlying basis for many research networks (RN) that collect and compare international data. The RN in turn each have one or more centres with experts that spend time and financial efforts in organising and managing the network and the data collection and analysis that goes with the work. Thus, depending on the level of maturity of the RN, they could receive support from DIPoH. Mature research networks may benefit from the advocacy, stamp of excellence and knowledge brokering by DIPoH to find funding from interested stakeholders (such as the EC, charities or NGOs in the health sector or private parties). Ultimately, the RNs are responsible for funding their day-to-day business, including the funding of their data collections and their executive staff. If the networks would 'sell' other assets through the web portal a percentage fee could go to DIPoH as another option.

To serve as a federated infrastructure, DIPoH will provide provisional funding for both NN and RN that serve as data hubs to connect to the e-infrastructure of DIPoH in the development and implementation phase.

Information sources

The BRIDGE Health project (2015-2018) and the InfAct project (2018-2021) have provided the building blocks for the application of DIPoH to the ESFRI road map 2021 and this business plan.

InfAct and BRIDGE Health outcomes are available from

- https://www.inf-act.eu/InfAct-outcomes
- https://www.inf-act.eu/bridge-health-outcomes

This includes:

- BRIDGE Health Consortium. Bridge Health: Concept Paper. Technical Report BRIDGE Health N° WP1_2016_03
- Bogaert P, van Oers, van Oyen H, for BRIDGE Health. Towards a sustainable EU health information system infrastructure: A consensus driven approach. Health Policy 122 (2018) 1340-1347

Other information sources used for or in the text of this business plan are the following:

- CSIL (Centre of Industrial Studies). Guidelines on cost estimation of research infrastructures. Commissioned by StR-ESFRI – Support to Reinforce the European Strategy Forum on Research Infrastructures. August 2019.
- Curran JA1, Grimshaw JM, Hayden JA, Campbell B. Knowledge translation research: the science of moving research into policy and practice. J Contin Educ Health Prof. 2011 Summer;31(3):174-80. doi: 10.1002/chp.20124.
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- Lateral Economics. Population Health Research Network (PHRN) impact and return on investment. October 2017
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- PWC. Third independent external evaluation of the ECDC in accordance with its Founding Regulation. https://www.ecdc.europa.eu/en/publications-data/third-external-evaluation-ecdc-2013-2017

Annex 1: Historical context for the needs and services (section 1.1)

Box A1: some historic context and EU considerations

- The Health Monitoring Programme (HMP) adopted in 1997 intended to pave the way for permanent EU health monitoring.
- EU parliament resolution[8] asked the EC in 2011 to consider and assess the possibility of extending the remit of ECDC to encompass non-communicable diseases and using it as a centre for data collection (remit was not extended).
- Multiple council conclusions[9], calling the EC to:
    - o "establish sustainable health monitoring systems at EU level" (2011)
    - o "Strengthen cooperation and make better use of existing networks and existing public health and related institutions, which investigate, monitor and research the impact of the health determinants." (2011)
    - o "further development and consolidation, while avoiding duplication of work, of a health monitoring and information system at EU level based on the ECHI and existing health monitoring and reporting systems". (2013)
    - o "to cooperate with a view to establishing a sustainable and integrated EU health information system. the potential of a **comprehensive health information research infrastructure consortium** (ERIC) as a tool." (2013)

BRIDGE Health (EU Grant 664691, 2015-17) in close cooperation with the European Commission (EC) and MS, recommended the setup of a Research Infrastructure (RI) to facilitate comparative research in population health.

The Joint Action on health information (InfAct, Information for Action!) has brought these recommendations forward (EU Grant 801553, 2018-21) with 40 partners in 28 countries, streamlining health information activities and working towards sustainability for population health research. This consortium of strong scientific, managerial and technical leadership joint forces submitted the ESFRI application for DIPoH .

These projects and other predecessors, covering a period of more than 20 years of focused activities and conceptual thinking, have been key in the preparation of the services to be delivered by the Research Infrastructure.

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[8] https://www.europarl.europa.eu/doceo/document/TA-7-2011-0390_EN.pdf
[9] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/126524.pdf;
http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/140004.pdf

Annex 2: Alternatives for setting up a research infrastructure, their strengths and weaknesses (section 1.2)

Several other options to face the health information challenges were considered before starting on the road towards this new structure in the form of an ESFRI project/landmark and a European Research Infrastructure Consortium (ERIC). To provide context to DIPoH they are elaborated on here.

The following options have been considered:

- Do nothing
- Strengthen existing structures
  - Expanding tasks of Eurostat
  - Extension of the scope of the European Centre for Disease Prevention and Control (ECDC**)**
  - Reorganisation of DG Health and Food Safety (SANTE)
  - Extending work plan of DG Joint Research Centre (JRC)
  - Outsource to the World Health Organization (WHO) Europe or the Organisation for Economic Co-operation and Development (OECD)
- Create a new structure
- Creating an independent new EU agency
- Research program
- Joint Action
- Supra-European structure
- Combination of new and existing structures
- For example, a health information division in ECDC to handle policy making, in addition to an ERIC which could incorporate research and data infrastructure.

The following elements have been essential in the evaluation of different structures:

- Acceptability and support of the Member States (MS) and the European Commission. Consideration
- Acceptability of the need for an appropriate governance of DIPoH, ensuring all relevant stakeholders are engaged without inhibiting progress.
- Feasibility in the short term and in the current legal, economic and political framework.
- Financial sustainability with resources from both EU programmes and the MS.
- Ability to carry out research and public health surveillance and monitoring in population health and health system performance.

Using multi-criteria analysis, the advantages and disadvantages are investigated of either strengthening existing structures or creating a new one. The different options were discussed in focus groups with national public health institutes and BRIDGE Health work package leaders by using SWOT analyses and the criteria described in Annex 4 of the concept paper of BRIDGE Health.

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A. Strengthen existing structures

At European level, various institutions and agencies carry out activities related to health information such as different Directorate Generals (DG) of the European Commission, decentralised agencies and international organisations. The advantage of working with an existing structure or a combination of existing structures is that, in general, the infrastructure and administration are already in place. There

is a basic legal mandate and framework, and the political setting with existing networks is set up. Rather than creating something new, one can build on existing knowledge and expertise. However, current activities of existing structures can diverge from the role envisaged for the proposed EU health information system, as new domains are tackled, and strong political support would be needed to allocate resources and/or change activities. Various options can be considered; separately or combined. Table 4.1 provides an overview of strengths and weaknesses of various options.

