BRIDGEHEALTH

BRidging Information and Data Generation
for Evidence-based Health Policy and Research

HIREP-ERIC

A research infrastructure to advance public health monitoring and research on health and care.

Technical and Scientific Description.

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I. Executive summary

EU countries[1] share the ambition of improving citizens' health, providing optimal prevention and universal access to safe, effective and efficient healthcare in a financially sustainable way. Ageing, technical innovations and growing citizen expectations increase the pressure on health systems. To make the most of health spending and investments at EU and Member State level, pro-active policy and decision making should be based on accurate and up-to-date information regarding population health dynamics and health system performance, and on thorough research outcomes resulting in a good and timely understanding of their determinants.

A strong working basis for gathering and providing health data is provided by EU agencies and the European Commission, such as Eurostat, European Centre for Disease Prevention and Control (ECDC) or the Joint Research Centre (JRC), and other international organisations, such as the Organisation for Economic Cooperation and Development (OECD) and the World Health Organisation Regional Office for Europe (WHO-EUR). Also, EU health information projects have provided useful research output. However, three key issues inhibit the availability and use of health information for research and policy-making: 1) much of the gathered evidence and knowledge is still dispersed, incomplete and difficult to access, 2) large differences can be found in terms of quality and, as a consequence, comparability of health information between and within EU countries, and 3) a wide range of health information activities are funded through ad hoc projects rather than through sustainable structures. Additionally, the evidence and knowledge produced by research using these data are not always readily available and may need further analyses, syntheses and translations to inform policy making.

The creation of a European Research Infrastructure Consortium (ERIC) to collect, process, analyse, report, and communicate health information can overcome these obstacles and can facilitate the governance of health information activities in the EU to allow comparative descriptive analyses and to facilitate research for multi-level policy use and targeted investments.

The ERIC builds its work on networks of national experts that will take up data definition, interoperability and harmonisation, central management, scientific analyses and reporting of health information on population health and health care systems. It provides central governance for regular availability and easy access to high quality and comparable data from EU countries for research purposes at national, EU and international level in fields of population health monitoring and health system performance assessment. The ERIC will foster interoperability of the EU countries health information infrastructure through investments in sharing expertise, capacity building and create common methods and tools for validation of indicators, data collection, analysis and knowledge translation. The organised transfer of knowledge and expertise between national experts and policy makers will spread relevant knowhow and increase the timeliness of actions.

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[1] This includes EU Member States, EFTA and EEA countries.

II. The current EU health information situation

In the past, EU health information research and evidence for policy has been taken forward through major investments in individual and independent EU projects and through the work of the European Commission and large international organisations such as the World Health Organisation (WHO) and the Organisation for Economic Co-operation and Development (OECD).

Under the EU Health Monitoring Programme, the EU Health Programme and the EU Framework Programmes, various EU projects have provided useful information and research on the state of affairs, trends and country-differences in health-related subjects as well as explanations and evidence to national and European decision-makers (1-3). They harmonised and collected health data across countries, created strong EU-wide research networks, exchanged best practices, established working protocols, produced research articles, helped to pool scarce resources and reduced the burden of health reporting at both Member State and European level. They also defined and validated indicators, and carried out research using these indicators or the data they are based on. These projects have demonstrated that there are significant gaps and deficiencies that need to be overcome such as:

- •   diversity of health information (infra)structures in Europe;
- •   fragmentation of databases and registries;
- •   health information inequalities regarding the availability and quality; and
- •   lack of sustainability of health information activities.

There is no established mechanism to include the results of these projects in the European Statistical System, as stipulated by 'Regulation 1338/2008 on the community statistics on public health and health and safety at work' (4). Previous major investments may therefore go to waste as sustainability cannot be assured (5) and major inefficiencies may arise. This lack of research continuity and continuity in utilizing the outcomes of these projects will result in losing expertise, active data collection mechanisms and research capacity as well as in outdated protocols and networks. As concluded by the European Core Health Indicators (ECHI) and consecutive activities, "further efforts at DG SANCO and Eurostat are needed towards a permanent health monitoring system" (6).

Under the co-ordination of Eurostat, the European Statistical System provides a solid working basis for gathering and providing statistical health data on a regular basis. Also the WHO and the OECD gather and analyse health information. The European Commission, WHO and OECD now coordinate a selection of statistical data collections and have increased their collaboration over the years. Eurostat, for example, as defined in the regulation 1338/2008, covers the following five areas of health information: health status and health determinants, healthcare, causes of death, accidents at work and occupational diseases and other work-related health problems and illnesses (7-9). In the eyes of stakeholders in the health information area, international organisations do not yet collaborate most efficiently, however. Gaps and deficiencies persist, there is no common health information strategy or reporting agenda and several different but overlapping indicator sets can be found.

Additionally, the different health information areas are not systematically or consistently covered in the EU and effective priority setting mechanisms in health information are lacking. Activities in drug control, infectious disease control, medicines, cancer and rare diseases are respectively covered by the European Monitoring Centre for Drugs and Drug Addiction, the European Centre for Disease Prevention and Control, the European Medicine Agency and the Joint Research Centre. This does, however, not by far cover the integral area of public health and healthcare. There is still a huge area in which no health data gathering or indicator sets of comparable quality exist, which makes adequate comparative research impossible. A good example is the limited coverage of non-communicable diseases, even though chronic diseases are the main cause of death, morbidity, disability and poor quality of life in Europe.

Besides not covering all the different health information areas, the current health information activities also nearly always focus on vertical approaches. This type of approach does not foster the development of a holistic public health approach including both the areas of population health and health systems. The fragmentation leads to internal competition between public health domains, a lack of coherence and balance, and a less efficient use of the existing health data for analyses and research that support evidence-based policy. This reflects the need for a coordinating and support structure that improves the interoperability, the availability of relevant, reliable and up-to-date information and provides opportunities for comparative health and health systems performance research in a number of specific policy relevant areas.

