HEALTHYCLOUD
Health Research & Innovation Cloud

Strategic Agenda for the creation of a European Health Research and Innovation Cloud – Final Draft

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Authors	C. Ohmann (ECRIN), M. Panagiotopoulou (ECRIN), M. A. Rujano (ECRIN), J. Demotes (ECRIN), S. Canham (ECRIN)
Contributors	Gary Saunders (EATRIS), Arshiya Merchant (ELIXIR), Niklas Blomberg (ELIXIR), Michaela Th. Mayrhofer (BBMRI-ERIC), Irene Schlünder (TMF), Davit Chokoshvili (PNED), Irène Kesisoglou (Sciensano), Pascal Derycke (Sciensano), Shona Cosgrove (Sciensano), Teresa D'Altri (CRG), Celia Alvarez-Romero (SAS), Carlos Luis Parra-Calderon (SAS), Silvia Rodriguez Mejias (SAS), Mark Dietrich (EGI), Gergely Sipos (EGI), Salvador Capella-Gutierrez (BSC), Laura Portell-Silva (BSC), Petr Holub (BBMRI-ERIC), Eva Garcia Alvarez (BBMRI-ERIC), Juan Gonzalez-García (IACS), Enrique Bernal-Delgado (IACS), Harald Wagener (CHARITE), Sina Barysch (EMBL), Sarah Karam (ECRIN)
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Change Log

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Executive Summary

The idea of a Health Research and Innovation Cloud (HRIC) for researchers, healthcare professionals, industry and policy makers across Europe was born during a workshop, organised by the European Commission (EC) in 2018. This workshop generated five major recommendations, summarised in a highly recognised publication in Genome Medicine [1]. As a direct result of this workshop, the HealthyCloud project was funded as a Coordination and Support Action (CSA) with the aim of developing the Strategic Agenda of the HRIC together with relevant stakeholders.

Due to the rapidly evolving research, regulatory and infrastructure framework relating to health research in Europe, even in the short time-period between 2018 and 2023, the work began by assessing the changing landscape, exploring the implications for the HRIC and the articulation of its relationship with existing large infrastructure initiatives like the European Open Science Cloud (EOSC) and HealthData@EU, the infrastructure for secondary use of health-related data of the European Health Data Space (EHDS). In a detailed analysis, gaps and uncertainties were identified as potential challenges for using and reusing data in health-related research and providing both a rationale and focus areas for the HRIC.

Starting from the background and taking the changing landscape into consideration, the HealthyCloud project developed a core vision and associated values for a future HRIC. Next, a draft of the Strategic Agenda was designed to support the discussion with the stakeholders, which took place across four workshops dedicated to specific stakeholder groups. It soon became clear that there was no need to create a new infrastructure for the HRIC. Instead, a minimal coordination and orchestration body would be sufficient to minimise the administrative overload. Under this body the HRIC should have a federated organisation based on existing partners, such as European Research Infrastructures (RIs), providing specific services to the research community, and other relevant stakeholders, e.g., policy-makers.

Five services were specified that the HRIC should provide. These services correspond to the gaps and needs identified:

- A monitoring service for health-related research
- A legal/regulatory guidance service
- A metadata standards and data interoperability guidance service
- A health research community interface service, with the EOSC
- A health research community interface service, with HealthData@EU

It is of critical importance for the HRIC to be aligned with the work of EOSC, EHDS and other relevant initiatives. Here, the consortium that developed the Strategic Agenda follows an agnostic approach, the options could be an affiliation to EOSC (“EOSC Health Research”) or a research part in the EHDS (“HealthData@EU for research”) or another construction. As part of this discussion, the possibility of creating a European Union (EU) Mission on “Health Research and Innovation” was explored. Possible governance models for the HRIC have also been proposed, but each is highly dependent on the envisaged organisational structure, which has not yet been decided. If a HRIC is affiliated to an existing organisation (e.g., EOSC), it must be integrated into the governance of that organisation.

With respect to the implementation and sustainability of the HRIC, the Strategic Agenda had to remain flexible due to the uncertainties that remain in the landscape, such as the ones linked to the development of the EOSC and the EHDS, and the absence of a specific funding stream for the HRIC and its services. Nevertheless, implementation and sustainability considerations were intensively discussed at stakeholder workshops and two key sequential phases are recommended for the further development of the HRIC:

- Development and pilot phase
- Maintenance and sustainability phase

The development and pilot phase would provide the procedures and tools required for technical implementation of the proposed HRIC services. This phase should be limited to 2-3 years and could be supported by project-based EC funding, such as a second CSA. Different types of financing should be carefully explored for long-term funding. During the stakeholder workshops, different options were discussed, such as “fee for services”, in kind contributions from existing RIs, funding through Member States contributions and EC funding by making use of the services an eligible category in EC projects. The maintenance and sustainability plan should be developed, approved and implemented during the development and pilot phase.

In this document, **Chapter 1** provides an overview of recent developments in the European research, regulatory and infrastructure landscape related to health research, with an emphasis given on implications deriving from the establishment of the EOSC and the EHDS. Potential gaps, needs and uncertainties are identified.

Chapter 2 sets the HRIC core vision and values. The HRIC should, among others, be collaborative and promote the application of the FAIR (Findability, Accessibility, Interoperability, and Reusability) principles and Open Science practices, while upholding the protection of privacy and promoting the safe use of citizens’ health data for research and innovation purposes.

Based on the above, **Chapter 3** details specific aspects for five proposed services that the HRIC would offer to complement the current European landscape in response to the gaps, needs and uncertainties identified. Similarities and synergies between the services are explored.

Maintenance, sustainability and implementation considerations for the HRIC are covered in **Chapter 4**. The main focus is around the topics of the HRIC affiliation/organisation, governance, authorisation and funding.

1 Introduction – The Requirements

1.1 Genesis and purpose of this document

In March 2018, the Health Directorate of the EC's Directorate-General for Research and Innovation (DG RTD) organised a workshop to explore the possibility of establishing a Cloud for Health Research and Innovation (HRIC), to be accessible by researchers and health professionals throughout Europe.

The workshop (reported in [1]) generated **five principal recommendations** for a HRIC, made *"to the funding agencies and the actors in the field"* shown, in abridged form, in Table 1 below.

Recommendation	Rationale
Provide and foster standards, good practices, and guidelines necessary to establish the European HRIC.	The HRIC should be supported by predefined standards, data formats, protocols, and templates. The data standards and guidelines applied in the HRIC should be designed to facilitate interoperability.
Develop and certify the infrastructure and services required for operation of the HRIC.	The HRIC should provide computational infrastructures and services and analytical and visualisation tools to all users as a platform to share knowledge, data, and guidelines.
Enable the HRIC to operate within an ethical and legal framework that is adequate for health systems.	A robust ethical and legal framework has to be developed that defines rules for privacy, security, ownership, access, and usage of data within the HRIC.
Establish a proper environment for the training of a new generation of data and medical scientists.	Education and training of health professionals need to be updated with the HRIC in mind, considering both international standards and practices for data sharing as well as national environments and regulations.
Fund public and private initiatives for the development of the HRIC through EU Framework Programmes (e.g. Horizon 2020 and Horizon Europe).	The EU and its Member States should, together with private investors, develop a coherent, ambitious, and long-term action plan supported by innovative funding mechanisms that consolidate the outcomes from the existing project portfolio into a long-term operational infrastructure.

Table 1: Recommendations relating to a HRIC, from the DG RTD workshop, 2018 [1] (Rationales abridged from the original publication)

The stated aim of these proposals was to allow health-related data generated from both research and clinical practice, research and clinical protocols, software, computational resources, methods, and publications to be more easily identified, more widely accessed and more efficiently reused, allowing a more complete application of the FAIR principles [2]. A suite of distributed “cloud” based infrastructures were seen as important technical components of the proposed HRIC, and there was general agreement that the infrastructure should be built upon and integrated with the developing European Open Science Cloud (EOSC).

The HealthyCloud project [3], a Horizon 2020 Coordination and Support Action (CSA), was funded to build on the recommendations of this workshop. HealthyCloud started in March 2021 and it will end in November 2023. The ultimate goal of the project is to provide a Strategic Agenda for the European HRIC. The project focuses on four key objectives: 1) Engaging stakeholders in the Strategic Agenda's development; 2) Addressing ethical, legal, and societal aspects in HRIC's design; 3) Ensuring sustainable access, use, and reuse of health-related data for research purposes in line with the FAIR principles; and 4) Providing guidance on the necessary technology for distributed health data analysis across Europe. Two real-world use cases (Cancer and Atrial Fibrillation) guide the project to ensure that the resulting outcomes respond to the real challenges researchers face, in terms of technical, ethical, and legal aspects.

In October 2021, a "Draft Strategic Agenda" for the HRIC was produced with input from the HealthyCloud consortium. The process began with the development of a discussion paper [4] that covered critical topics: Legal issues, Ethics, Metadata, Data quality, Technical infrastructure, and Sustainability. Later on, discussions focused on the “vision” and “mission” of the HRIC. A face-to-face "Strategic Agenda Consensus Development Workshop" was held in Paris on June 27, 2022, involving the HealthyCloud Work Package Leaders. The collaborative "Draft Strategic Agenda" has been authored by 39 HealthyCloud partners and is available on Zenodo[1] [5].

After delivering the "Draft Strategic Agenda'', HealthyCloud initiated a series of four stakeholder workshops to gather feedback on its contents and proposed services. These workshops engaged technical experts, ethical and legal specialists, patient and citizen associations, relevant EU projects, industry, policy makers, and EOSC and European Health Data Space (EHDS) key actors. During each workshop, the HRIC's objectives, positioning, and services were discussed, leading to a restructure of the planned services based on stakeholders’ feedback.