Expanding tasks of Eurostat

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Eurostat already has long-standing experience with data and statistics. Its task to provide the EU with statistics at European level that enable comparisons between countries and regions, corresponds with the gaps of the current EU health information system and indicators could be included in the European Statistical System. Eurostat also has a legal mandate for the collection of health data as defined in the regulation 1338/2008 covering health status and health determinants, healthcare, causes of death, accidents at work and occupational diseases and other work-related health problems and illnesses. The weaknesses of selecting Eurostat are linked to the fact that Eurostat focusses on data and statistics which are to a majority not linked to public health. Eurostat provides strong governance on the statistical system, but does not provide this from a public health point of view which is needed in this context. Additionally, Eurostat has a wide range of activities, but as a statistical office it does not focus its work on translating data into knowledge for evidence-based policy-making.

Extension of the scope of the European Centre for Disease Prevention and Control (ECDC)

The major strengths of extending the ECDC are its focus on health and the fact that one can build on existing knowledge and expertise acquired through the work on infectious diseases. The ECDC has experience in managing large networks and carrying out capacity building. This centre is also mostly linked to public health functions and has existing links with the Member States. However, infectious diseases are the main focus of the ECDC and there is no wider mandate for health information in other domains. The visibility of the ECDC is linked to infectious diseases and there is no experience in non-communicable diseases. The name of the centre does refer to disease prevention and control which could fit within the need for strengthening the EU health information system. Adding one or more units within the ECDC focusing on wider activities than infectious diseases could tackle some of the issues. Finding the necessary political will and resources for this could be very challenging. This was also reiterated in the third ECDC evaluation in 2019.

In response to the pandemic, the discussion option is being reconsidered. In July 2020 European Parliament again asked questions about extending the mandate of the ECDC to include Non-Communicable Diseases[10]. In April 2021 a group of organisations[11] urged the Working Party on pharmaceuticals and medical devices to strengthen the mandate of the European Centre for Disease Prevention and Control (ECDC) to cover an integrated approach to public health as part of proposals for a European Health Union[12].

Reorganisation of DG Health and Food Safety (SANTE)

The strength of DG SANTE is their existing knowledge and expertise in public health, in addition to their mandate of the health programme[13]. However, the activities of DG SANTE orient towards policy rather than towards research. The operational capacity is also low and long-term continuity cannot be assured. The role of advanced health information tools in Europe is critical both for research and policy-making.

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[10]https://www.europarl.europa.eu/doceo/document/E-9-2020-004064_EN.pdf

[11]All.Can, BioMed Alliance, European Chronic Disease Alliance (ECDA), EU4Health Civil Society Alliance, EU Health Coalition, European Health Union Initiative, EuroHealthNet, European Public Health Alliance (EPHA), European Public Health Association (EUPHA), European Diabetes Forum (EUDF), Self Care In Europe (SCiE), Senior International Health Association (SIHA)

[12]https://europeanhealthunion.eu/extension-of-the-mandate-of-the-european-centre-for-disease-prevention-and-control-ecdc/

[13] Now EU4Health, covering 2021-2027; https://ec.europa.eu/health/funding/eu4health_en

Extending work plan of DG Joint Research Centre (JRC)

The JRC has developed expertise and experience in certain aspects of health such as cancer and rare diseases. It translates health information for policymakers and can adjust its work plan according to the needs of DG SANTE. This, however, may limit the sustainability of its activities as they may change over time. The main focus of the JRC is not public health but research, and the institution has limited interaction with the MS.

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Outsource to the World Health Organization (WHO) Europe or the Organisation for Economic Co-operation and Development (OECD)

To avoid duplication of activities, outsourcing activities to the WHO or the OECD may be considered, similarly to what is currently done for the report "Health at a Glance". Both international organisations have expertise and experience in public health and core data set work. The weakness of working with such an organisation is that they are not solely EU- focussed and may therefore have their own agenda, different mandates and policy aims.

B.   Create a new structure

A new structure allows more flexibility in terms of activities and scope. It can tailor its activities to current needs and demands. It can cover the gaps of existing structures and provide an overview of existing initiatives in health information. A new structure can also have a voice of its own for better advocacy and visibility. It can build on the knowledge and experience of previous EU projects using health information or health data. However, similar to existing structures, political support is needed and financing (mechanisms) need to be found. The strengths and weaknesses of chosen various options are described in Table 4.1 and 4.2.

Creating an independent new EU agency

Creating a new EU agency would, besides the strengths discussed above, also operate within the EU framework. It would have a strong legal basis and it is questionable why such an agency does not exist yet. In the current economic climate, it is however not realistic to set up a new EU agency, but it could be a long-term goal. A strong political will would be needed. BRIDGE Health also found out during discussions that current institutions may also perceive a new EU agency as threatening.

European Research Infrastructure Consortium (RI)

The strength of an RI is the relatively short term needed for its setup following a known procedure and the fact that an RI has a legal framework. It is a practical solution with a flexible format and financial framework. An RI can receive funding from e.g. the EU Health Programme. Research and development are part of the solution and international collaboration can be assured. An RI can grow and be built up. Moreover, good examples exist and can be learned from. As many other structures, sustainability cannot be assured. An RI is Member State-driven and therefore depends on the willingness of the MS. In relation to the governance, a major drawback is that the European Commission cannot be a member of DIPoH and not all EU MS need to be part of the RI, which means its success depends almost entirely on the willingness of the MS. Additional weaknesses include its lack of mandate to steer health information in the EU.

Joint Action

A Joint Action is easy to be set up and can provide a transition between the BRIDGE Health project and any structure that may be created. This may be necessary as most other options (even setting up an RI, which is a rather medium-term solution) may take several years. The weakness of a Joint Action is that not all EU MS need to participate, there is a lack of mandate and it is only a temporary solution as it is project based.

Supra-European structure
Creating a supra-European structure such as a Codex Alimentarius Commission may be prestigious and has high credibility and visibility, but it will not be EU-focussed. There is also no legal status and a high administrative burden.