EU countries have also taken up national, regional and local activities in assessing system performance, policy evaluation and data collection in many different ways. However, EU countries face large differences in the ability to collect relevant health data of adequate quality. Also the scientific capacity for analysing these data and for translating the information produced into evidence to inform public policies varies between EU countries. Moreover, the lack of interoperability, comparable data and comparative research abilities in health and health systems performance impairs assessing the national or regional health situation, identifying the determinants of health and diseases, and informing efforts aiming at improving current prevention and care practices and policies.

This situational analysis calls out for more Member States[2] involvement, better and more transparent coordination and some form of central governance.

Improvements should focus on 6 key points:

1) improved identification and prioritisation of data needs,
2) harmonisation and coordination in the definition and collection of health data and in the production and reporting of indicators,
3) better access to comparable health data for research,
4) capacity for health system and population health analysis and research,
5) support for more and stronger health research networks and communities for instance by focussed capacity building and a better exchange of expertise and knowledge, and

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[2] Inculding EFTA and EEA countries.

6) capacity for evidence synthesis and knowledge translation for policy and interventions.

III. <u>An ERIC on health information</u>

A European Research Infrastructure Consortium on Health Information for Research and Evidence-based Policy (HIREP-ERIC) will establish a basis and infrastructure for a better integrated and sustainable EU health information system. The HIREP-ERIC will provide a backbone and sustainable infrastructure to support the policy relevant research fields of population health monitoring and health system performance assessment. The HIREP-ERIC will be based on two pillars: research and policy. The research carried out in the HIREP-ERIC supports evidence based policy making and the knowledge is translated for policy makers.

The ERIC will provide scientific and technical services. It will support health research, provide a sustainable structure for best practice exchange and support mutual learning between EU countries including Member States, EDTA and EEA countries. It will support and expand existing data collection if needed, fill the gaps where data collection is lacking and analyse comparable datasets from EU Member States. The knowledge generated by the HIREP-ERIC provides harmonised and comparable health data allowing high quality research and comparisons within and between EU countries supporting informed decision-making at national and EU level.

The HIREP-ERIC will function as a network of networks, linking sets of national experts and research facilities and allowing health information and research collaboration across Europe with strong ties to existing research collaborations and projects and national and international institutions and organisations. The national public health institutes or equivalent national health information authorities can have an active role in the HIREP-ERIC and be an important driving force.

A. Mission

The HIREP-ERIC enhances people's health and health system performance in the EU by stimulating, facilitating and supporting comparative health information and research to enhance our knowledge about EU citizens' health and health systems and to facilitate multi-level decision-making and actions.

B. Vision

Through its support to improved health and health systems performance data collection, and to more and better comparative research and innovation, the HIREP-ERIC will provide a sustainable policy relevant knowledge base to improve the well-being and health of EU citizens and populations.

C. Goals

Through coordinated data collection and comparative research, the HIREP-ERIC supports policy-making in the EU and all EU countries by ensuring the collection, analysis, integration and exchange of health data and evidence, and the translation of the evidence to policy.

This requires:
1. ensuring transparent coordination and centralised governance of EU health information;
2. aiming at high relevance and usefulness of the information (through a transparent priority setting method);
3. ensuring interoperability through collecting more and better comparable data (by (pre-/post-)harmonisation and standardisation of definitions, tools and methods);
4. delivering high quality information and research (timeliness, high internal and external validity);
5. reducing information inequalities between EU countries and addressing knowledge needs;
6. solving gaps and enhancing efficiencies in health information;
7. providing better access to comparable health data, methods and tools;
8. supporting stronger health research networks and communities (through capacity building and exchange of expertise and knowledge);
9. enhancing evidence synthesis and knowledge translation;
10. addressing relevant ethical and legal issues (privacy, data security).

D. Services and tasks provided by the HIREP-ERIC

The HIREP-ERIC provides central governance for regular availability and easy access to high quality and comparable data from EU countries for research purposes at national, EU and international level in fields of population health monitoring and health system performance assessment. It will provide an organisational structure and methods to achieve this in a streamlined and efficient way.

The HIREP-ERIC will not do what other stakeholders already do, but liaise and guide institutions in charge of health information and researchers to available and comparable data. The HIREP-ERIC will facilitate and support network building, carry out horizon scanning activities and coordinate research project development, in particular in new or underdeveloped health policy areas in the EU.

A variety of services that will support research are to be provided by the HIREP-ERIC. The core activities of the HIREP-ERIC will revolve around generating knowledge, hosting knowledge, exchanging knowledge and translating knowledge. This includes support in planning health information strategies and liaising with stakeholders.

1.   Generating knowledge: health data and indicators

The HIREP-ERIC will provide technical and expert support for the development of comparable, standardised and accessible data and indicators for health status and health determinants, health services and health systems.
This includes updating and developing new indicators, where needed, and improving and evaluating existing indicator sets. Also the indicators will be more clearly related to the decision making processes at Eurostat, WHO and OECD. This will allow to reduce duplication within the European health information sphere.

The HIREP-ERIC will facilitate the regular generation of comparable data sets. It will identify gaps in health information, e.g. regarding key determinants of health, ill-health and on key cross-cutting issues, such as better regional information, inequalities, and specific population groups.

It will then facilitate finding solutions to data gaps, exploiting efficiencies in data collection and in the utilization of existing data, or developing recommendations and providing technical assistance for the collection of new data if necessary.