The final list of proposed HRIC services is:

- Service 1: A monitoring service for health-related research
- Service 2: A legal/regulatory guidance service
- Service 3: A metadata standards and data interoperability guidance service
- Service 4: A health research community interface service, with the EOSC
- Service 5: A health research community interface service, with HealthData@EU

[1] Metrics from 30/08/2023: 592 downloads and 944 views

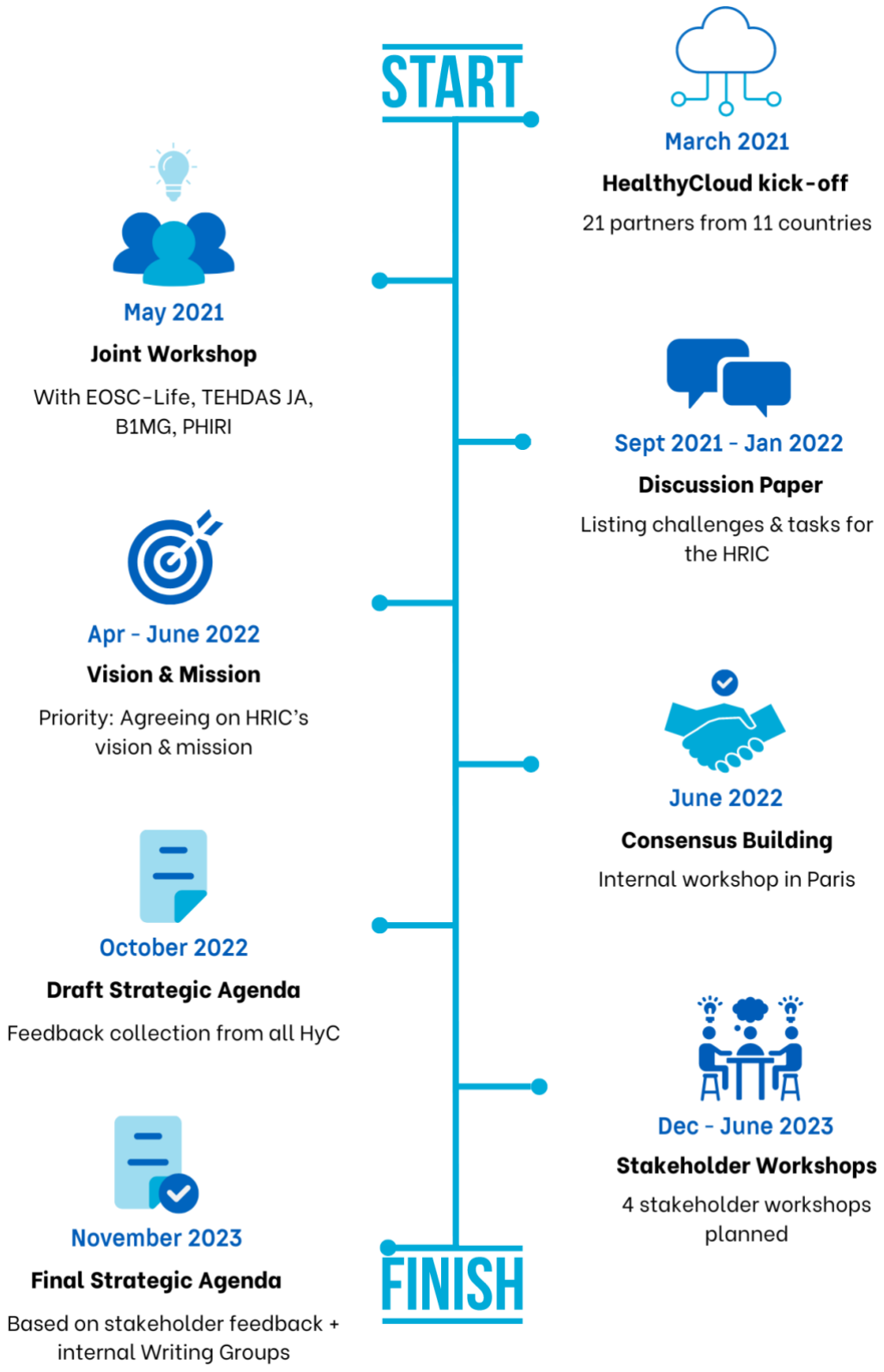

Figure 1: Timelines of the development of the Strategic Agenda

1.2 The changing landscape

A constant challenge in generating the Strategic Agenda for a HRIC has been the rapid development of the research, regulatory and infrastructure framework for the use of health-related data for research in Europe, even over the relatively short time period between 2018 and 2023. Key developments include:

a) The ***European Strategy for data***, published in February 2020 [6], which aims to create a single market for data to support Europe's global competitiveness and data sovereignty. "Common European data spaces" were proposed to ensure that more data becomes available for use, in both a commercial and social context, while keeping the organisations and individuals who generated the data in control. Data driven applications are expected to benefit citizens and businesses in various ways, for example by improving healthcare, creating safer and cleaner transport systems, generating new products and services, reducing the costs of public services, improving sustainability and energy efficiency.

b) As part of the European Strategy for data, the Commission proposed in November 2020 a Regulation on European data governance (***Data Governance Act***) [7], which was finally published in May 2022 [8] and is applicable from 24 September 2023. The Data Governance Act aims to make more data available for reuse and to facilitate data sharing by supporting the establishment of the "Common European data spaces".

c) The Data Governance Act was complemented by the Commission's proposal for a regulation on harmonised rules on fair access to and use of data (***Data Act***) published in February 2022 [9]. The Data Act aims to break data silos by optimising its accessibility and use and creating a competitive and reliable European cloud computing market, ensuring that the benefits of the digital revolution are shared by all. The proposal is awaiting formal approval by legislators to be definitely adopted [10].

d) The Artificial Intelligence Act (***AI Act***) [11] was proposed by the Commission in April 2021 and aims to introduce a common regulatory and legal framework for artificial intelligence. The rules ensure that AI developed and used in Europe is fully in line with EU rights and values including human oversight, safety, privacy, transparency, traceability, non-discrimination, and social and environmental well-being [12]. Its scope encompasses all sectors (except for military), and all types of artificial intelligence. In June 2023, the European Parliament adopted its negotiating position on the AI Act. Talks with Member States on the final form of the law have begun, and the aim is to reach an agreement by the end of 2023.

e) The ***Path to the Digital Decade***, initially proposed by the Commission in 2021 [13], has now evolved into the ***Digital Decade Policy Programme 2030***, which came into force in January 2023 [14]. This programme sets up a monitoring and cooperation mechanism involving the European Commission and EU Member States to achieve concrete common objectives. To this end, the Path to the

Digital Decade establishes a governance framework consisting of a structured, transparent and shared monitoring system to measure progress towards each of the targets, an annual 'Report on the state of the Digital Decade' to assess progress and provide recommendations, a Digital Decade strategic roadmap reviewed every two years where the EU Member States describe the actions adopted or planned to achieve the 2030 targets, and a mechanism to support the implementation of multinational projects [15]. The main areas of interest of the programme are digital skills, digital infrastructures, digitalisation of businesses and public services.

f) The ***European Declaration on Digital Rights and Principles*** was introduced in January 2022 and signed by the European Commission, Parliament, and Council in December 2022 [16]. It is the foundation for the Principles for the Digital Decade, signifying the EU's commitment to a secure, safe, and sustainable digital transformation. The Declaration aims to advance a distinct European approach to digital transformation, which i) puts people at the centre, ii) is built on European values and EU fundamental rights, iii) reaffirms universal human rights, and iv) benefits all individuals, businesses, and society as a whole.

g) The ***Proposal for a regulation on the EHDS*** [17], published by the Commission in May 2022, aims to support, and empower individuals to take control and use their own health data at national and EU level. It is the first regulation for a data space and promotes a single market for digital health services and products, and importantly, includes provisions for setting up a reliable framework for the secondary use of health data for research, innovation, policy-making and regulatory purposes, while ensuring compliance with EU data protection standards (Chapter IV of the proposed regulation, known as HealthData@EU). The legislative proposal is currently under discussion between the European Parliament and the Council and is likely to change considerably before implementation.

h) ***GAIA-X***, a joint public-private endeavour launched to establish a federated digital infrastructure ensuring European digital sovereignty, connects cloud service providers and users within a trusted environment. In this setting, data sharing is facilitated, and users retain control over their data. Initiated by France and Germany, GAIA-X was introduced to the public at the Digital Summit 2019 in Dortmund (Germany) and actively supports health-related data sharing, potentially leading the way for the EHDS [18]. In March 2023, GAIA-X launched GXDCH (Gaia-X Digital Clearing House) [19], a compliance verification service enabling participation in the GAIA-X ecosystem.

i) The continuing development of the ***EOSC***, especially regarding numbers of services and the development of mechanisms for supporting onboarding [20]. EOSC is recognised by the Council of the European Union as one of the actions of the European Research Area (ERA) policy agenda 2022-2024. EOSC is also recognised as the "science, research and innovation data space" which will be linked to the other data spaces defined in the European Strategy for data,

although how exactly the EOSC will interact with the data spaces is still unclear [21]. A public procurement action was launched in 2022 with a budget of €35,000,000 and the objective of implementing and deploying a fully operational infrastructure for EOSC [22].

j) The further development of ***National plans for Health Data Hubs*** (e.g., the French Health Data Hub, FinData [23, 24]). This should be seen in the context of a ***greater recognition of the potential value of real-world data (RWD)*** not only as a research and policy making resource, as exemplified by the EHDS proposal and such initiatives as the EHDEN project [25], but also for supporting regulatory decisions, as with the EMA's Data Analysis and Real-World Interrogation Network (DARWIN EU) initiative [26].