Table A1: Strengths and weaknesses of adding health information to existing structures

Strengths	Weaknesses
Expanding Eurostat's tasks • Existing infrastructure • Existing expertise and experience • Works with MS • Does data collection in health with EU regulation • Has a baseline on indicators • Has good knowledge of data • - Deals with cross-cutting themes (other directorates outside of health)	• Focuses on data and statistics • Majority activities not related to public health • Does not provide any governance involving Public Health structures in MS • Has no focus and knowledge translation • Misses a link with Ministries of health since the main link of Eurostat is with statistical institutions
Extension of the scope of the European Centre for Disease Prevention and Control (ECDC) • Existing infrastructure • Possibility for relatively quick start with clear legal context and political mandate • Existing experience and success • Managing large networks • Capacity building in countries • Provides a link between existing work on infectious diseases and EU health information system • Is linked to public health function • Governance from Commission with MS monitoring of outcomes • Possibility of programming and prioritisation • Possibility for cooperation and alignment with other institutions	• Focusses on infectious diseases • Mandate for wider health information does not seem to be supported (2019), although the discussion recently flared up again in response to the pandemic. • Visibility only connected to infectious diseases • Has no experience on non-communicable diseases • Uncertain how broad scope could be (e.g. comparative health care research) • Uncertain how ECDC could fund capacity building • Politics will play larger role • - Financing of CD and NCD would have to be disconnected
Reorganisation of DG SANTE • Existing infrastructure • Existing expertise and experience • Has mandate of health programme	• Politically oriented • Misses scientific dependence • Operational capacity • -Long-term continuity
Extending the work plan of the Joint Research Centre (JRC) • Existing infrastructure • Expertise and experience in cancer and rare diseases • Translates data into policy • - Flexibility	• No public health focus • Sustainability • - Limited interaction with MS

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Outsource: WHO, OECD	
• Expertise and experience in public health • Core data set work • Avoid duplication • Expertise and knowledge on international comparison of health care systems	• Not EU-focussed • Own agenda, different mandate and policy aims • Little influence on EU • Sustainability

Table A2: Strengths and weaknesses of creating a new structure for health information

Strengths	Weaknesses
Independent new EU agency • Tailored to specific needs and demands • Visibility for public health • Have a voice of its own • Strong basis • Clear vision and goals • Operate within EU frame	• Not realistic in current financial climate due to high constraints • May be perceived as threatening to existing programmes • Needs to start from scratch • Needs strong political will • Long time to be set up • High governance/administrative costs
European Research Infrastructure • Practical solution due to the availability of legal framework • Can be set up in relatively short term • Is flexible in format and financial contributions • Research and development are part of the solution • Collaborate with international agencies • Can grow and be built up • Can receive EU funding from e.g. EU Health Programme • Based on institutional agreement and MS political commitment	• Sustainability depends on funding provided by MS • Does not require involvement of all MS • Depends on willingness of MS • European Commission cannot be a full member • Lack mandate to steer health information in the EU
Research program • Better possibility to effectively address challenges, by strategic coordination	• A research program in itself will not ensure sustainable governance, MS collaboration and collective memory
Joint Action • Easy to set up • An interim solution	• Short-term solution • Not sustainable • Limited funding • Not all MS need to participate • Lacks mandate to steer health information in the EU

Supra-European Structure (e.g. Codex Alimentarius Commission) • Prestigious, credible and visible	• No legal status • Administrative burden and coordination • - Not EU-focussed

C. Combination of new and existing structures

Using the strengths of an existing structure, a new structure could be built to take up the activities that remain. The strength of this format is that existing institutions are not overridden, the role of coordination and governance could be taken up by an EU institution and a long-term way of working together could be established. One of the challenges would be the coordination between those structures. Many different options can be considered combining the options described above e.g. a health information division in ECDC where the policy thinking would happen, in addition to an RI which could incorporate research and data infrastructure.

Annex 3: Expected impacts (section 1.5)

DIPoH is expected to have the following impacts:

- **Impact on research capacities**

DIPoH will increase knowledge sharing, expertise and training to improve population health research and knowledge translation. Using innovative technical solutions, DIPoH's federated infrastructure approach will help to overcome major current hurdles for pan-EU research. DIPoH will facilitate data availability, comparability and use to enlarge the pool for research within and beyond the health sector, allowing regular monitoring, trend analysis and future predictions. By facilitating the data reuse, tools, IT, computational and ELSI (Ethical, Legal, Social Implications) experience and expertise, DIPoH can support the development of national data hubs, increase the national population health research capacities and encourage further (inter)national collaborations. DIPoH will enable MS and EU to optimise funding allocation and to achieve optimal return-on-investment from international health information activities and health research. National investments and those at European level can be aligned more effectively. Joint programming and research agendas will be more feasible. DIPoH will curate knowledge generated by European researchers and their international networks and reduce health information inequalities.

- **Impact on data innovations and data quality**

DIPoH will reduce burden by increasing harmonisation of international data collection to reduce duplication and assist in providing the data to international sources. It will be an opportunity to collectively adopt the FAIR data principles and align with the European Open Science Cloud (EOSC). DIPoH will make an important contribution to the European Health Data Space, with the setup of data hubs (see section 2.2), linkage of health systems, health data and non-health data, and the inclusion of advanced techniques of analysis.

DIPoH will maximize the potential of e-health generated data. Through DIPoH, new methodologies and cutting-edge innovative research developments are enabled regarding tools for data access, quality assessment, reuse, analysis, interpretation, reporting and archiving. DIPoH will provide the conditions necessary for rich new insights into the dynamics of population health, healthcare interventions, and technological development. It increases capabilities and expertise on big data, data linkage, new emerging data sources, artificial intelligence, machine learning, thus enhancing abilities for priority setting and   horizon scanning. Overall DIPoH will contribute to increased EU competitiveness in a key field of the digital economy, such as health and wellbeing.

- **Impact on associated and applied sciences**

DIPoH will support a cross-sectoral/multidisciplinary research approach, through facilitating and making data available from various domains, which can influence population health. DIPoH will serve research in other sectors such as sustainability, climate change, ecosystems, food security and economy. Keeping in mind, healthy citizens are a prerequisite for economic sustainability.

- **Impact on policy and decision making**

DIPoH will contribute to closing the gaps of population health information in Europe, making the best knowledge available for evidence-based and timely informed policy-making. This will mainly be through the support of a proactive knowledge translation strategy and methodology, optimising instruments to facilitate the provision and uptake of latest and best evidence on population health for decision making.

- **Impact on health of EU citizens**

DIPoH will inform improvements to health and social sector policies, practices and technology, to increase citizens' wellbeing through better health and/or lower health and social services costs. This by allowing rational allocation of resources based on latest evidence, addressing health needs according to each specific area, and eventually, improving the health of EU citizens.