The HIREP-ERIC will not only provide information about health and health systems' performance problems but also key elements of best practice in how to address them. The HIREP-ERIC can help to bring together knowledge about what health policies and interventions work in order to support future decision-making at international, national, regional and local level.

Services:

- Maintaining the ECHI
    - o Relate indicators to decision making process at international organisations and reduce duplication within the European health information sphere
    - o Have a forum that can evaluate, and, if necessary, update or improve the ECHI, according to requests, thereby agreeing on the indicators and standards thereof.
- Provide support
    - o Provide technical and expert advice for members to optimise their health information systems;
    - o Provide assistance to national public health institutes;
- Provide information on population health and health system performance
    - o Provide detailed information on determinants of health, ill-health and threats that are considered relevant to the overall health information landscape ;
    - o Provide better information on healthcare quality and outcomes;
    - o Enable sustainable data collection, regular assessment and analysis.

2. Knowledge management centre

The HIREP-ERIC will facilitate and support the development and hosting of virtual and interoperable repository platforms. It will provide central coordination for EU countries to provide data and exploit economies of scale by facilitating the extension of existing data repositories where possible. The HIREP-ERIC will provide or promote the development of repository platforms for data and metadata that are not stored elsewhere, and facilitate data merging and linkage. The HIREP-ERIC aims to mediate in hosting these data sets in a sustainable and highly accessible way, either under its own mandate or in collaboration with a dedicated European organisation.

The HIREP-ERIC will also provide centralised documentation through repository platforms for tools and methods for data collection, quality assessment, analysis, reporting and knowledge translation. This is needed because the evidence supporting the validity of the

data collected and of the information produced is not always complete and available. The repository platform includes data collection protocols such as guidelines, education and handbooks for implementing surveys and developing and maintaining registries; and tools and methods for pre- and post-harmonisation. Since the HIREP-ERIC will also play a role in knowledge translation as described in the following section, the repository platform will also include policy briefs e.g. the policy briefs prepared by the European Observatory on Health Systems and Policies.

Setting up repository platforms also includes the development of state-of-the-art distributed analytical platforms with adequate protection of personal data, and of tools and procedures ensuring data protection and respect of privacy issues, addressing both ethical and legal issues.

In case the data is stored elsewhere, the HIREP-ERIC will guide users to available and comparable data. As health and healthcare cover an enormous subject area, the HIREP-ERIC activities will include looking to create 'meta-access' and meta-structures to data sources suited for international comparisons, aiming at knowing where national and international data sources and repositories are located and how to access and use them. This will also allow for better access to data for research purposes.

The HIREP-ERIC will use the gathered information to support methodology developments based on expert reviews of existing tools and procedures and on specific research, including the development of new and more efficient methods and tools for data collection, quality assessment, use, analysis and reporting as well as knowledge translation. More specifically, methods to improve the quality of the information produced; validation of these methods can be performed through expert reviews or through specific validation studies; the development of new research methodology might come in with respect to the analysis of large data sets; and the shift in the analytic paradigm from descriptive analytics to prescriptive analytics.

Services:

- Help researchers and institutions in charge of health information in finding and using specific data sets and metadata, as well as tools and guidelines.
- Facilitate interoperable access to relevant information, data and meta-data on repository platforms hosted by the HIREP-ERIC or elsewhere;
- Set-up a platform for comparable, standardised and accessible data and indicators, including pre- and post-harmonisation methods;
- Guide users to locate and access required information;
- Provide a pool of existing good practices, methods and tools;
- Provide guidance on data protection and privacy issues; and
- Support methodology developments based on expert reviews of existing tools and procedures and on specific research when appropriate.

3. Knowledge exchange and transfer for policy and decision-making,

Knowledge sharing and dissemination activities will include the publication of newsletters, scientific papers and organisation of meetings and workshops as well as expert exchanges,

the strengthening of networks and capacity building. The HIREP-ERIC will strengthen European health information networks towards more sustainable data collection and regular assessment and analysis. Capacity building activities will be organised in the EU countries. A yearlong training program will be set-up in health information e.g. similarly to the European Programme for Intervention Epidemiology Training (EPIET) program. This programme will create a cohort and link people that work in the same methodological way. In addition this will enhance researchers' and health information experts' mobility and provide the EU countries with the necessary tools to e.g. carry out their own health system performance assessment.

The evidence and knowledge produced by research are not always readily available and may need further analyses, syntheses and translations to inform policy making. The HIREP-ERIC will support the exchange and transfer of health information and research outcomes into policy through dissemination activities, the strengthening of networks and capacity building. The HIREP-ERIC will disseminate policy-relevant monitoring reports and critical synthetic reviews of scientific articles, and internet-based tools from the area of comparative population health research and from comparative research in the area of health system performance assessment. The HIREP-ERIC will improve the knowledge translation of health information and research outcomes from the ERIC activities to the general public and to policymakers by collecting and disseminating best practices that will enable researchers and institution in charge of health monitoring to optimise their output to better inform policymakers and citizens.

Services:

1) to strengthen health information systems:

- Organise workshops and meetings to strengthen networks and exchange of expertise;
- Organise an annual conference bringing together all relevant health information projects with workshops on particular topics;
- Organise capacity building activities upon request from users of the HIREP-ERIC;
- Best practices exchange and recommendations for linkage of routine databases on health;
- Organise a yearlong training program with country exchange;
- Support EU countries in realising development goals while enhancing the abilities that will allow them to achieve measurable and sustainable results;
- Regularly report on state of health information of EU countries;
- Draft a report on the yearly state of health information in the EU and MS;

2) to improve transfer into policy making :

- Disseminate reports, synthetic critical reviews of scientific articles, internet-based tools and repository for policy briefs;
- Support institutions in charge of health monitoring and researchers to optimise their outcomes to better inform policy-makers and citizens; and
- Support and monitor the utilization of information in practice.