k) Growing interest in the use of ***Secure Processing Environments (SPEs)***, also known as Trusted Research Environments (TREs) or data safe havens, to allow controlled access to sensitive data [e.g., 17, 27]. Such infrastructures will be key in the development of the HealthData@EU and other data spaces. They are one example of ***developments in infrastructure and technologies*** to support the management of sensitive data, including progress in encryption techniques (e.g. homomorphic encryption [28]), the development of federated query techniques [29, 30], progress in natural language processing [31], and the application of machine learning to data mining from large datasets [32, 33]. The EC, recognising that there is a gap on sensitive data management within the EOSC, launched in December 2022 a Call on "Trusted environments for sensitive data management in EOSC", with one of the expected outcomes being engaging with the health sector [34]. Selected projects are expected to kick-off in early 2024.

l) The ***Joint Action Towards the European Health Data Space (TEHDAS)*** project [35] that ran from February 2020 until June 2023 to promote and develop concepts for the secondary use of health data to benefit public health and health research and innovation in Europe. TEHDAS' results are already feeding the European Commission's legislative proposal on the EHDS [36]. The **HealthData@EU pilot** project kicked off in October 2022 and includes concrete use cases testing the TEHDAS recommendations in different health-related research fields [37]. In January 2024, the QUANTUM project will kick off, aiming to provide guidance on the design of a data quality, utility and maturity labelling mechanism as input for the implementation of the HealthData@EU label.

m) ***Greater public and political awareness*** of both the promises and the risks involved in using and reusing sensitive data. The COVID-19 pandemic demonstrated the importance of bringing data together from different sources, but cases of poor transparency in data reuse, including by big technology companies for algorithm development [e.g., 38, 39], and lax security leading to data breaches [e.g., 40] has lowered confidence, at least for a portion of the public, in the proper long-term management of personal health and research data.

n) Funding for the development of new thematic data infrastructures such as the ***European Genomic Data Infrastructure (GDI)*** [41] and the ***European Cancer Imaging Initiative (EUCAIM)*** [42], which are expected to establish a legal framework for the use and reuse of genomics and cancer imaging data obtained from research activities and from patients that have consented the use of their healthcare data for research purposes. Both consortia are expected to operate as European Digital Infrastructure Consortia (EDIC) [43] and interact with the EOSC and the HealthData@EU for specific use-cases.

Considered in isolation, the majority of the aforementioned developments have been acknowledged as significant strides towards improved data management, leading to more efficient and effective secondary use of health-related data. When viewed as a whole, however, this multiplicity of parallel changes has raised concerns and questions linked to the fact that many of the listed developments are still in the proposal or early implementation phase, making it unclear how and when they will be fully implemented in practice. Specifically, within the context of HealthyCloud, there has been a substantial debate regarding the implications for the HRIC and the articulation of its relationship with existing infrastructures like EOSC and HealthData@EU.

1.3 Gaps, needs and uncertainties.

This section discusses perceived gaps or uncertainties that have been identified as potential challenges for using or reusing data in health-related research. One approach to specifying the HRIC involves describing the necessary services and infrastructures required to fill the identified gaps and important needs.

a) The timeframes of implementation – the need for coordination

Many of the current initiatives and proposals, once they undergo the necessary phases of system development, piloting and refinement, will require a significant amount of time for full implementation. The extended timelines introduce uncertainties regarding the specifics of these initiatives, such as the ultimate configuration of HealthData@EU, the national health data hubs, various aspects of EOSC, and the extent and nature of interactions among these major infrastructures. The potential risk is for different initiatives to advance in parallel and relatively independently, lacking the ability to coordinate effectively with one another due to their ongoing development. Elements for the EHDS, for example, have been co-designed through the TEHDAS Joint Action and HealthData@EU pilot projects, but this effort has not built upon technical developments around EOSC, with a concrete collaboration plan between the two initiatives still lacking. In this context, there is inherent value in establishing mechanisms for ongoing coordination.

b) Specifics of sensitive data – the need for sensitive data management support

Sharing sensitive data presents greater time and resource demands compared to non-sensitive scientific data due to ethical and legal requirements like informed consent or opt-out mechanisms, contractual agreements, as well as technical necessities such as data pseudonymisation and anonymisation. Concerns arise regarding the adequate resourcing of data sharing in the research sector, potentially resulting in underutilised infrastructures like HealthData@EU and EOSC. The number of listed services in the EOSC

Marketplace focusing on sensitive data management is still rather limited but gradually growing (e.g., the Service for Sensitive Data (TSD) in Norway [44], CHARITÉ's Virtual Research Environment (VRE) in Germany [45]). EOSC's primary focus on open data and metadata means it lacks currently inherent access control systems. The different sensitive data communities need to stipulate their data management requirements, for example, the need for timely and demonstrable deletion of sensitive data, when it is no longer required at the point of computation. This introduces additional management and cost requirements into the data life cycle, which must be recognised and integrated within funding processes.

c) A rapidly evolving and complex legal landscape – the need for guidance

The General Data Protection Regulation (GDPR) has not fully addressed data sharing challenges in health-related research, with the derogations available with respect to research leading to different interpretations and national legislation variations across the European Economic Area (EEA). Key terms like "anonymisation" remain debated, making it difficult to establish guidance for personal sensitive data sharing, especially in cross-border settings. The EHDS proposes a new legal framework but won't amend the GDPR, creating uncertainty about their interaction [46]. European legislation typically undergoes extended testing and interpretation periods, delaying consistent implementation. The evolving legal landscape, including the Data Governance Act, Data Act, AI Act, and the proposed EHDS regulation, emphasises the need for clear guidance, policies, and best practices for health researchers, especially those preparing data for long-term storage or sharing. Authoritative guidance should ideally result from discussions between regulatory bodies (e.g., the European Data Protection Board) and the scientific communities.

d) Data access organisation – the need to support multinational research

While the EHDS and EOSC development aim to enhance health data access, support for managing and preparing such types of data for research may need improvement. The EHDS plans to establish a health-specific data sharing framework with clear rules, common standards and practices, infrastructures, and a governance framework for the secondary use of health data. It will extensively use SPEs and introduce new national entities (e.g., Health Data Access Bodies or HDABs - Art.36, National Contact Points for Secondary Use of Health Data - Art.52) to manage access to data for secondary use. However, health-related research (e.g., clinical trials, observational studies, epidemiological work) often makes use of data from several different countries at the same time. It is unclear how the HealthData@EU infrastructure will facilitate this, raising questions about the need for additional systems to support data sharing in multinational health-related research.

e) Data heterogeneity – the need to support greater interoperability

In the rapidly evolving health-related data ecosystem, a vast array of data types emerges from diverse sources, encompassing clinical observations, biomarker tests, genetics, radiology images, surveys, and more, collected across various contexts such as routine healthcare, clinical research, and population studies. These data can pose significant challenges, including varying languages, unstructured textual components, and diverse units for numeric components. Even data of a similar type can exhibit different

structures and employ distinct vocabulary and ontology systems. EHDS aims to regulate uniformity in Electronic Health Record (EHR) systems and health data, but widespread EHR standardisation may take many years. Additionally, clinical trial data often relies on CDISC standards, which differ from controlled vocabularies like SNOMED-CT used in routine healthcare. Bridging these gaps in semantic and syntactic interoperability is a recognised challenge. Therefore, decisions are necessary before data standards become entrenched, with the goal of fostering interoperability, improving data availability for reuse, and potentially establishing common vocabularies and data structures at the source.

f) Improving findability – the need for better discovery metadata

The COVID-19 pandemic highlighted the growing need for scientists to access research and data from diverse domains to facilitate interdisciplinary investigations [47, 48]. Currently, this process is often challenging, as not all valuable data is catalogued, forcing researchers to search for data through personal contacts or networking opportunities. According to the Findability principle, the data should be described with metadata that is indexed or registered as findable resources. In this sense, interoperable metadata catalogues are needed in all areas of health research, with relevant work in projects like EOSC-Life [49], BY-COVID [50], EOSC Future [51], FAIRCORE4EOSC [52], and PHIRI [53], as well as national initiatives like NUM-CODEX [54] in Germany. The EHDS plans to extend the Resource Description Framework (RDF) Data Catalog Vocabulary DCAT by creating a dedicated application profile for health (i.e. Health DCAT-AP extension) to enhance health data collection discoverability. For comprehensive discoverability across health-related research, coordination and harmonisation of FAIR data approaches in EOSC and EHDS are essential, ultimately requiring a uniform schema for findability across all health-related research domains. The EHDS legislative proposal includes an obligation for member states to set up such health-related metadata catalogues.

g) EOSC and EHDS – the need for clarity

The representation of health-related research and secondary use of health data in infrastructures such as EOSC and HealthData@EU needs to be further specified. "EOSC Health Research'' has been proposed within HealthyCloud as an extension of EOSC, encompassing health research services, epidemiology, public health, health policy, clinical research, and more. The scope of the EHDS also covers a similar range of activities, with the proposed regulation explicitly stating its jurisdiction over various health and health-related scientific data. However, there is currently a perception among stakeholders that HealthData@EU primarily focuses on data from routine healthcare sources, such as EHR or registries, potentially overlooking the specific requirements for governing clinical, genetic, or social science research data. This perception stems from the enormous challenge HealthData@EU faces in managing real-world data obtained from healthcare, possibly limiting its capacity to handle diverse data sources. As the scopes of EOSC and EHDS become clearer, overlaps are to be expected, which will require ongoing collaboration, possibly directly or through an intermediary body. Ideally, communities using both services should actively participate in this collaboration.