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Annex 4: User segments and estimated market size (section 1.6)

Table A3: DIPoH user segments

Users	Absolute (K)	% of total potential users
1. Population Health Researchers	25	45
2. Policy makers	12,2	22
3. Students	5,6	10
4. Data providers in health information domains	5	9
5. Industry	3,3	6
6. International organisations	1,7	3
7. Citizens and patient organisations	1,6	3
8. NGO's & charities	1,3	2
9. The media	0,3	1

Annex 4: User segments and estimated market size (section 1.6)

Annex 5: Services (section 1.6)

The services are categorised along the DIPoH pillars:
- One stop shop: Collections for population health
- Innovative research: Working with data and information
- Capacity building
- Knowledge Translation and Strategy

Table A4: Overview of the DIPoH services along the DIPoH pillars

Service	Access mode
Collections for population health	
Catalogue of national EU data resources for public health	Open access via portal to the searchable catalogue
Catalogue of EU networks	Open access via portal to the searchable catalogue
Catalogue of EU experts	Open access via portal to the searchable catalogue
Catalogue of EU National focal points	Open access via internet portal to the searchable catalogue
Links to guidelines, tools, recommendation and best practices: 1. data collection, data storage, data models, advanced statistical models, ethical/legal/social implications, 2. (open) software, interoperability, standards, classifications, reporting, knowledge translation	Primarily open access via internet portal to the documents and tools. Some material may have more limited access through request.
Links to international training options	Open access via internet portal as static materials, training videos or corresponding format. Some (specifically tailored material may have more limited access through request)..
Links to main indicators in bigger Europe (WHO, OECD, etc.)	Primarily open access via internet portal to the documentation of indicators and indicator tables/dashboard. Some material may have more limited access through request.
Latest news	Open access via portal and to feed health news media.

Working with data and information	
Access: 1. Metadatabase of EU data sources (advanced search function) Providing search tools	Open access via portal to the searchable catalogue
Data collections: 1. Supporting the collection of data from the public health research networks Mapping data gaps in health research areas and signalling areas with low-quality data	Open access via portal to the searchable catalogue
Interoperability and standards: 1. Activities in context of FAIRification and interoperable common data model (IOCDM) ELSI and FAIR guidelines	1. Open access via internet portal for general guidelines On request, case specific consultation can be provided
Computing and software tools: 1. Provide assistance for the development of self-contained distributed analytical pipelines 2. Provide automated research outputs report and dissemination (via templates and/or API) 3. Distribute open software solutions on continuous basis 4. Provide analysis software development kit 5. Provide advanced statistics using Machine Learning Techniques to estimate health outcome indicators using linked data Provide Burden of Disease calculations and foresight calculations	On request: 1. Specific scripts can be prepared 2. Specific statistical analysis can be conducted or support to do them locally provided. 3. Upon request 4. Upon request 5. Upon request On request specific statistical analysis can be conducted or support to do them locally provided.
Capacity building	
Offer European Health Information Training Programme (EHITP)	Yearly special programme on HI. Open access via internet portal as static materials, training videos or corresponding format. Some material may have more limited access through request.

Provide regular training on health information and data related issues: 1. abilities to use common data models and data architecture, full application of the analytical pipeline 2. application of FAIR and ELSI principles 3. standardising data and metadata 4. EHES, data collection 5. health system performance assessment Burden of disease	Based on a health information roadmap, an annual programme offer will be defined. Some courses/ workshops open access via internet portal, possibility for video courses, and some upon request. Visiting programme as physical visits.
Provide training or workshops on topics requested by a customer.	
Provide training on how to set-up a National Node	Available for members
Develop handbooks to support researchers that are new to a certain area	Available for members. For non- members can be a fee for service
Advise on building a productive network	Available for members. For non- members can be a fee for service
Develop accreditation process/excellence criteria, facilitate development of Centres of Excellence	Limited access available for members. For non-members can be a fee for service
Provide support in acquiring funding	Available for members. For non- members can be a fee for service
Provide PhD research training and development	Available for members. For non- members can be a fee for service
Provide MSc module on comparative health information analysis	Available for members. For non- members can be a fee for service
Knowledge Translation and Strategy	
Support joint population health research agenda- setting/prioritisation in health information	Available for members. For non- members can be a fee for service
Provide expert assessment of international research project proposals involving population health information	Available for members. For non- members can be a fee for service

Provide strategic advice on data quality improvement, data linkage and interoperability for health information systems	Available for members. For non- members can be a fee for service
Preparation of thematic or targeted reports	Available for a fee for service
Summarise health information related research	Available for a fee for service
Lead a full expert group	Available for a fee for service
Provide knowledge on health reporting	Available for members. For non- members can be a fee for service

DIPoH e-services

DIPoH e-infrastructure services will be constituted by: a) the Health Information Portal acting as front-end of DIPoH, giving information and manage user authentication and DIPoH services brokerage; b) a metadata storage of the data sources of the consortium; c) an analytics services supporting the deployment of the distributed analysis tools and compiling the processed outputs; and d) a peer-to-peer network of data hubs where actual data is stored, also acting as distributed analysis services' back-ends.

The main e-infrastructure services initially required by DIPoH will be those supporting the deployment of the portal and all associated services. The research institution acting as coordinator of DIPoH consortium, Sciensano, will manage the hosting and e-infrastructure services supporting the portal within their own e-infrastructure, setting up dedicated servers and maintaining an adequate flexibility to scale to future change of needs, including fast expansion of membership or a widening scope of the portal..

DIPoH e-infrastructure will leverage the connectivity and the data storage, management and analysis capabilities of the data hub peers included in DIPoH. For instance, the capacity required for each node or network is estimated at a minimum of a server with at least 16 processing cores, 128GB RAM, 4Tb storage and 1Gbit network connectivity. Therefore, partners may contribute their own servers, or outsource them to European RIs, such as EGI, EUDATA or PRACE, on an on-demand basis whenever needed.

DIPoH will rely on distributed data storage and computing for the federated analysis, this depends on the maturity of the e-infrastructure of partners to perform the data management and analysis tasks. Partners lacking the required e-infrastructure capacities will be supported and encouraged to achieve those capacities using services provided by available EU e-infrastructures acting as providers, such as EUDAT, EGI or PRACE. DIPoH will promote global collaboration schemas between those infrastructures providing e-infrastructure services and participating partners. DIPoH will act as a one-stop shop joining the data, the methods for analysis and the technological means to exploit them for population health research purposes. Research studies requiring vast amounts of computing resources will leverage high-performance computing resources upon request using preferentially the capabilities of the existing e-infrastructures like EGI or PRACE upon the connectivity and information and communication technologies provided by GEANT.

DIPoH will concentrate efforts in partnering with these other infrastructures through promoting the participation of partner institutions in each other's consortia, enhancing mutual capabilities and promoting common research projects.

Examples of overarching services

DIPoH may also integrate its different services to support overarching goals.

- Example 1: European Health Data Space (EHDS)[14].
DIPoH is aiming to serve as a cornerstone of the EHDS. It can provide an infrastructure, technical know-how, and national contacts.