4. Prioritising and financing health information

The HIREP-ERIC will carry out horizon scanning activities to detect early signs of potentially important developments through a systematic examination of potential threats and opportunities, with emphasis on new technology and its effects on the issue at hand. It will explore novel and unexpected issues as well as persistent problems and trends. This will allow the HIREP-ERIC to guide EU countries, the European Commission and international organisations in designing workplans, setting priorities and drawing up agendas in health information.

The HIREP-ERIC will also define research priorities and coordinate research project development in fields of population health monitoring and health system performance assessment. All to be guided on the basis of clear criteria for priorities in comparable health data collection and on the basis of priorities and data needs that are shared among multiple European countries.

Research project support by the HIREP-ERIC will be threefold:

1. Strengthening and maintaining research projects that collect comparable, policy relevant health data and information and use scientific analyses for policy support. They will also work towards harmonizing nationally representative data collection mechanisms and developing new scientific methods for policy relevant indicator development and knowledge translation.
2. Developing and strengthening research projects that need expanding their European country coverage as well as expanding and defining comparable data collections and/or improving their methods and tools for health data collection and comparative research.
3. It will assist projects in obtaining funding. The HIREP-ERIC will enable its participants to better partake in EU-funded research projects, such as the Horizon 2020 programme, the public health action programmes, and any others.

Services:

- Carry out horizon scanning activities in population health and health system performance;
- Highlight areas of action to Members of the ERIC in population health and health system performance;
- Support agenda setting and work plan development upon request;
- Assist health information activities and projects in obtaining funding;

5. Liaise with regional, national, European and international organisations

The HIREP-ERIC also aims to bring together regional, national, European and international organisations. The HIREP-ERIC will take into account existing infrastructures and build on existing expertise and knowledge. It will also give special attention to initiatives promoted at the European level and their integration at the global scale. The HIREP-ERIC will

provide a forum for international cooperation and collaboration on health information. The HIREP-ERIC will facilitate the interaction of national and international stakeholders.

EU countries can request the HIREP-ERIC to liaise or coordinate relevant players in the ERIC competence area in their country. They can decide on the format this service should be provided. The HIREP-ERIC can also enhance coordination of participating organisations of researchers working in the ERIC competence area.

Some of the partners the HIREP-ERIC would need to liaise with are:

- The Expert Group of Health Information (EGHI) and other consultative structures in the Commission such as the Expert Group on Health System Performance, Joint Assessment Framework (JAF) on Health.
- European agencies, 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;
- European Commission services are also vital partners, such as SANTE, ESTAT, RTD, JRC, and others such as EMPL, ENV, ECFIN, GROW, REGIO and MOVE.
- Partner organisations at international level, in particular the WHO Regional Office for Europe, in particular its European Health Information Initiative, and the OECD;
- Members of the other European Institutions with an interest in health information;
- Stakeholders in health information within Member States or associated countries, such as governmental institutions or agencies, regions, research institutions, universities, health professionals and their professional bodies, healthcare purchasers and providers, and patients' organisations;
- Expert organisations such as universities, research and health institutes within EU countries and at European level;

Services:

- Provide a forum for regular interaction of relevant actors in health information across the EU;
- Facilitate international cooperation and collaboration in health information;
- Provide an overview of activities in health information in the EU;
- Provide an interface for bottom-up responses to current issues and needs in health information.

E. Phased approach

A phased approach will be used for the implementation of the HIREP-ERIC. This will allow to scale up the activities and ensure a solid foundation. The phases will be split in three terms: the short term (0-3 years), medium term (3-5 years), and long term (5+ years).

For the short term (0-3) years, the HIREP-ERIC focuses on the following activities.

A. Map the existing entities producing health information, and/or contributing to the production of health information
   a. Periodically report on the state of health information
   b. Provide in depth reports on specific topics upon request
B. Develop a prioritisation method for the uptake of research networks in the ERIC
C. Provide a continuous set of core services to the members of the ERIC
   1. Provide technical support for members
   2. Provide expertise on a wide range of health information activities only available through ERIC due to its far reaching network of networks
   3. Guide researchers and policy makers to requested health information
   4. Carry out forecast and horizon scanning activities to support agenda setting
   5. Organise annual conference with relevant health information stakeholder
   6. Enhance national health information and research capacity through sharing know-how and setting up a first cohort within a training programs
   7. Assist members to obtain funding for health information activities, to which the ERIC will have better access
   8. Liaise with international organisations whilst representing members interest
   9. Increase visibility of national health information activities through dissemination of reports and papers
   10. Set-up virtual repository for policy briefs

The areas of support can be further developed based on the continuation of activities in EU projects within the domain specific nodes. However, prioritisation in the uptake of EU projects in the ERIC will further define the areas of support.

F. Economic model

The HIREP-ERIC will have three types of financial resources. The HIREP-ERIC will apply for national, European and pan-European funding.

Its first source of revenue will be the contribution provided by the members and observers of the HIREP-ERIC. A basic membership fee will be contributed that will ensure the operation of core activities of the HIREP-ERIC. Members will then have access to the services corresponding to the basic functions of the HIREP-ERIC. The basic membership fee is elaborated further in the statutes.

Secondly, it will apply to calls of the European Commission for projects that contribute to the implementation of an EU programme or policy such as the Horizon 2020 programme, the public health action programmes, and any others EU financial resources.

Thirdly, additional services may be commissioned to the HIREP-ERIC. Fees will be requested to carry out those additional services.

The member's contributions are being developed and discussed.