h) Infrastructure components – the need for SPE development

EOSC and EHDS are poised to significantly interact in the domain of SPEs, which are integral for the management and analysis of sensitive data, although their current availability remains somewhat limited. The EHDS legislative proposal outlines plans for health data to be accessed through SPEs in the HealthData@EU infrastructure, emphasising the implementation of appropriate technical and security measures (guidance has been prepared within the TEHDAS Joint Action [55]). In parallel, EOSC could incorporate a network of SPEs, featuring transparent governance and security attributes [34]. These SPEs would enable users to select the most suitable one for their needs and facilitate secure data movement for processing. Within the HealthyCloud project, SPE technical aspects have been explored, leveraging insights from existing national computing infrastructures and guidelines for establishing a federated computing infrastructure across Europe. These guidelines require updates, completion, and implementation, serving as input for SPE development. As SPEs become increasingly prevalent in both EOSC and EHDS, ongoing monitoring, resource pooling, and integration of technological advancements (e.g., cryptography) will be pivotal. The overarching objective remains the continuous identification and rectification of service gaps and issues from a researcher's perspective to enhance their overall effectiveness.

i) Public engagement – the need to retain trust

From both an ethical and pragmatic perspective, researchers have a responsibility to transparently communicate the fair use of health-related data. This ensures that all parties involved, including the data contributors, particularly citizens, grasp the importance of reusing health data while preserving individual privacy. A number of critical issues need to be addressed, such as refining consent processes (including opt-in and opt-out systems), operationalising the return of results to research participants, and recognising the potential of data altruism in health research. Neglecting these issues poses a risk of reducing public trust and understanding, which could impede the broader reuse of sensitive personal data for research purposes. Addressing this challenge necessitates a collaborative effort across the entire health-related research landscape, transcending individual disciplines. As an example, the EHDS legislative proposal has received criticism from patient and citizen organisations, highlighting the need for more clarity on how the EHDS complements the GDPR [56].

j) Links to research infrastructures – the need for communication mechanisms

Research infrastructures, given their established connections with scientific communities, can serve as a valuable communication mechanism. However, establishing a framework that links these RIs with major infrastructures, particularly the EHDS and EOSC, is imperative. In the EHDS, EU Member States collaborate on cross-border digital infrastructures for sharing health data for secondary use, with National Contact Points serving as entry points and HDABs facilitating the availability of the data for research and policy making. While some RIs, such as life science ESFRIs (European Strategy Forum on Research Infrastructures), may become users or producers of EHDS data, their broader objectives extend beyond this scope, including the development of research services, standards, quality assurance, translational processes, and innovation transfer. This complexity poses challenges in defining the exact role of RIs in the EHDS ecosystem. In EOSC, the task forces of the EOSC Association actively engage various stakeholders. As part of the EOSC landscape, there is already some involvement of

health-related ESFRIs (e.g., in the EOSC ESFRI Working Group) but this needs to be strengthened and certain research communities, such as population health actors need to be included. Therefore, both EHDS and EOSC could benefit from improved mechanisms to engage health-related ESFRIs, ideally through an intermediary forum, to foster collaboration and to address the concerns of all stakeholders involved.

k) Ensuring new services are used – the need for training

The extensive developments discussed in section 1.2 emphasise the necessity to train researchers to ensure awareness and effective utilisation of relevant resources. Many researchers will require training for optimal use of SPEs, understanding or implementing new metadata schemas, or accessing data under controlled access at national nodes. Currently, extensive health research-specific training is offered by RIs and large projects. There is no need to replace this training but rather to complement and coordinate existing initiatives, ultimately enhancing capacity building across Europe and facilitating the adoption of new data sharing services. Training programs might also include certification and the provision of credentials or a registry for suitably trained researchers.

In summary, the rapidly changing landscape of health-related research, with its many gaps and needs, has not fundamentally altered the need for some form of HRIC. The original 2018 workshop findings remain valid and have been reinforced by HealthyCloud outcomes. There is still a requirement for enhanced data standardisation and "FAIRification", specialised secure data storage and processing services, seamless integration of real-world health data into multinational research, regulatory framework clarification, training of researchers, and adequate resource allocation.

2 Core vision and values

This section attempts to set out a basic framework for the HRIC by defining its core vision and values.

As an initial step, a core "vision statement" was constructed, given below.

> *The vision of the HRIC is to improve the health and well-being of people by increasing the quality and impact of data-driven health-related research. Its focus is on the most effective and efficient reuse, for research purposes, of health-related data from a wide variety of sources.*

This statement was deliberately kept short and simple, to emphasise the central purpose of the HRIC. However, it prompts the question of what "health-related research" encompasses, a term used throughout this document with minor variations. This phrase was deliberately chosen to be inclusive, recognising the multitude of factors influencing human health. It emphasises that the HRIC should be able to accommodate data from diverse sources to study any health determinant. The HRIC would encompass traditional clinical research data, mechanisms to access healthcare-derived data (e.g., EHR, registries, dispensing records, insurance claims), as well as data from basic biological research (such as genetics and microbiology) and social, psychological, economic, and environmental research when relevant to human health. A fundamental aim of the HRIC is to reduce barriers between different health-related research domains and data sources. Much of this data will originate from identifiable individuals, making it personal sensitive data, subject to GDPR and other data protection regulations. This is the main difference between the services proposed by a HRIC and services in other domains within EOSC, while it is more similar to services proposed for managing healthcare data under the EHDS.

The attributes listed below are identified as **key values** of the HRIC. They are predicated on the assumption that any HRIC will be a relatively persistent initiative, existing beyond the lifetime of a single project.

a) *The HRIC must be **collaborative** and have a **multi-stakeholder approach***, whether as an independent entity or a sub-part of another organisation. This collaboration, primarily at the European level, involves working with EOSC, the EHDS, the EC, other projects (at European, national and regional level), infrastructures, and science clusters. Such collaboration is not an optional addition, but an integral part of the HRIC for delivering the services that the research community needs.
b) *The HRIC must be **global**, but retain a European focus:* It is expected that the HRIC will be supported by European funds and resources; especially if embedded within European infrastructures. It will be used mainly by researchers based in Europe, with a focus on data relevant to the health of European populations. On the other hand, research is inherently global, and research endeavours and tools, including evolving data standards for interoperability, often have a global scope. Therefore, the HRIC must remain open to global developments, interactions, and

collaborations in health-related research, in addition to the European context. It must plan and implement activities with this global perspective in mind. Some tools and services should be designed and offered as global resources, mirroring how European researchers currently utilise resources developed elsewhere (e.g., the Maelstrom repository of cohort research originating in Canada [57]). This approach contributes to ensuring the recognition and value of European research and researchers on a global scale.

c) *The HRIC must be demonstrably **useful to research communities**:* The purpose and value of the HRIC needs to be clear to, and supported by the associated research communities, i.e. all those concerned with health-related research. This means having clear short-term and long-term aims, and metrics with which to measure them, plus arrangements for ongoing dialogue with the health research community – the HRIC's users – as well as funders.
d) *The HRIC must **promote the application of the FAIR principles** to data:* This is a major challenge for health-related research, and "FAIRness" must therefore be a key driver and metric in all HRIC activities, and apply to all stages of the data life cycle. The HRIC should also contribute to the further development of ideas around what "FAIR" means in practice for health-related research data, especially sensitive personal data.
e) *The HRIC **commits to the Open Science principles**, acknowledging that this is still a major challenge for health research.* Open science is an approach to the scientific process that focuses on disseminating knowledge as soon as it is available, using digital and collaborative technology, expert groups, publications, news and events [58]. Promoting open science is a policy priority for the European Commission, and applying the FAIR principles is one of the instruments to achieve it. However, Open Science goes beyond FAIR to also include collaborative networking and mutual learning, new generation of science metrics, the future of science communication, incentives and rewards for data sharing, education and digital skills, and citizen science.
f) *The HRIC must **uphold the protection of privacy and promote the safe use of citizens' health data**:* A commitment to FAIR data must never mean that individual privacy is threatened. On a technical and policy level, the HRIC should strive to monitor, uphold and promote the protection of privacy, both within its own systems and within those of referenced data sources.
g) *The HRIC must **be integrated with existing systems where possible**:* As an example, if some parts of the HRIC require user's identification, i.e. Authentication and Authorization Infrastructure (AAI) features, existing systems should be used (e.g. the Life Science AAI already developed in the EOSC-Life project [59]), rather than developing a new service. Whether or not the HRIC requires a separate web portal remains an open question. If EOSC/HealthData@EU do not provide or integrate portal facilities for a high proportion of health-related research resources within a reasonable timeframe, then a separate 'HRIC portal' is likely to be necessary. Nevertheless, users would find it easier to use resources and resource descriptors embedded in the wider EOSC/HealthData@EU systems.
h) The management of healthcare data for potential secondary use will largely be handled within HealthData@EU. There is no point in a HRIC trying to duplicate

that functionality, though it might conceivably be involved in complementing the EHDS services by, for example:

(i) Interacting with the EHDS to ensure healthcare data resources (often pre-processed in some way to allow their secondary use) are easily visible to researchers, to allow assessment of their potential value.

(ii) Interacting with the EHDS to establish systems allowing researchers to more easily import or access that data, especially when comparing or integrating it with other data related resources, or when seeking to use data from multiple countries at the same time.

(iii) Help existing data hubs to curate their data following the FAIR principles as well as the requirements to provision this data under the EHDS regulation.

(iv) Finding synergies between existing services already available on EOSC that may be used to provide EHDS services, as the already identified TREs/SPEs.

3 HRIC services

This section details the five proposed HRIC services for implementation. All of them have been suggested at one time or another as potential features of a HRIC. Originally there were ten services under consideration, but the discussion at the stakeholder workshops and within the consortium suggested simplifying and concentrating the service portfolio. The five services finally selected correspond to the gaps and needs listed in Section 1.3, although the ordering of suggestions is different. Issues around how such services might be organised, implemented, and funded are discussed within Chapter 4 on implementation and sustainability.