- Example 2: The Mission on Cancer[15].
DIPoH can support the 13 recommendations by the Mission Board, e.g. by facilitating access to expertise, data, innovative technologies and capacity building.

- Example 3: The European Core Health Indicators.
DIPoH may provide an infrastructure, research networks for technical indicator work, national experts.

- Example 4: The European Open Science Cloud.
DIPoH will contribute to EOSC providing sharing and discovery services for the FAIR reuse of population health data, not currently present in the EOSC catalogue. For this purpose DIPoH will adhere to EOSC rules of participation embracing the principles of openness, transparency and inclusiveness.

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[14] https://ec.europa.eu/health/ehealth/dataspace_en
[15] https://ec.europa.eu/info/publications/conquering-cancer-mission-possible_en

Annex 6: SWOT analysis (section 1.7)

Strengths and opportunities of DIPoH are summarised in the following tables.

Table A5: Strengths and opportunities for a Health Information Research Infrastructure

Strengths	Opportunities
• Flexible and responsive to MS needs and may extend its activities and become larger over time • Provide sustainable structure for best practice exchange between MS • Data collection and regular assessment and analysis • Capacity building and increased cooperation between national and international experts, public health institutes and research institutes • Builds on existing expertise and structures (research projects and national and international organisations) • Provides a holistic approach to population health monitoring and health system performance • Provide overview and coordination of EU health information activities and methodologies at MS-level and within expert networks • Mutualised learning and data access to the Health Information Portal • Better participation in EU funded research project • Assist with elements of overarching project management • Pool resources for more effective resource allocation • Best practice exchange between MSs and EU-population health information research networks	• Demands from EU political bodies • MS ownership • Innovation in domains of data collection • Complex health indicators • Possibilities for data linkage • Diversity of stakeholders • Provide overview in health information activities • Interaction with national public health institutes • Closing health information gaps • Responding to increasing demands in health information • Provide health information to new initiatives such as the EU health cycle and the JAF health etc. • Through the consultation platform there is an opportunity for alignment of EC entities and international organisations

Annex 6: SWOT analysis (section 1.7)

Table A6: Weaknesses and threats for a Health Information Research Infrastructure

Weaknesses	Threats
• The Consortium for the ESFRI application does not include all MS but already 10 letters of political support, 16 Memorandum of Understanding, 8 Letters of intent have been provided and more countries have indicated their interest through letters of support.	• Some institutions/EU research networks that are not part of the project do not find sufficient incentives to join the DIPoH (Low risk) • Users/data owners are not convinced that sharing of data is safe and do not want to participate in the process (Low risk) • EU MSs are sceptical of the return of investment for the DIPoH (Medium risk) • No workable solutions for a viable funding model on the long term can be found (Medium risk)

Annex 7: Development and implementation in more detail (section 1.8)

DIPoH's development and implementation phase is developed in two three-year programmes. The preparatory phase (2022-2024) prepares for the implementation and establishment of the legal entity. These are divided into 3 sub-tasks:

1. Research development and technical construction: all the technical and scientific challenges are addressed. The technical component and design of the Health Information Portal is constructed and the metadata catalogues are piloted with national nodes (NN) and research networks (RN); the e-infrastructure backbone for the functioning of DIPoH is developed and piloted, together with the necessary technological aspects needed for the different NNs and RNs serving as data hubs; common data models are developed and piloted.

2. Organisational agreements: all the socio-cultural challenges are addressed. A communication strategy is developed. This task covers the necessary agreements among the DIPoH partners and stakeholders for the implementation and operation of DIPoH: the governance structure and business plan will be finalised; funding resources and investment strategies are prepared; collaboration agreements with NNs and RNs are further sought and signed through an MoU; further political support from MS/AC are sought through bilateral discussions and agreements; advisory boards are set-up; stakeholders and user forums are implemented to ensure their engagement in further developing and updating DIPoH services; discussions for collaborations with other RI's and specifically linking to EOSC; finally, the statutes for the legal entity are drawn up.

3. Central facilities specifications: all access challenges and specifications for the central office are addressed. The site is selected for the central office in preparation for recruitment once the legal entity is established. The service support unit is set up and possible services are piloted. For all services a plan for implementation will be developed; the data catalogues inventory is set up with a maintenance and automatisation plan together with the NNs, RNs and experts; capacity building programme plans are set and possibly piloted; a data management framework is set, together with a data and user access policy and a code of conduct; a risk management plan is set and mitigation measures defined.

The implementation phase (2025-2027) contains finalising all aspects for the deployment of the legal entity of the operational RI. This phase ensures the commitment of the members is signed and legally binding, and ensures that DIPoH is on all relevant national RI roadmaps or any other political documents. The business plan and budget are agreed upon. This secures the funding for the central office during operation in a sustainable way for at least five years. In this phase all the agreements for collaboration with other organisations, RIs, EOSC are set.

The deployment of the organisation and management structure is implemented. This entails that the central office site is agreed upon and personnel recruited, including the implementation of the appropriate human resources policy. During this phase the training of the central executive management team takes place in order to ensure adequate and viable progress into the operational phase.

The technical specifications of the e-infrastructure including the Health Information Portal are up and running: the portal reaches operational capacity with the corresponding metadata catalogues available for use by the users; DIPoH supports NNs in implementing their role in the RI; services and expertise provided by RN are agreed upon and piloted; capacity building programme ready for operation; helpdesk and support functions are implemented; the process for linking data hubs in DIPoH members pilot is finalised and planned for scale up and the common data model adapted.

Annex 8: KPI for monitoring progress (section 1.6 and 1.8)

DIPoH will use the RACER principle to develop a set of KPI that are relevant, accepted, credible, easy, and robust. The KPIs are divided into:

1. **User metric KPIs**
   - Number of users: number researchers, policy makers, public sector, industry, students
   - Number of user per field, level of expertise, geographic distribution, type of organisation
   - Number of national nodes
   - Number of research networks and partnering institutions
   - Number of user requests for training, data models, expert support
   - Number of access and approved access requests
   - Number of requests for data access
   - Number of documents downloaded
   - Number of queries in Health Information Platform
   - User opinion on experience and evaluation of services
   - User queries/questions/complaints/suggestions for improvement

2. **Operational metric KPIs**
   - Access provision by types of access possibilities
   - Number of access provided
   - Amount of data downloaded
   - Number of services used
   - Number of expert trainings
   - Number of HIS assessments
   - Number of doctoral students
   - Number of trainees
   - Number of provided operational support for specific services
   - Portal down time
   - Visibility of communication through social media indicators
   - Number of returning users
   - Number of validated data models