G. Governance of the HIREP-ERIC

The governance structure of the HIREP-ERIC is shown in Figure 5 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 nodes which are represented in the Network Committee. The organisational structure is discussed in the next section. Practicalities regarding the different boards are discussed in the Statutes.
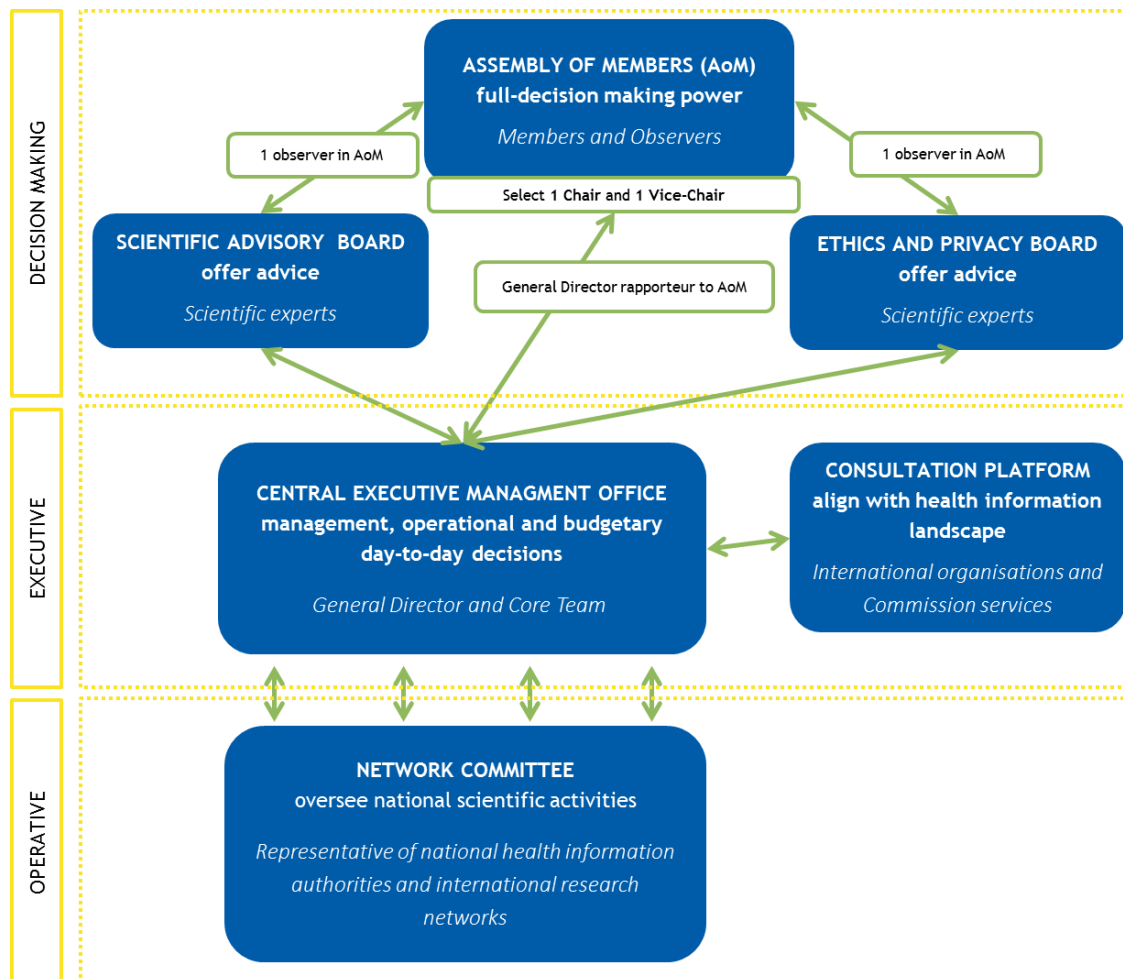

Figure 5. Governance structure of HIREP-ERIC.

1. Decision making

A. The Assembly of Members

The Assembly of Members is the governing body of the HIREP-ERIC and is composed of representatives of the members of the ERIC. Both scientists and administrators can be part of the Assembly of Members. As defined in the ERIC practical guidelines, the HIREP-ERIC must have at least one Member State and two other countries that are either Member States or associated countries as members (10). The Assembly of Members may decide to accept observers with no voting rights. The Assembly of Members is the highest and ultimate governing body of the HIREP-ERIC with full decision-making power. Each member and observer nominates an official representative to participate 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.

B. The Scientific Advisory Board (SAB) and Ethics and Privacy Board (EPB)

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. 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 HIREP-ERIC including the strategic and operational objectives.

The Scientific Advisory Board and EPB 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 Scientific Advisory Board and Ethics and Privacy Board.

2. Executive

A. The Central Executive Management Office: Director General and Core Team

The Central Executive Management Office is composed of the Director General and a Core Team. The Central Executive Management Office is the executive body of the HIREP-ERIC. 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 HIREP-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 HIREP-ERIC. The Core Team is responsible for daily operations (such as preparations of meetings), the implementation of the HIREP-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 comprise legal and technical expertise, which is necessary for a large distributed research infrastructure and the effective interfacing and coordination.

B. *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 will compose the platform.

- A representative from the Expert Group of Health Information (EGHI) and the Expert Group on Health System Performance other consultative structures in the Commission such as the Joint Assessment Framework (JAF) on Health.
- 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;
- A representative 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 two types of nodes: domain specific nodes and national nodes.

3. Operative

A. *The Network Committee*

The Network Committee consists of a representative of the nodes that are operational in the HIREP-ERIC (cfr. G. organisational structure). The Network Committee shall be responsible for scientific activities related to HIREP-ERIC. The Committee will meet to maintain coherence and consistency across the nodes, 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.