For each of the services it was suggested to consider the following relevant aspects:

a) Whether it would add sufficient value to justify its cost, both directly to researchers and as a way to improve health and well-being in the wider society.
b) Whether the service is already provided (or likely to be provided) by other existing developments, or whether it represents a genuine gap that needs to be filled in some way.
c) If not already provided, whether funding for the proposed service is likely to be available, taking into account the various options that exist, both for implementation and sustainability.
d) Whether currently covered elsewhere or not, and whether the activity should be included within a "HRIC" or is more easily developed within existing (e.g., EOSC or the EHDS) or new structures.

Whilst future funding decisions remain unknown, the purpose of this section is to help the community to reach a clearer conception of the proposed HRIC services and functionality it would like to see implemented in order to enable more productive discussions with funders. The final Strategic Agenda presented in this document captures the different views of stakeholders on the various proposals. The final Strategic Agenda is not proposing a clear "roadmap" for the HRIC and the services listed below due to the absence of funding decisions at this stage.

3.1 Input from the HealthyCloud project

The document has been drafted taking into consideration the outcomes of the different HealthyCloud Work Packages (WP) and stakeholder consultations. More particularly each WP contributed as follows:

- WP2 *"Ethical, Legal and Societal impact of cross-border health data access for cloud analysis"* worked towards validated technical and organisational safeguards, governance models and guidelines that should allow the HRIC to consider all ethical, societal, and legal aspects involved. In collaboration with WP5 and the EOSC-Life project a workshop was organised to capture best practice around use of SPEs [60].
- WP3 *"Health data landscape analysis"* performed a landscape analysis of data availability in relevant publicly funded health data repositories, registries and infrastructures and evaluated the FAIRness maturity for some of the identified collections. It demonstrated gaps and needs in the practical application of the

FAIR principles within health-related research and provided guidelines for FAIR metadata catalogues.

- WP4 *"Experiences on health data management: national, regional and domain-specific data hubs"* analysed governance patterns in the identified health data hubs, reported on current discoverability solutions and the FAIR adoption levels of the health data hubs and proposed an incentive system that could lead to improved health-related research data sharing.
- WP5 *"Designing a decentralised cloud for health data research"* gave insights on the functioning of computational infrastructures, including Ethical, Legal and Social Issues (ELSI), orchestration mechanisms for distributed computational analyses, technical guidelines that the HRIC should consider for building sustainable systems and an analysis of existing security policies and protocols for breaches.
- WP6 *"Reference architecture for a FAIR health data portal"* focused on providing recommendations for a HRIC portal (or associated portals). Expected interactions with users based on different user profiles were stipulated. Guidelines for discoverability of FAIRified health datasets through a HRIC portal and high-level specifications for data access were also delivered.
- WP7 *"Reference use-cases as mechanisms to evaluate specifications"* captured functional requirements through two real-world use cases, cancer, and atrial fibrillation. Proposed solutions from the HealthyCloud WPs were discussed under the prism of real-life practices and at the end a gap analysis was performed to match theory with practice.

In addition to the input collected by the HealthyCloud consortium, the authors of this report collected feedback from external stakeholders in a series of four stakeholder workshops (with technical experts, ethical and legal experts, patient and citizen associations, users, RIs, EOSC and EHDS actors, the EC). During these workshops the draft Strategic Agenda was presented and extensively discussed and suggestions for improvements were collected. The views of the stakeholders have been embedded in the description of the five proposed services (in contrast to the ten proposed in the Draft Strategic Agenda) together with the possible implementation and sustainability options.

3.2 Overall conception of the HRIC services

A core vision with associated values of a future HRIC has been developed in the HealthyCloud project taking into consideration a wealth of background information and a changing health research landscape. Instead of proposing a new infrastructure with governance and functional units, it was decided to focus specifically on the gaps, needs and uncertainties identified and to try to design solutions with a minimum administrative overhead. Firstly, the main areas of current and future needs have been identified, and they are:

- High-level overview on the main initiatives and projects related to health-related research
- Legal/regulatory aspects of health-related research
- Metadata standards and data interoperability in health-related research
- An interface of health-related research to the EOSC

- An interface of health-related research to HealthData@EU

As a result of the intensive discussion within the HealthyCloud consortium and its working groups, and following the recommendations given by the stakeholder groups involved in the workshops, the decision was taken to focus on specific services targeted at the areas listed above. To ensure structured and detailed description of the HRIC services, a model template was developed and applied. This template has the following structure:

- Title
- Summary
- Targeted issue
- Potential benefits
- Potential difficulties
- Focus of service
- Type of service
- Service organisation
- Service conception
- Relevant existing services
- Users
- Potential service providers
- Development capacity needed
- Software needed
- Hardware needed
- Expert involvement
- Resources needed

To facilitate alignment and comparability between the services, the use of a standardised terminology was proposed, where deemed useful. As part of this strategy, individual Writing Groups were set up and asked to provide a standardised description of the allocated service (leading partner in bold). The individual services specified as a result of the writing process are presented in the next section.

3.2.1 Service 1: A monitoring service for health-related research

Title	**A monitoring service for health-related research**
Writing Group	**ECRIN**, EATRIS, ELIXIR
Summary	This is a high-level monitoring service that tracks the status of health-related research. Its primary audience is the research community, but it also caters to the needs of research infrastructures, funders, policymakers, and other stakeholders. The service is Europe-centric, offering both short-term and long-term perspectives and involving the public. It takes a comprehensive approach to health research, encompassing various fields like life sciences, social sciences, humanities, and environmental sciences. The service regularly assesses the progress of health-related research initiatives in Europe, such as the EHDS and the EOSC, and monitors the development of necessary and beneficial health-related services. It also extends its monitoring efforts to other planned services within the HRIC. Feedback from the research community is gathered, and suggestions for improvement are relayed to the EC. This service is managed by a high-level expert group with representation from the health-related research community and is supported by a permanent secretariat. If deemed beneficial, the EC could authorise the service, and experts could be appointed, possibly through a Commission Expert Group or an EU Mission focused on "Health Research and Innovation". The expert group plans regular meetings, data collection from existing documents, surveys, interviews, and workshops with defined stakeholder groups. Periodic reports, approximately every 2 years, will be provided to the research community and the EC, along with regular dissemination workshops.
Targeted issue	Problems and needs arising from inadequate, delayed, or uncoordinated implementation of health-related research initiatives/programmes in the EU.
Potential benefits	● Opportunity to (better) implement EOSC; especially to serve health research. ● Added value would be oversight and transparency on health-related research initiatives/programmes. ● Regular and common cross-project/initiative evaluation with proposals for adjustments when needed. ● Open discussion and sustained effort to inform key stakeholders in a meaningful way. The current situation creates confusion. ● Work against fragmentation of initiatives/programmes. A coordination layer is needed. ● Bringing cost-effective solutions forward. ● Initiating cross-domain activities, which is currently not covered in most health-related projects.
Potential difficulties	● Increasing complexity and administrative burden hampers research. ● Limited number of experts available to support this service.
Focus of service	● Main focus: Health research. Specifically, the perspective of the health research community should be captured, covering all actors working on health determinants (e.g., also social sciences, environmental sciences). The service is mainly academic-oriented, but a broad representation of stakeholder involvement

	is expected (e.g. the general public, industry). Funders and relevant policy makers should be involved as observers. ● The service should aim to establish a common long-term view but also to capture the "*status quo*" and disseminate information about short-term developments of ongoing projects/initiatives. Gaps, needs and opportunities should be explored and new and emerging innovations and trends occurring across healthcare should be monitored ("horizon scanning") providing a high-level overview on the status of health-related research. ● The geographical focus: Europe-centred. ● Assuring input of the RIs into the EHDS. ● Supporting sustainability of community-maintained tools and services. ● The service should not set up new national Mirror Groups but coordinate with existing ones, such as the ones set for the 1+ Million Genomes (1+MG) initiative. Advice on how to best integrate national services with pan-European efforts will be provided.
Type of service	● Evaluate the status and progress of health-related research initiatives/programs towards goals (e.g., EOSC, EHDS, HRIC). ● Monitor progress towards implementation of health-related research services that have been identified as needed and useful ("high level" monitoring). ● Collect feedback on gaps and needs from the research community and make suggestions for improvement (e.g., informing EU calls). Monitor distribution of funds to address gaps (e.g., funding streams within EOSC, EHDS).
Service organisation	The service should not be affiliated to an existing entity (e.g., EOSC, EHDS, RIs) and should be an independent HRIC service. Experts involved in providing the service should be mandated by a health-related subgroup of the RIs.
Service conception	● High-level standing expert group with adequate representation of the health-related research community. ● Adequate representation of the relevant RIs as one major stakeholder group. ● Co-development of services with EOSC/EHDS to assure adequate orchestration. ● Additionally: Forum representing all relevant stakeholders (all health determinants, including general public representatives, industry). ● Establishment of a permanent scientific secretariat headed by a secretary general (this is strongly recommended).
Relevant existing services	● ESFRI working group in the EOSC [61]. ● Commission Expert Group "EU4Health Steering Group" (complementary to the planned service) [62]. ● European Commission Directorate-General for Research and Innovation: European Research Data Landscape (2022) [63]. ● WHO: Emerging trends and technologies: a horizon scan for global public health (2022) [64]. ● NIHR: Innovation observatory (2023) [65].