3. **Financial metric KPIs**
   - Contribution of access funding to the financial sustainability of the platform
   - Annual revenues
   - Economic return of investment
   - Types and amount of funding sources

4. **Strategic metric KPIs**
   - Number of countries as members
   - Research projects funded involving DIPoH
   - Private organisations and companies using DIPoH services
   - Number of publications (peer reviewed papers)
   - Number of communication activities at workshops and conferences
   - Number of users involved in training activities
   - Job creation (direct and in-direct employment)
   - Number of joint meetings and projects with other RIs and relevant organisations

Annex 9: Governing bodies (section 2.1)

(i)   **The Assembly of Members:**

The Assembly of Members (AoM) is the governing body and is composed of representatives of the members of the ERIC. The Assembly of Members is the highest and ultimate governing body of the ERIC with full decision-making power. Each member and observer nominates an official representative to participate in the Assembly of Members. One representative of the Scientific Advisory Board and the Ethics and Privacy Board is invited as an observer in the Assembly of Members. The Assembly of Members elects amongst its members a Chairperson and a Vice-Chairperson to chair the meetings. One representative of the Scientific Advisory Board and the Ethics and Privacy Board is invited as an observer in the Assembly of Members. The Director General is the rapporteur of the Central Executive Management Office to the Assembly of Members.

(ii)   **The External Support Team:**

Two external support boards are still part of the DIPoH final structure: (i)The Scientific Advisory Board consists of up to ten independent and internationally recognised scientists involved in population health monitoring and research and health system performance assessment acting on their personal title and strategic experience; (ii) The Ethics and Privacy Board similarly consist of experts in ethics and privacy. The Scientific Advisory Board and Ethics and Privacy Board will offer advice on request of the Assembly of Members and may be consulted by the Central Executive Management Office on all scientifically and technologically relevant matters including questions regarding the research agenda, scientific strategies, ethical issues and the annual work programme. The Scientific Advisory Board is also tasked to periodically evaluate the activities and products of the ERIC including the strategic and operational objectives. The Scientific Advisory Board and Ethics and Privacy Board can select a representative to participate in the Assembly of Members as an observer. The Assembly of Members defines the selection procedure, appointment and duration of the Scientific Advisory Board and Ethics and Privacy Board.

(iii)   **The Central Executive Management Office:**

The Central Executive Management Office is composed of the Director General and a Core Team. The Central Executive Management Office is the executive body. It is responsible for the management, operational and budgetary day-to-day decisions. The Central Executive Management Office provides an administrative governance structure, which carries out scientific, technical and administrative coordination tasks in addition to the delivery of core services. These tasks are decided by the Assembly of Members. There is a clear frontier between the strategic decisions taken by the Assembly of Members and the executive part carried out by the Central Executive Management Office in order to avoid any conflict of interest within the ERIC. The Director General is appointed for six years by the Assembly of Members and is assisted by the Core Team. The Core Team is in charge of the coordination and support office of the ERIC. The Core Team is responsible for daily operations (such as preparations of meetings), the implementation of the ERIC programme, servicing the various Boards and Committees, external relations and communications, providing services to support the nodes and the user community, and grant-application functions. The Core Team comprises legal and technical expertise, which is necessary for a large distributed research infrastructure and the effective interfacing and coordination.

(iv)   **The Consultation Platform:**

The Consultation Platform will align with the current European health information landscape and liaise with different organisations. The platform will seek synergies between international entities. A representative from the following organisations may compose the platform.

- A representative from expert groups or consultative bodies in DIPoH's related fields such as the Expert Group on Health System Performance, the Joint Assessment Framework (JAF) on Health, the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP).

- A representative from European agencies dealing with health information, in particular the European Centre for Disease Prevention and Control but also others such as the European Environment Agency, the European Monitoring Centre for Drugs and Drug Addiction, the European Medicines Evaluation Agency, European Agency for Safety and Health at Work, and the European Foundation for the Improvement of Living and Working Conditions;

- Representatives from European Commission services are also vital partners, such as SANTE, ESTAT, RTD, JRC etc.

- A representative from partner organisations at international level, in particular the WHO Regional Office for Europe, the OECD and the European Observatory on Health Systems and Policies;

- A member of IANPHI representing the national public health institutes of EU countries

- A representative of the national nodes and research networks.

- Representatives of selected research infrastructures such as ELIXIR, BBMRI, EATRIS, ECRIN, CESSDA, ESS and SHARE.

(v)   **The Network Committee:**

The Network Committee consists of a representative of the NN and RN that are operational in DIPoH. The Network Committee shall be, and is responsible for scientific activities. The Committee will meet to maintain coherence and consistency across the networks, to discuss issues related to the activities of the nodes, and to interact with the Central Executive Management Office. The Committee may support the Central Executive Management Office in developing the programme, scientific strategy and grant-funding opportunities.

Annex 10: DIPoH detailed activities (section 2.2)

I.   Core activities

Catalogue of collections of FAIR data

- Search engine: find data, find a network, find an expert, find data tools, knowledge translation tools and services
- Develop and maintain repositories for: international comparative datasets, indicator sets, research articles and reports from the networks, standards and guidelines, methods, metadata
- Access to relevant classification methods and standards
- Map of open access software solutions
- Literature searches and reviews
- Collective memory EU population health and health systems projects

Advisory services

- Guidelines to FAIR data and being in line with ELSI requirements
- Building a productive research network
- Working with complex/big data; data model development, analytical pipelines, customized selection of data models
- Writing hands-on guides on methodologies and tools for health information practitioners and researchers
- Addressing different audiences with the result of your research

Capacity building

- Support researches in MSs new to domain specific areas (setting up registries, surveys, improving quality of registries and surveys, stimulate data provision, data management plans, metadata, …)
- Real world data reuse
- Science of data
- Development of federated data infrastructures
- Manage specific capacity building projects
- Facilitate learning networks for researchers
- Organise and support expert exchange and teaching options
- Translational research methods

Communication

- News from the international health information field (EU focus)
- Organise and signpost information on hey health information research issues
- Maintain calendar of relevant health information events
- Allow domain specific networks to present their news
- Summarise bodies of health information related research for policy makes

II.   Supporting activities

Research development support

- Propose and design EU-wide data collection efforts- (Standardisation, interoperability)
- Help with legal and ethical aspects; forms, standards, regulations
- Finding matches for research and funds/pools
- Give advice when drawing up project descriptions
- Provide general information and advice about European and other international research programs
- Courses and information meetings
- Contact and coordination in relation to EC staff in Brussels
- Templates of EU projects and across sectors

Research into practice support

- Interface for bottom-up approach for current issues and needs in health information
- Support the development of national/EU strategies for health information
- Support and monitor the utilisation of information in practice
- Relate indicators to decision making process
- Draft reports on how to use health information
- Methodologies for knowledge translation

III.   Strategic activities

Knowledge brokering

- Broker for access to experts or expert advise
- Broker for commissioning a full expert group
- Broker for commissioning a specific report, review or data analysis
- Broker for strategic advise and data improvement, data linkage, interoperability issues, etc.