B. *Organisational structure*

The HIREP-ERIC will operate as a distributed research infrastructure. It is structured on the basis of a decentralised node model. The coordination of HIREP-ERIC's mission and activities is executed by the Central Executive Management Office. It handles the organisational, technical and infrastructure interactions with the HIREP-ERIC nodes and other infrastructures.

The HIREP-ERIC will operate through two types of nodes:

1. The national nodes. These are located in EU countries national counterparts that are member of the HIREP-ERIC. Each member of the HIREP-ERIC will designate an institution that coordinates a consortium of national institutes working on health information. It will provide national health information and interact with the different entities of the HIREP-ERIC. The national node will thus have a dual role as a national health information provider and health information coordinator. The national nodes work on cross-cutting issues. The number of national nodes is fixed.

2. The domain specific nodes. These are network coordinators in health information domains. They are content specific and respond to current priorities and projects. The domain specific nodes carry out deep analysis in area for which capacity does not always lie at national level. They can liaise with national nodes providing guidance on how to collect and analyse data at national level, and through this, harmonise activities. The node is the coordinating partner in a domain specific network. Individual EU countries may opt to coordinate one or more domain specific node. The numbers of domain specific nodes are variable.

A National Node may decide to be specialized and become on top of its responsibility as a national node a Domain specific Node.

The HIREP-ERIC nodes, national or international research institutes, which enter into a collaboration agreement with the HIREP-ERIC, provide the delivery of technical services and interoperability. Each HIREP-ERIC node is hosted by an institute that has its own legal personality and provides a defined set of services on behalf of or for the HIREP-ERIC. These services and the terms and conditions of their delivery are specified in Collaboration Agreements entered into by the HIREP-ERIC nodes and the Central Executive Management Office.
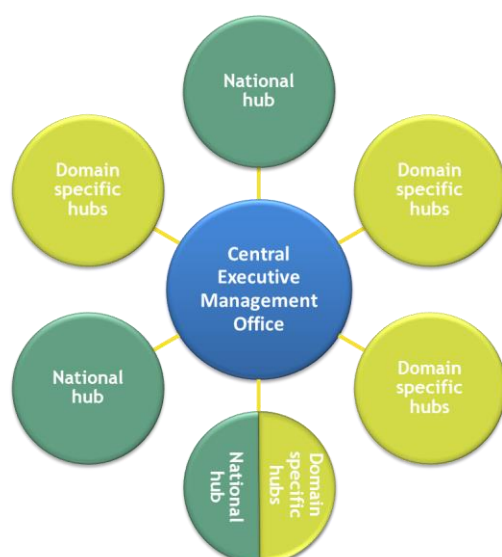

Figure 6. HIREP-ERIC organisational structure

H.   Interaction with existing institutions

The HIREP-ERIC finds it important to interact with and connect existing institutions, especially with the aim to reduce duplication. The main interaction with existing institutions will be organised through the consultation platform. Key stakeholders in the European health information sphere will be connected as described above. Also, as described in the tasks, the HIREP-ERIC will be the facilitator for data availability and meta-data to be used in different organisations and fine-tune the data to respond to the needs of the organisation the HIREP-ERIC serves. Some stakeholders may additionally have specific interactions with the HIREP-ERIC some examples are described below and others may be further developed once the HIREP-ERIC is set-up.

1.   Expert Group on Health Information (EGHI) and the Expert Group on Health Systems Performance Assessment (HSPA)

The Expert Group on Health Information (EGHI) and the Expert Group on Health Systems Performance Assessment (HSPA) is a consultative structure with representatives from EU Member States, EEA/EFTA and candidate countries as well as international organisations; to support the overall implementation mechanisms for the health strategy with regard to health information and health system performance respectively. The HIREP-ERIC should interact with the EGHI/HSPA on regular basis to enhance solutions for health information and health system performance in the EU and interact on on-going activities. This interaction can be threefold:

1. A representative of the EGHI/HSPA can have an observer status at the Assembly of Members of the HIREP-ERIC.
2. A representative of the HIREP-ERIC can assist in the EGHI/HSPA meetings.
3. An annual meeting can be organised to discuss common issues.

2.   National Public Health Institutes (NPHI)

Many National Public Health Institutes (NPHI) have a central role in the national health information system, and often they have close relations with the Ministries of Health, with the Institute of Statistics and with other organizations involved in Research (National Research Council, Universities, etc). Therefore, a coordinating and liaising role for the NPHIs in the HIREP-ERIC seems logical, and also indispensable. Furthermore, NPHIs typically have comprehensive tasks related to the generation of health information: not only are they involved in data collection, but also in data analyses, health reporting and knowledge translation. This broad expertise is needed in the HIREP-ERIC. Moreover, NPHIs have many interaction and collaborations with research teams at national level.

Contemplating the above, specific functions or tasks of the NPHIs in the HIREP-ERIC logically include:

- Representation of their country in the ERIC at operational level;
- Liaising with the other main health information stakeholders in their country to keep them informed about the HIREP-ERIC and to seek their input in relevant strategic and operational issues, and coordinate their responses;

- Liaising with the ministry of health to ensure alignment between policy and operational level;
- Liaising with research teams who collaborate with the NPHI at national level in all areas of health information including foresight activities;
- Dissemination of health information and health information tools produced by the HIREP-ERIC to researchers, policy and public;
- Creating a platform function with other NPHIs for sharing knowledge and expertise;
- Contributing to the analysis, interpretation and reporting of data and information for products produced by the HIREP-ERIC.

Individual NPHIs clearly could have a clear and important role in the HIREP-ERIC. However, particularly for strategic issues, it is also important for the institutes to speak with one voice. A clear representation on behalf of all the institutes is not only beneficial for the institutes themselves, but also for the effectiveness of and support for the ERIC. The International Association of National Public Health Institutes (IANPHI) could play a role here. How this could be best organized is to be discussed, however, and is also dependent on how the final design for the governance structure for the ERIC will look.