	● EC DG RTD & CONNECT: Evaluation of the first implementation phase (2018-2020) of the European Open Science Cloud (EOSC) (2020) [66]. ● The Path to the Digital Decade [13] and the Digital Decade Policy Programme 2030 [14] (complementary to the planned service).
Users	All user profiles/personae/RIs are relevant for this service either as members of the expert group or as stakeholders: ● Researchers ● Healthcare professionals ● Policy and decision makers ● Data management profiles ● Citizens ● RIs ● Publishers, funders, and editors
Potential service providers	It should be explored whether implementation as an EC Expert Group or as an EC Mission "Health Research and Innovation" is possible. If that is the case, the service should be authorised, and the members of the expert group appointed by the EC. Selection of expert group members as a continuously open call for applications.
Development capacity needed	N/A
Software components	N/A
Hardware requirements	N/A
Expert involvement	● Regular meetings of the expert group. ● Data collection from existing documents within health-related research initiatives/programs (e.g., EOSC, EHDS, HRIC). ● Actively perform surveys and interviews with key actors. ● Perform workshops (with defined stakeholder groups). Outputs: ● Provide regular reports to the stakeholder research communities and the EC (e.g., every 2 years). ● Use a dedicated expert group page in the EC website for dissemination. ● Hold regular dissemination workshops with key stakeholders.
Resources needed	Minimum implementation: ● Another CSA or a Joint Action to design the services with involvement of both the EHDS and the EOSC. **This should be seen as a preparatory phase for establishing mature and sustainable services similar to the way the ESFRIs were matured.** Maximum implementation: ● An operational service as an expert group with a secretariat & Terms of Reference. ● An EU Mission on "Health Research and Innovation". The tasks of the service need a reasonable budget.

3.2.2 Service 2: A legal/regulatory guidance service

Title	**A legal/regulatory guidance service**
Writing Group	**BBMRI-ERIC**, PNED, TMF
Summary	This service will have three areas of focus, serving the interests of various stakeholders within the HRIC ecosystem in both direct and indirect ways. The three components are: 1. HRIC Legal/Regulatory Community Resources 2. HRIC Legal/Regulatory Support 3. HRIC Legal/Regulatory Policy Monitoring
Targeted issue	The motivation behind the service is two-fold: 1. Existing ELSI Services on local and pan-European level cater to some but not all ethical, legal, and societal needs relevant to the HRIC ecosystem. Most notably, individual organisations participating in the HRIC ecosystem are confronted with legal challenges, uncertainties, and the resultant non-compliance risks. These organisations require interpretative guidance, education, and, especially where adequate in-house compliance expertise is missing, a step-by-step legal/regulatory compliance support. 2. The European health-related research community is notably diverse and currently lacks a unified approach. Despite sharing a common goal of enhancing the reusability of health data, there is currently no central, coordinated initiative aimed at effectively advocating for the community's interests. Consequently, the collective voice of the health-related research community is not adequately heard in the ongoing policy, regulatory, and legislative dialogues at both the European and Member State levels.
Potential benefit	The proposed service will address the aforementioned challenges. On the one hand, it will provide guidance and support to individual organisations seeking to share and/or access and use biomedical data for research purposes, especially data providers without in-house support that operate within the HRIC ecosystem. On the other hand, it will seek to represent the collective interests of the HRIC community in the policymaking, regulatory, and legislative process. The Legal/Regulatory Guidance Service (“Service 2”) will complement and synergise with the other proposed HRIC Services, especially Service 1, which aims to monitor the relevant European initiatives, policies, and legislative developments (i.e., “horizon scanning”). In this respect, the contribution of Service 2 will include detailed impact assessments (e.g., of relevant legislative proposals), alongside targeted strategies for meaningfully engaging European policymakers, regulators, and legislators around specific high-priority issues. Service 2 will also contribute ELSI expertise to the HRIC Services 4 and 5, alongside enriching the broader-scope community resources and knowledge bases to be collected by these Services.
Potential difficulties	Resourcing: 1. Supporting individual organisations to achieve compliance is resource-intensive, requiring expertise and time investment. Charging organisations on a pay-per-service basis raises serious equity concerns, as the organisations in the greatest need for such external support will likely be excluded. 2. Representing the interests of the HRIC community in the context of the European regulatory and legislative processes is a classic example of a

	public good: while all members of the broad HRIC community would benefit, there is little incentive for any individual organisation to contribute resources.
Focus of service	The proposed service will consist of the following **three components:** **1. HRIC (legal/regulatory) Community Resources**, including: i) general training and educational materials; ii) catalogue of the relevant European/national/local laws and the corresponding competent authorities (e.g., in the case of the GDPR, data protection supervisory authorities; in the case of laws concerning reuse of medical data, national and/or regional research ethics committee(s)); iii) standards and guidelines relevant for the HRIC community. **2. HRIC Legal/Regulatory Support,** geared towards organisations involved in data processing within the HRIC data ecosystem, most notably data providers without in-house legal support. This can include but is not limited to training/education aimed at in-house capacity-building. **3. HRIC Legal/Regulatory Policy Monitoring,** tasked with advancing the community's overarching goal of enabling biomedical data reuse through the HRIC. It will pursue this objective by seeking to influence the legal, regulatory, and policy frameworks under which the HRIC operates. This component of the Legal/Regulatory Guidance Service can be thought of as a hybrid of a community advocacy group and a policy-oriented think tank. Having a dedicated thematic focus, this component will synergise with Service 1, contributing specialised expertise, (legal/regulatory) impact assessment capabilities, and strategies for meaningfully engaging European policymakers, regulators, and legislators around specific high-priority issues.
Service organisation	Flexible. It can be a separate entity, or a composite service (with or without a distinct legal entity behind it) with the resources and capabilities enabling its three components spread across (or even outsourced to) other entities, such as ECRIN, BBMRI, and EATRIS. The service could cater to stakeholders under both EOSC and EHDS frameworks, as both sets of stakeholders are part of the broader HRIC community.
Service conception	Hybrid. Existing services (below) provide services relevant for the HRIC community. Where a gap is identified, the services can be set up and maintained by the HRIC or the respective service provider (as applicable). A minimum of central coordination is required (especially if major components are outsourced to existing services to ensure that the user needs are met). Coordination - Central. Structure - hybrid (certain components will be partially or fully outsourced in order to leverage existing external resources, competences and capabilities).
Relevant existing services	**ECRIN Campus** [67]: Partially overlaps with the Community Resource catalogue of laws and competent authorities under Component 1; for example, ECRIN CAMPUS lists national/regional research ethics committees, which, in some jurisdictions, are also responsible for the oversight of studies involving reuse of biomedical data. However, the focus of ECRIN CAMPUS lies on clinical trials and their ethical and legal requirements for transnational studies. It provides a country-specific

	overview on regulatory and ethical requirements, including national contact points. **BBMRI-ERIC ELSI** Services & Research [68]: Significant overlap. ELSI Helpdesk, Ethics Check, and the IT Service BBMRI Negotiator are all examples of services falling under Component 2 of the proposed Legal/Regulatory Service. The BBMRI ELSI Knowledge Base and ELSI Dialogues and training workshops are examples of a community resource falling under Component 1, whereas joint replies to public consultations fall under Component 3. BBMRI-ERIC promotes existing standards and drafts up new guidelines and training as needed. The focus lies on biobanks and biomolecular resources, but ethical principles and societal challenges remain similar across the life sciences. **EATRIS Regulatory Service and Support Center** [69]: Minimal overlap in terms of thematic areas of focus; however, the operating model of EATRIS with respect to serving stakeholders in the medicinal development space, constitutes a valuable case study (e.g., Regulatory Service, Innovation Helpdesk) operationalising the proposed Legal/Regulatory Guidance Service (especially Components 1 and 2). With a translational approach in mind, it aims to help navigate the regulatory aspects, most notably for improving and optimising preclinical and early clinical development of drugs, vaccines, and diagnostics. **EOSC-Life Toolbox on Sensitive Data Sharing** [70]: Partial overlap; the pilot Toolbox is developed to provide a central reference point to existing ethical, legal and technical recommendations, procedures and best practices as well as software tools. While sustainability remains a challenge, the Toolbox seeks to create high value through the provision of resources comprised centrally for shared topics across Life Science RIs ('one stop shop').
Users	Any of the stakeholders involved in data processing within the HRIC ecosystem (data producers, data providers, infrastructure providers, SPEs, data hubs, data users, etc.), as regards to Component 1. Presumably, at least with respect to Component 2 of the Legal/Regulatory Guidance Service, data providers without in-house legal/regulatory support would be the most natural highest-priority target group. However, virtually all stakeholders involved in the data lifecycle within the HRIC would benefit from the service. Expectantly, data users would be the second highest-priority target group.
Potential service providers	If part of the capabilities/resources required for operating the service were to be outsourced, BBMRI-ERIC would be a suitable service provider, especially for Components 1 and 2 (e.g., the BBMRI ELSI Knowledge Base fits into Component 1; the BBMRI ELSI Helpdesk, Ethics Check for proposals, as well as the BBMRI Negotiator fit into Component 2). For signposting to existing tools, such as recommendations relevant to sensitive data, the EOSC-Life toolbox could be the central tool once sustainability aspects are clarified. Component 3 is best coordinated by the HRIC centrally, as this component synergises with other proposed HRIC services, especially Service 1.

Development capacity needed	Negotiations and contractual service agreements across existing services to specify who does what (scope, sustainability) including opening existing services to the HRIC community and developing new building blocks.
Software components	Minimal, maintenance costs.
Hardware requirements	N/A
Expert involvement	High, resource intensive. As described above, all three components can either be implemented in-house, or, at least partially, outsourced, subject to an economic and feasibility assessment. EU-AMRI [71], the alliance of BBMRI, ECRIN and EATRIS, currently utilises some of the listed existing services. It is conceivable that certain resources and capabilities required for the Legal/Regulatory Guidance Service could be deployed by tapping into the same organisations.
Resources needed	The nature of the proposed Legal/Regulatory Guidance service is such that it requires public funding. In particular, with respect to Component 2 (Legal/Regulatory Support, including training/education), other forms of funding raise equity and accessibility concerns. With respect to Component 3, the proposed service runs into the classic "public good" conundrum: despite the utility of the service for the entire HRIC community, there is little incentive for any particular member of the community to contribute, as each member would maximise its utility by acting as a "free rider". Component 1 of the Legal/Regulatory Guidance Service could potentially be created through in-kind contributions of the relevant parties. However, Component 1 alone would be of limited value to the community.