Link to/collaborate with other ERICs

- Share and provide services
- Prevent duplication

Horizon scanning
Support for joint research agenda and priority setting
Advocate for EU health information

Annex 11: Research Network quality criteria and proof of concept (section 2.2)

Research Networks: criteria quality, impact and policy relevance

A research network is a living network of national and/or regional experts from several countries that performs comparative research in a specific health research area (information domain). The criteria for a DIPoH research network's (ultimate) quality, impact and policy relevance are:

Research networks will be relevant for DIPoH if they:

Cover a topical area (domain) that is part of the domains of the research infrastructure on Health Information, i.e. the domains of population health monitoring and/or health system performance assessment
Have a track record in international comparative research in that domain
Have a proven ability to link international experts and address information gaps in that domain

Performance criteria for research networks:

1. **Policy relevance and impact of the research**

Covers a research area that was mentioned as being important in recent EU policy documents or EU regulations or in national or regional health policy documents of Member States (relevant).
Provides research output and evidence that is expected by experts to be able to feed into effective and actionable health policy options and recommendations (actionable)
Covers a research domain that has recently become a more urgent health policy priority in several countries or regions (urgent)
Produces research reports/papers asked for by governing or healthcare managing bodies at local, regional, national or international level (effective)
Produces new information and data from its research in a policy relevant format (policy briefs) (innovative)
Uses its research expertise to creates indicators that can be easily understood and used by health professionals, policy makers and other stakeholders (practical)
Creates research output that evokes or contributes to health policy debates; recent policy documents refer to its publications (leading)

2. **Uniqueness**

Is the only substantial research network in that specific domain in Europe (EU/EFTA)
Performs original research mainly based on new data collections, i.e. data that are not part of regular statistical data that come from other sources

3. **Sustainability**

Actively performs research, e.g. by collecting comparable data, producing research papers or reports, harmonizing data collections and organizing network meetings and exchange of good practices. It has been doing this for several years (sustainable, active, collaborative)

4. Geographical coverage

Consists of actively participating researchers and/or data collectors that represent a significant number of European countries or regions
Collects data that are representative for a significant number of EU/EFTA regions and/or countries

5. Scientific excellence

Creates output with a high scientific quality as measured by the volume and impact of its publications and by its recognition by other experts, stakeholders and policy makers
Has a rigorous approach to fostering and improving the quality of its data and publications
Works on the harmonization of data and indicators and on developing new methods and tools to serve its research domain in Europe
Has received funding from national and/or international funding organisations
Translates its research outcomes effectively and enables decision making to collect new or better data

6. Data management and access

Regularly collects timely, new data that are comparable between and representative for EU/EFTA countries and/or regions and as far as possible comply with European and/or international quality standards and definitions
Generates repositories and/or data platforms that allow easy access to comparable (aggregated) data and/or indicators and meta-data in agreement with criteria for good data governance, privacy and accessibility.
Makes data collected by the network available for other researchers and policy makers outside the network ready for easy access with as little publication delay as possible

7. Governance

Has clearly defined aims and objectives and a transparent governance structure, including a management board, explicit coordinating roles and a clear process to make decisions and take on board new network participants and take on new research projects
Organizes regular meetings and implements processes and procedures by which decisions are made among the participants that deal with governance, strategy and priorities

8. Liaising

Brings together data collectors, researchers and stakeholders to integrate evidence generated by the network that supports the implementation of specific interventions and policies
Liaises with other networks, organisations and key stakeholders that cover complementary and related research and policy domains
Will not take up research that other networks are already doing well, but is willing to collaborate with other networks if feasible, relevant and efficient

9. Capacity building

Develops and implements forms of capacity building. This can for instance take place by organizing expert exchanges (workshops) or developing and exchanging tools and methods.
Engages in quality support among its members, i.e. by performing site visits or quality audits, including the provision of advice that serves research capacity building

10. Advocacy and communication

Advocates for its 'domain' and the relevance of its research outcomes and policy messages
Organizes or participates in international meetings with experts and counterparts to exchange their methods and findings
Communicates its achievements and proceedings regularly in different media

11. Societal impact

Creates output (articles, reports) that receive a high degree of positive media coverage in several European regions and/or countries and/or within professional communities
Creates output that generates local, regional or national discussions in media or political fora

Proof of concept

DIPoH benefits from the accumulated experience of previous EU funded projects: the different population health research networks which were joined together through BRIDGE Health and the Joint Action InfAct. Both latter projects were, and are, led by researchers in the domains of public health and HI. This fruitful collaboration will allow improved technical and conceptual collaboration in the further development of DIPoH.

Examples of Pan-European research networks included in DIPoH working on population health domains and some of the activities they have carried out towards the setup of DIPoH are listed here.

Euro-Peristat, (www.europeristat.com), a research network focusing on pregnancy and infancy, benchmarking on a set of 30 indicators. Its results are used in many countries to underpin policy and practice guidelines; Euro-Peristat, coordinated by INSERM, uses its network of data providers in 28 MSs + Iceland, Norway and Switzerland to produce harmonised datasets for comparative assessments of maternal and child health and healthcare. It leverages its network of multidisciplinary experts (obstetricians, midwives, paediatricians, public health professionals, epidemiologists, data providers, parent representatives) to interpret and report on data and to generate high-impact research publications. Euro-Peristat is currently working with MSs to expand best practices related to data linkage to improve the quality and breadth of data available for monitoring. A particular focus is placed on improving data to monitor socioeconomic disparities in new-born outcomes because of their role in the cross-generational transfer of social inequalities.

The European Health Examination Survey (EHES), (www.ehes.info), a research network focusing on health status and determinants of health based on data collected through health examination surveys, surveys including questionnaires, physical measurements and collection of biological samples in representative population samples. EHES, coordinated by THL, has prepared standardised guidelines for collection of data on individual health status and determinants of health through surveys. It has also developed a training module for these issues as well as some reporting guidelines. All these are publicly available and can be included in the Health Information Portal.