3. Eurostat

Preliminary discussions have taken place between the BRIDGE Health Project and Eurostat, in which Eurostat agreed in principle that they would take over indicators developed by the ERIC and integrate these into the European Statistical System. This provides one model for how the ERIC's research could influence EU countries evidence-based health policy.

IV. Landscape ESFRI

The current research infrastructures in the European Strategy on Research Infrastructure (ESFRI) Roadmap relevant to public health and policy are summarized in the table below.

Name	Full name	Roadmap entry and operation	Legal status	Capital Value (M€)	Operational budget (M€/year)
BBMRI ERIC	Biobanking and BioMolecular resources Research Infrastructure	2006, 2014	ERIC, 2013	170-220	3.5
EATRIS ERIC	European Advanced Translational Research Infrastructure in Medicine	2006, 2013	ERIC, 2013	500	2.5
ECRIN ERIC	European Clinical Research Infrastructure Network	2006, 2014	ERIC, 2013	1.5	2
ELIXIR	A distributed infrastructure for life-science information	2006, 2014	ELIXIR Consortium Agreement, 2013	125	95
CESSDA	Consortium of European Social Science Data Archives	2006, 2013	Norwegian limited company, 2013 ERIC under preparation	NA	1,9

| SHARE | ERIC Survey of Health, Ageing and Retirement in Europe | 2006, 2011 | ERIC, 2011 | 110 | 12 |
| ESS ERIC | European social Survey | 2006, 2013 | ERIC, 2013 | NA | 6 |

None of the existing ERIC deals with health information on population health and health system performance. There is a need for continued effort to generate better coherence of health information activities in the EU. Completing the landscape with an ERIC on Health Information for Research and Evidence-based Policy is crucial to better address the challenges that we face, notably in the provision of sustainable information on population health and health system performance. The HIREP-ERIC appears as a legacy of EU Public Health actions having been able to take on board scientific-research technics and tools to the field of health information, but not under DG RTD umbrella, which has been the typical start-up environment of ESFRI initiatives.

V. ERIC requirements

A. Necessity

The necessity for an improved EU health monitoring system and EU health information system has been repeatedly stated at senior EU level meetings.

The Council Conclusions on closing the gaps within the EU through concerted action to promote healthy lifestyle behaviours of December 2011 called on the European Commission to *"consider the need for better deployment of existing data and additional comparative data and information on unhealthy lifestyle behaviours, social health determinants and non-communicable chronic diseases. This should be obtained from a sustainable health monitoring system already in place or which might be established at EU level."*

Furthermore, the Health Ministers invited the Commission and the Member States in the Council conclusions on the reflexion process on modern, responsive and sustainable health systems from December 2013 *"to cooperate with a view to establish a sustainable and integrated EU health information system. This should build on what has already been achieved by different groups and projects exploring in particular the potential of a comprehensive health information research infrastructure consortium as a tool"*.

Also at Member state level this need has become more apparent. EU countries are facing increasingly common challenges such as ageing populations, rising expectations for high quality services and the emergence of new, more expensive technologies. These common challenges have become even harder to overcome with the curbs on public spending in the wake of the financial crisis (12). Setting up a structure at EU level will allow to tackle current challenges much more effectively.

The HIREP-ERIC will strengthen cooperation mechanisms and coordination processes between EU countries with a view to identify common tools and best practices that create synergies, bring EU added value and lead to economies of scale, and support evidence-based policy making.

The HIREP-ERIC will provide a backbone and sustainable infrastructure to support population health monitoring and health system performance assessment, and related research, by:

1. generating knowledge on health data and indicators,
2. hosting a knowledge management centre with repository platforms for data, tools and methods,
3. supporting knowledge exchange and transfer for policy and decision-making,
4. Prioritising and financing health information, and
5. Liaising with regional, national, European and international organisations.

The HIREP-ERIC 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.

In addition, the HIREP-ERIC provides a governance body which has the following advantages:

- AN ERIC is not project based which is more sustainable.
- An ERIC has authority and a strong legal base. It provides instant legal recognition at EU level.
- Through the participation of countries it is in a better position to support sharing of research results and data, and the adoption of methodologies by the research community and by operators of infrastructures at the national level.
- An ERIC can apply for funding from EC programmes as a full consortium.
- An ERIC can assure continuity, maintenance and sustainability.

B.   Strengthening the European Research Area (ERA)

The HIREP-ERIC strengthens the ERA by providing joint access to better and comparable data, tools and methods. Joint research across Europe requires joint access to the data collections, across national frontiers. By interconnecting these collections and providing virtual access, the HIREP-ERIC constitutes a key facilitator for transnational research in health information. This will give the ERA new impulses.

Furthermore, the HIREP-ERIC will strengthen research and research input by expanding knowledge, disseminating existing knowledge, and enhancing research capacity in the EU and partner countries. It expands knowledge and builds new research on the achievements of earlier efforts, where the results can be broadly and more sustainably disseminated. The HIREP-ERIC will be an instrument to share on a European scale results obtained through national or international research activities. It will allow to interconnect researchers, their data, methods and results across national and discipline borders. The HIREP-ERIC will also contribute to relevant research outputs such as new research tools, new data collection methods and gathering, platform for ad hoc databases, (pre-/post-) harmonisation of data collection, and methods development though innovating research. Finally, the HIERP-ERIC will enhance the research capacity by supporting new or existing research networks. This involves training and capacity building for research, support actions and coordination of activities and networks.