3.2.3 Service 3: Metadata standards and data interoperability guidance service

Title	**Metadata standards and data interoperability guidance service**
Writing Groups	**Sciensano**, CRG, SAS
Summary	The importance of metadata in supporting the "Findability" of datasets and other resources is widely acknowledged, but so is the problem that we have a large number of different metadata schemas which do not always consider the same objects and attributes and hence there is a lack of metadata interoperability. Data interoperability is highly dependent on the use of standards, and in particular on shared controlled vocabulary systems. There is a need to ensure consistent use of standards, from the point of data collection. The metadata standards and data interoperability guidance service should provide information, training and guidance to improve data findability and interoperability through the use of standards. The service could be organised in a hybrid manner, with some central services and some provided in a federated manner (e.g., training at the country level available in different languages). Where the service could be provided remains a discussion point e.g., HealthData@EU central services, EOSC Health Research, RIs. Each approach has advantages and disadvantages. Resources will be needed to support personnel (including experts in specific standards and domains), as well as to support the technicalities needed.
Targeted issue	*Metadata standards guidance service* Currently, data is not being reused as much as it could be, and there is a need to support its findability, in line with the principle "Create once, use as many times as possible". There are a large number of different metadata schemas which do not always consider the same objects and attributes to describe a dataset. There are many initiatives working towards metadata catalogues, their interoperability, and mappings. If discoverability is to span all health-related research, these and similar initiatives should be encouraged, monitored, and ideally orchestrated, across all domains relevant to health. There is a need for the different approaches and schemas used for creating FAIR data in EOSC and the HealthData@EU infrastructure to be understood, coordinated, and harmonised. Ultimately, the schemas applied for supporting findability should be the same or interoperable across all health-related datasets and data infrastructures. Therefore, the metadata standards support service could provide information, guidance and training about available standards and support data providers in the creation of standardised metadata records for their datasets using common descriptive metadata standards, also improving the machine actionability of metadata. *Data interoperability guidance service* To use data from different collections and potentially link them at individual level, it is important to have them structured using the same standards (data models). Otherwise, data needs to be mapped to a common data model. Therefore, it is firstly important to structure data at source, at collection level and this support service would encourage the use of commonly recognisable standards at international level.

	Overall, this service aims to ensure the use of commonly recognised international metadata and data standards to facilitate findability and interoperability of datasets.
Potential benefit	● Improved reuse of health-related data. ● Findability of datasets and interoperability for efficient reuse of datasets. ● Indirect benefit on reproducibility of research. ● Capacity building for data holders and data users.
Potential difficulties	● Relies on engagement from data producers/data providers to adopt the standards and create metadata records for their datasets. Incentives may be required. ● Retrospective mapping of existing data. ● Defining how far the service can go and defining responsibility. ● Risk of duplication of this service with existing initiatives. ● How to position this service among other initiatives, providing a mandate.
Focus of service	● Training and materials. ● Data & metadata standards.
Type of service	● Guidance. ● Catalogue. ● User support. ● Expert support.

Service organisation	This service should be affiliated to or within larger initiatives, to ensure it is up to date with relevant changes:
	
	The EHDS legislative proposal provides the need to have data structured and interoperable. The implementing acts should mention the different data standards to be used. Moreover, the legislative proposal is highlighting the need for every data provider to create a metadata record for their datasets. Therefore, this support service could be either integrated as part of the activities of an RI or as part of the activities and services provided by EOSC. The EHDS proposed regulation proposes that requirements and specifications will be provided through implementing acts but there is always the need for a service that will support this implementation in the longer term.
	
	There are different possibilities for where this support service could be provided:
	● HealthData@EU central services:
	  ● Pros: direct link to EHDS.
	● Research infrastructures:
	  ● Pros: existing infrastructure available, staff available, experience, domain specificity and stable funding (but limited).
	  ● Cons: limited scope/domain.
	● EOSC Health Research:
	  ● Pros: can support implementation of the EHDS by accompanying the process.
	  ● Cons: not already existing, long time to implement.
	● Others, as funders see appropriate.

	Training could be federated and provided at national level (to be in the native language). Data standardisation bodies and Working Groups could be of high relevance for this service and help to avoid duplication by bringing them on board (e.g., CDISC, OMOP, FHIR). Some training could be provided through them, or guidance co-developed with them. Training/guidance could be provided by experts, personalised to the specific needs of the requestor.
Service conception	Depends on where the service is provided. Most likely could be **hybrid**: some central services for coordination, expert group, and provision of guidance documents etc. Some parts of the service should be federated, with support and training provided by local branches in different languages.
Relevant existing services	*Metadata standards guidance service* ● Existing initiatives (FAIRsharing [72], FAIRCORE4EOSC [52]). ● HealthData@EU pilot [37]: The project is designing the health extension to the DCAT-AP metadata standard that will be used for the descriptive metadata records in the HealthData@EU infrastructure. Guidelines and specifications will be provided for the implementation of this metadata standard. *Data interoperability guidance service* There are several services providing guidance etc on interoperability standards. ● FAIR Impact (FAIRness assessment for semantic artefacts) [73, 74] ● NCI Metathesaurus [75] centralised system for mapping. ● OMOP [76], FHIR [77], CDISC [78], SNOMED [79], EHDEN [25]. ● The planned TEHDAS2 and the recently awarded QUANTUM project dealing with the development of a data quality and utility label. ● EHDS for primary use: It will help increase standardisation & data quality. ● EOSC interoperability framework [80].
Users	Potential users (listed by priority): ● Data holders. ● Data providers. ● Healthcare professionals. ● Researchers. ● Data curators. ● Data stewards.
Potential service providers	● Research Infrastructures. ● “EOSC Health Research”. ● HealthData@EU central services. ● National training through RI nodes.
Development capacity needed	Take up guidelines and specifications provided by the HealthData@EU pilot project and the upcoming TEHDAS2.
Software components	Promote open-source solutions to support the services (e.g., FAIR Data Point for metadata catalogue supporting DCAT).
Hardware requirements	Cloud services offer scalability, agility, and elasticity to deploy services.
Expert involvement	Involvement of experts on specific standards to provide training, draft guidance etc.

Resources needed	Resources needed to develop, implement, and sustain the service: ● Technical resources. ● Personnel, including experts. ● Financial resources (to support personnel, provide incentives to data holders/data users for using data and metadata standards).

3.2.4 Service 4: A health research community interface service, with the EOSC

Title	**A health research community interface service, with the EOSC**
Writing Groups	**BSC**, BBMRI-ERIC, CHARITE, EATRIS, ECRIN, ELIXIR, IACS
Summary	"EOSC Health Research" acts as a proxy for the interaction of service providers and researchers in the health-related research realm, connecting with the rest of the proposed HRIC services. Such effort should reflect on the needs of researchers and how the EOSC generic (or specific) service providers can respond to them. When no specific service is identified, this space can act as a forum to drive its development and deployment, including its connection with the associated procured services.
Targeted issue	1) Need of a health research component in EOSC, or at least connected with EOSC, as health-related service providers/users are under-represented in EOSC. 2) Need alignment of existing service providers that are relevant to the community in terms of technical aspects and the associated training. 3) How SPEs developed within EOSC can enable health-related research; and how they can connect among them to facilitate transnational data analyses. 4) Need of clarity on the management and use of health-related data in the context of EOSC.
Potential benefit	1) Reference point for service providers and health researchers on how to engage with EOSC - especially with the core services - and how to benefit from using EOSC. 2) Serve as a gateway for EOSC to the health-related community of service providers and researchers. This gateway should serve EOSC for better understanding of what researchers may need/expect and what services can be provided.
Potential difficulties	1) How to show the added benefits of engaging with EOSC to existing service providers. 2) Make sure that service providers increase their visibility by being part of EOSC Health Research (not being hidden because of it). 3) Lack of existing capabilities that end-users can use right now for their research activities, e.g. computational capabilities for processing sensitive data. 4) Lack of clarity of the EOSC governance model dictating how to participate and contribute in the use of health-related data in connection with the EHDS.
Focus of service	*Characterisation of the focus of the service* 1) Serve as a reference point for the development of the health-related services in the context of the EOSC by bringing in all relevant stakeholders. The development of a roadmap should ensure this effort. 2) In the context of the proposed "EOSC Health Research", identify all relevant elements, e.g. training materials, data & metadata standards, specific sensitive data services, computational capabilities, quality frameworks among others, relevant for the community. Those elements would be ideally provided by the EOSC although specific requirements might need further developments, most likely in conjunction with the EHDS.

Type of service	This service can be integrated in the rest of the HRIC list of services following various paths: Path #1: 1) Community-driven portal keeping up to date materials that serve as guidance to various stakeholders using all possible elements: best practices, tutorials, wizards, workshops reports, etc. 2) Federated meta-catalogue visualising existing health-related data and computational infrastructures, including SPEs. Path #2: Through EOSC core services with a specific labelling of those elements relevant to the health-related community. Path #3: As part of the HRIC permanent structure and in connection with other services (e.g. Service 1).
Service organisation	*Affiliation of the service to or within larger initiatives* 1) EOSC, through a dedicated focus group or similar structure, in connection with other relevant services envisioned by the HRIC. 2) Connected to the governing body of the EHDS. 3) Aligned with the Data Spaces Support Centre blueprint [81, 82] 4) EDIC associated with ongoing projects like GDI and EUCAIM. 5) Research Infrastructures from the health-related domains together with existing Joint Actions or similar actors from the health-related research fields. 6) EC special interest group, including representatives from the above three groups.
Service conception	*How the service will be constructed* 1) Depends on the EOSC organisation, and the creation of a dedicated structure to host this effort (for example, implement as a "Thematic EOSC Node" [83]). 2) Include industry, patient association representatives, ELSI experts, data standards communities relevant for health-related research, RIs, population health institutes representatives and other stakeholders in collaboration with existing task forces and fora in EOSC, e.g., Working Group for ESFRI interactions. 3) Iteratively leveraging current efforts across different EOSC projects (e.g., EOSC-Life, EOSC4Cancer [84]) and EOSC Association task forces (e.g. FAIR metrics and data quality task force). 4) Services to be provided in a federated manner (meaning that the EOSC would rather serve as a single-entry point). 5) Consider using existing national nodes (this could help to be aligned with the HealthData@EU; even though it is not the main aim of this service, "EOSC Health Research" should be in line with it).
Relevant existing services	*Existing and planned services with overlap to the planned HRIC service* 1) INFRA-EOSC-01-06 projects will tackle the provision of TREs for sensitive data in the EOSC. This will tackle collection of specifications from different types of sensitive data owners, use cases and interoperability and quality aspects. 2) FAIRsharing has already catalogued a lot of the services provided by Life Science RIs, mostly related to data and metadata aspects.