The European Health and Life Expectancy Information System (EHLEIS) (www.eurohex.eu), a research network addressing the increasing societal urgency of ageing populations to assess whether life years gained are healthy. EHLEIS is the European branch of the global network REVES. It produces yearly country reports in a format that is useful for decision makers;

European Collaboration for Healthcare Optimisation (ECHO) (www.echo-health.eu), is a research network on health care performance assessment that, using individual- level data, analyses population exposure to health care at geographic and hospital levels, and benchmarks care performance according to uneven utilisation, unequal access to effective care, and variability in the provision of low-value care; ECHO developed a data model and RI for international healthcare performance research; specifically, the ECHO Data Model specification[16] can be used as part of the tools provided by the Health Information Portal. An evolution of this data model is now in development to translate the specification to a distributed approach.

IctusNet (www.ictusnet-sudoe.eu) has been proving the concept for the development of a log builder and an analytical pipeline for process mining in several European regions. Specifically, the docker with the distributed pipeline[17] can be used as part of the tools provided in the Health Information Portal. In InfAct, IACS is expanding the IctusNet concept to other pilots and thus, other data models and analytical pipelines; in particular, to acute care of ischaemic stroke linking emergency and hospital

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[16] https://zenodo.org/record/3253684#.Xbgyo02ouUk
[17] https://zenodo.org/record/3230671#.Xbwd_L97kb1

care, to the development of an indicator of population resilience using electronic health records and hospital discharges, and to the analysis of dementia costs using primary care, hospital care, emergency care and prescription claims. Those distributed pipelines will be included as part of the Health Information Portal once the works come to an end.

European Burden of Disease Network, COST Action CA18218 (www.burden-eu.net). The European Burden of Disease Network aims to serve as a technical platform to integrate and strengthen capacity in the burden of disease assessment across Europe and beyond. It currently has over 200 members from 38 European countries, 5 non-European countries, the World Health Organization, and the European Observatory on Health Systems and Policies. Amongst others, the COST Action is collecting information and drafting guidelines on how to calculate the disease burden for COVID-19.

Annex 12: Detailed financial analysis (section 3.2)

A. Estimated costs for human resources in DIPoH

Table A7: Human resources in the operational phase* (yearly costs)

		FTE	2028
Central Office			
1.	General director	1,00	96.000,00 €
	Administrative support	1,00	96.000,00 €
	Financial officer	1,00	96.000,00 €
	Business manager	1,00	96.000,00 €
	Legal and Ethical Officer	0,50	48.000,00 €
	Data Protection Officer	0,50	48.000,00 €
	Communication specialist (website, social media, events)	1,00	96.000,00 €
2. Services Support	National Node liaison Officer	1,00	96.000,00 €
	Research Networks liaison Officer	1,00	96.000,00 €
	Services support Officer (public health specialist)	2,00	192.000,00 €
	Trainer/Organiser Capacity building	0,80	76.800,00 €
3.Health Information Portal	Health Information web portal officer	1,00	96.000,00 €
	IT expert support (helpdesk)	1,00	96.000,00 €
	Infrastructure Network Systems Administrator	1,00	96.000,00 €
	Infrastructure Network Architect (1.Design, 2.Implement/maintain)	1,00	96.000,00 €
	Software Developer	2,00	192.000,00 €
	Data Scientist - Analyst	2,00	192.000,00 €
		18,8	1.804.800,00 €
National Nodes			
MS Focal point/general health information generalist (0,5 FTE)		12,50	1.200.000,00 €
		(25 countries)	
Research Networks			
Type of personnel depending on need (Project manager, data manager, data scientist, domain expert, capacity building organiser or trainer)		15,00	1.440.000,00 €
		(15 networks)	
Institute serving as Data Hub to connect with e-infrastructure (NN and RNs that own data)			
system administrator (in contact with Health Information Portal officer in the central office)		35	3.360.000,00 €
		(35 data hubs)	
Total		81,30	7.804.800,00 €

*A separate cost book was prepared in preparation of the ESFRI application based on ESFRI instructions:
https://www.esfri.eu/sites/default/files/20190626_StR-ESFRI2_STUDY_RIs_COST_ESTIMATION.pdf

B.   Technological resources in the operational phase (yearly costs)

The following considerations are included for the estimation of technological costs:

- Hybrid infrastructure under IaaS provision model (Infrastructure-As-A-Service) thus, dynamically scalable on-demand ~200,000€ maximum

- 30 data hubs (~3,500 € each/annually allowance for maintenance)

- Additional ~150,000 € max. per year for e-infrastructure subcontracting (or in-kind) budget prospective data owner institutions joining DIPoH to ready their sites for service integration and compliance with data policy and data management plans (~10,000€ to 15,000€ each up to a max. of 15 data hubs joining each year). Either local data hubs or research data hubs.

This amounts to a yearly cost estimate of 305.000,00 €

Annex 13: Membership contributions (section 3.3)

Options for MS membership contributions
There are several ways in which DIPoH basic membership contribution by MS can be shaped.

Flat rate = equal contribution
Fixed fee + variable fee based on GDP
Fixed fee + variable fee based on GDP per capita
Fixed fee + variable fee based on GDP (50%) and GDP per capita (50%)
Fee based on GDP only
Fee based on GDP per capita only
Fee based GDP (50%) and on GDP per capita (50%)

The most simple one is to use a flat rate, i.e. each MS pays the same amount.
However, when developing the statutes it is expected that most countries will opt for a form in which the MS' size and economic power are also being taken into account and weighed. This variable part can be added to the fixed rate (e.g., 75% variable, 25% fixed) or the full sum (100%) can be variable. GDP can be used as a measure of size or population size, and GDP per capita as a measure of economic power.

When deciding on the structure, stability needs to be taken into account as an important factor, i.e. if a MS with high economic power (e.g. country X has ~25% of the EU27's GDP) first joins but later leaves it should not increase the other countries' membership fee or decrease the total budget of DIPoH too greatly.

First, it needs to be decided which part of the operational costs need to be covered by the membership fee. In section 3.2 presents an estimated sum of 10 million per year is needed to operate an RI for 25 countries. If the full 10 million needs to be covered, this results in a fixed fee of 400k euros per year for each MS. For 7.5 million this is 300k and if only the ~2 million euros needed to operate the Central Office is funded, this is 80k.

From here, a differentiation of the memberships based on GDP (per capita) can be made.
For example:
Country X had a ~15 times higher GDP than Country Y (24.7 vs 1.6 % of the EU27 GDP in 2019).
Country X had a ~2 times higher GDP per capita than Country Y (4.7 vs 2.4 % of the EU27 GDP per capita in 2019).
Estimations based on GDP may lead to an extreme difference in expected payments by MS.

Further decisions to be made:
-which part of the annual running cost will come from MS membership;
-which part of the membership will come from a fixed fee;
-which part of the membership will be based on GDP or population size.

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