C.   Access

The HIREP-ERIC will provide open and effective access to its knowledge management centre. This is composed of virtual and interoperable repository platforms. This includes access to a range of data, meta-data, tools, methods, guidelines, protocols and reports. Access will be allowed to a wide range of stakeholders such as academics, professional users, policy makers and the public. The HIREP-ERIC website is the portal through which researchers access both documentation and data. Each of the Domain Specific Nodes will coordinate their own data sets with minimum requirements defined by the Assembly of Members. Also here open and effective access will be ensured. The HIREP-ERIC will through its digital services also enable collaboration among users across scientific domains and geographical boundaries. By promoting open science and open innovation, the HIREP-ERIC will be able to assemble a critical mass of people knowledge and investments and contribute to regional, national, European and global development.

D.   Mobility

The information infrastructure allows virtual exchange of knowledge within its environment. Researchers can access from behind their desk data, metadata, tools and services while residing in different parts in Europe. The HIREP-ERIC overcomes in such a way not only geographical boundaries but also scientific domains. Health information in population health and health system performance will be brought together. Networks between researchers are facilitated where exchange of knowledge will be made possible. Also physical mobility of experts will be supported as the HIREP-ERIC will carry out capacity building activities in the EU countries in areas needed with training programmes. More specifically a yearlong training program will be developed in which scientists will be able to gain experience in another country. This will increase the creativity in and efficiency of research and bridge the gap between highly developed and lesser developed regions and countries.

E.   Dissemination

The HIREP-ERIC contributes to having more and better evidence and knowledge for health policy-making by harnessing a larger and more relevant health research capacity, but also focusses on distributing and sharing this evidence and knowledge. This involves dissemination of outcomes (reporting, scientific publications, websites, congresses) and integration of the evidence in the decision-making process. Better informing health professionals and citizens about possible improvements in health and healthcare and in living and working conditions and personal health behaviour is a key objective. Between researchers the HIREP-ERIC provides a facility to share and disseminate data, tools and methods on a European scale and support the production of expert based policy relevant health reports.

F.   Conclusion added value

Taken this together, the HIREP-ERIC provides a backbone and sustainable infrastructure to support the research fields of population health monitoring and health system performance assessment, by:

- Facilitating access to better and comparable data, tools and methods
- Advancing scientific knowledge in the ERA in health and beyond
- Building capacity and targeting research
- Informing decision-making, practice, and policy
- Dissemination and transferring knowledge

The HIREP-ERIC would contribute to having more and better evidence and knowledge for health policy-making by harnessing a larger and more relevant health research capacity, by enhancing research into methods for transferability of evidence to policy actions. The ERIC thus contributes to new or improved institutional and national policies, new or better regulations, more and better research and research methodologies, and more efficient resource allocation and intervention programmes. The HIREP-ERIC also contributes to better informing health professionals and citizens about possible improvements in health and healthcare and in living and working conditions and personal health behaviour.

In this way, the HIREP-ERIC contributes to improvements in health and well-being and economic and social prosperity in Europe by enhancing the output, capacity, quality, dissemination and efficacy and efficiency of European health information-related research.

The benefits for stakeholders are summarised in Table 1, including researchers, decision-makers, healthcare providers, citizens, administrators or data providers, and financers.

Table 1. Benefits for stakeholders in Member States

Policy-makers	Researchers
- High quality data and information for evidence-based decisions, priority setting, programme evaluation - Better preparedness - International comparison: evaluate and discuss how to tackle similar challenges, understand and resolve differences - Organise and coordinate public health expertise and systems - Better access to existing knowledge and expertise	- EU-comparative data - Better data quality, availability and comparability - Sustainable data availability - Enhanced research capacity - Larger study populations and cohorts - Enhanced data access flow - Structured scientific exchange - Quicker results - Better access to existing knowledge and expertise
Healthcare providers	**Citizens**
Data to set standards and protocols for evidence-based care and to evaluate their policies	Improved health and wellbeing and reduced health inequalities if policy decisions are improved by

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	enhanced monitoring of health risks, health status, health determinants, and the safety and quality of healthcare services
• Benchmarking i.e. learning from best practices • Better access to existing knowledge and expertise	• Better access to existing information, knowledge and expertise
Administrators/data providers	**Financers**
• Reduce burden by increasing harmonisation of international data collection to reduce duplication • Assist in obligation to provide data to international sources • Standardisation and norms	• Better value for money in international health information activities and health research • Optimise funds allocation
Industry	
• Information and support tools • Innovation • Data provision and access	

VI. Risk assessment for implementation

A "strengths, weaknesses, opportunities, and threats" (SWOT) analysis is shown in Table 3.

Table 3. Risk assessment for implementation of HIREP-ERIC

Strengths	Opportunities
- Flexible and responsive to Member States needs - Can extend its activities and become larger over time - Provide sustainable structure for - best practice exchange between Member States - data collection and regular assessment and analysis - Link national and international experts, public health institutes and research institutes - Potential for larger more relevant health research capacity - Builds on existing research projects and national and international organisations - Provides an holistic approach to population health monitoring and health system performance - Better partake in EU funded research project - Assist with elements of overarching project management - Pool resources for more effective resource allocation	- Demands from EU political bodies - Member States 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 an opportunity for alignment of EC entities and international organisations
Weaknesses	**Threats**
- Priority setting in initial stage of the tasks and activities will be challenging - Not all Member States will and have to be involved - Health and health sector benefits will need time to become visible	- Budgetary restrictions by Member States and EU funding - Length of finding agreement on statutes - Timeframe to set-up the ERIC may be lengthy - High pressure workload - High expectations - Recruitment of suitable personnel - Not to be able to assure better governance and coordination at EU level - Health information gaps - Timeframe to set-up the ERIC - Competing initiatives - Once it exists: issues with data interoperability.

VII.   References

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