	3) This could overlap with the proposed monitoring service from the EOSC. Thus, Service 4, in connection with the envisioned Service 1 could provide the health-related perspective to EOSC. 4) This can be enhanced with the existing EOSC (core) services once the connection is formally established.
Users	1) Researchers 2) Policy makers 3) Data specialists (Data curator, data manager and data steward) 4) Infrastructure providers
Potential service provider	Research Infrastructures, universities, research Institutes, public health institutes, e-Infrastructures, industrial partners, data standards consortia (e.g., OHDSI, OpenEHR), standards development organisations SDOs (ISO, CEN, HL7) national nodes (e.g., HDABs at HealthData@EU).
Development capacity needed	A Maturity Model could be useful to define what, who, where, when can address those needs.
Software components	The Open Science should be present in the development of any software component being utilised in this space to guarantee its potential reuse, inspection, and sustainability over time. Ideally, any software component should incorporate security and privacy elements by design when dealing with potentially sensitive data to minimise the risk of data misuse.
Hardware requirements	Special hardware, e.g., data encryption in memory, could be considered although the use of adequate software components should reduce this particular need.
Expert involvement	Different levels of expertise needed: 1) To build a health research community within EOSC: Biomedical Research Infrastructures working with health-related data, e.g. ECRIN, BBMRI, EATRIS, ELIXIR, Euro-BioImaging; Joint Actions or similar actors from the health research fields, ELSI experts, experts working on data and metadata standards for health research. 2) Industry representatives, e.g., SMEs, EFPIA, to discuss the implementation at scale and to cover the innovation component. 3) Patient organisation representatives to ensure that they can take an active role on how their data is being utilised for research and to serve as a dissemination mechanism with the general public. EDICs associated with ongoing projects like GDI and EUCAIM. 4) One or more Research Infrastructures from the Biomedical domains together with existing Joint Actions or similar actors from the health research domain. 5) EC special interest group, including representatives from the above three groups.
Resources needed	*Resources needed to develop, implement and sustain the service.* Need people willing to be part of "EOSC Health Research", and the software and hardware requirements mentioned above.

3.2.5 Service 5: A health research community interface service, with HealthData@EU

Title	**A health research community interface service, with HealthData@EU**
Writing Group	**IACS**, ECRIN, Sciensano
Summary	This service is intended to capture the necessities and requirements of the health-related research communities to aid them in the adoption of the EHDS capabilities. It includes both the data users and the data providers.
Targeted issue	The EHDS will be a disruptive actor when accessing health data for research purposes (among others). It would be necessary to have a direct communication channel to health researchers to inform about its capabilities to maximise its usage.
Potential benefit	Guarantees the alignment of the requirements of the communities represented. Increase the uptake of the HealthData@EU infrastructure by the communities.
Potential difficulties	Effective development of the EHDS per se, specially related to: ● Setup of the HDABs per Member State. ● Inclusion of data providers/holders in the EHDS ecosystem (possible resistance). ● Data users' adoption due to fragmentation of data discovery and data access between healthcare data in the EHDS and existing research data in other existing databases/repositories.
Focus of service	Monitoring the evolution of the HealthData@EU services, data and metadata standards of choice (some overlap with Service 3) and technological solutions provided for SPEs.
Type of service	● Monitoring ● Guidance/User support ● Data provider support
Service organisation	Interest group/association including representatives of different RIs/research domains. ● EOSC (capacity provision). ● EHDS (legal framework, data discovery and provision, capacity provision for analysis). ● Health-related RIs (capture community demands, curate high quality data resources, guarantee interoperability).
Service conception	Central service for monitoring the EHDS evolution and generating materials for the data users/data providers. It might require a federated side to tackle the particularities on how data providers may interact with local HDAB. Dedicated groups/task forces to capture and analyse requirements. Dedicated groups to translate the requirements to the different levels of interoperability (legal, organisational, semantical, technical).
Relevant existing services	EHDS is expected to provide: ● Data cataloguing (standard under development) ● Data Discovery (to be derived from the cataloguing) ● Data access request (technicalities to be described) ● Data analysis/SPEs (technicalities to be described) In general, EHDS specific semantic/technical interoperability is delegated to implementing acts.
Users	● Data users ● Data providers

Potential service provider	Health-related RIs / e-Infrastructures: Personnel from these institutions should provide the strategic and technical capacity.
Development capacity needed	Generation of materials to aid in the capacity building of data users/data providers.
Software components	Portal to gather the guiding and training materials.
Hardware requirements	N/A
Expert involvement	Software experts to facilitate semantical and technological interoperability. Hardware experts to facilitate technological interoperability.
Resources needed	Personnel to monitor and generate the guidelines and training materials and central and federated level.

3.3 Similarities and synergies between services

There are similarities in the way the services are conceptualised and how a possible work programme could be organised. The following components are foreseen for the HRIC for one or more of the services:

- Central coordination (minimal)
- Federated organisation
- Expert/focus/interest group
- Monitoring
- Catalogue of resources
- User portal
- Provision of material (training, guidance)
- Active support

Table 2 provides an overview of the distribution of the components foreseen for the individual services.

Component	***Service***				
	1	*2*	*3*	*4*	*5*
Central coordination	*yes*	*yes*	*yes*	*yes*	*yes*
Federated organisation	*-*	*yes*	*yes*	*yes*	*yes*
Expert/focus/ interest group	*yes*	*yes*	*yes*	*yes*	*Yes*
Monitoring	*yes*	*yes*	*-*	*-*	*-*
Catalogue of resources	*-*	*yes*	*yes*	*yes*	*yes*
User portal	*-*	*yes*	*yes*	*yes*	*yes*
Provision of material	*yes*	*-*	*-*	*yes*	*yes*
Active support	*-*	*yes*	*yes*	*-*	*-*
Other	*-*	*-*	*Linked to EHDS*	*Linked to EOSC*	*Linked to EHDS*

Table 2: Overview of the HRIC service components

All services need at least a (minimal) central coordination and all but one a coordinating expert/focus/interest group:

- Service 1: A monitoring service for health-related research (*High-level expert group with permanent secretariat*)
- Service 2: A legal/regulatory guidance service (*Minimal central coordination and a specific expert/focus group*)
- Service 3: A metadata standards and data interoperability guidance service (*Minimal central coordination by expert group*)
- Service 4: A health research community interface service, with the EOSC (*Minimal central coordination by focus group*)

- Service 5: A health research community interface service, with the HealthData@EU
  (*Minimal central coordination by interest group*)

It needs to be determined how synergies in the design of the services can be used to minimise the administrative overload and avoid duplicating efforts. Another worthwhile task would be to develop a strategy for how the different central components of the services can be organised and orchestrated.

Service 1 is a bit different from the other services in that it plans to provide monitoring of health-related research initiatives and activities from a high-level perspective and not specifically dedicated to certain infrastructures/initiatives (e.g., EOSC, EHDS) or specific topics (e.g., legal/regulatory aspects). Service 2 also has a monitoring component but restricted to policies related to legal/regulatory aspects. There is a clear need to coordinate these monitoring activities between Service 1 and Service 2. Furthermore, it is foreseen that Service 1 will monitor and report on the progress of all the other services offered under the HRIC initiative.

All services (except Service 1) foresee the involvement of existing partners to provide the services. The idea is to implement a federated approach, using existing infrastructures, skills, and resources as much as possible. A major need for the involvement of all relevant health-related RIs in the provision of services is considered by Service 2 (here mainly BBMRI-ERIC) and all other services (except Service 1 which has another target).

All services rely on the involvement of an expert/focus/interest group, however with a different focus and conception.

All services (except Service 1) plan to provide a catalogue of relevant resources related to their target as well as a platform to support users. It would certainly make sense to coordinate these activities and integrate the different catalogues and portals into a single system.

Three services are planning to generate new material related to their service. Service 1 proposes to publish regular reports evaluating the progress of health-related services against goals and providing feedback on gaps and needs from the scientific community. Service 4 aims to provide a reference-point in EOSC for health-related research services with development of a roadmap, and Service 5 plans to generate guidelines and training material for engaging data providers/users with the HealthData@EU.

Active support services are foreseen only by Service 2, with advice on legal and regulatory aspects related to projects, and by Service 3, offering training to users on metadata and data standards.

Service 4 will be closely linked to EOSC and its governance, and Service 5 to the HealthData@EU and related activities. Here it is of major importance the way the link with the governance structures can be established to ensure optimal communication and input into relevant decision-making processes.

The overall concept for the HRIC and its services are illustrated in Figure 2. The HRIC will be managed by a (minimal) coordination and orchestration body. The services as such

will be organised by expert/focus/interest groups and will be provided in a federated manner by existing RIs and via other partners (e.g. data standards consortia). The instruments, tools and procedures applied differ between the services and cover catalogues of resources, a user platform, provision of material and active support services. The EOSC and the HealthData@EU will be active partners during all the phases of the development and maintenance of the services.

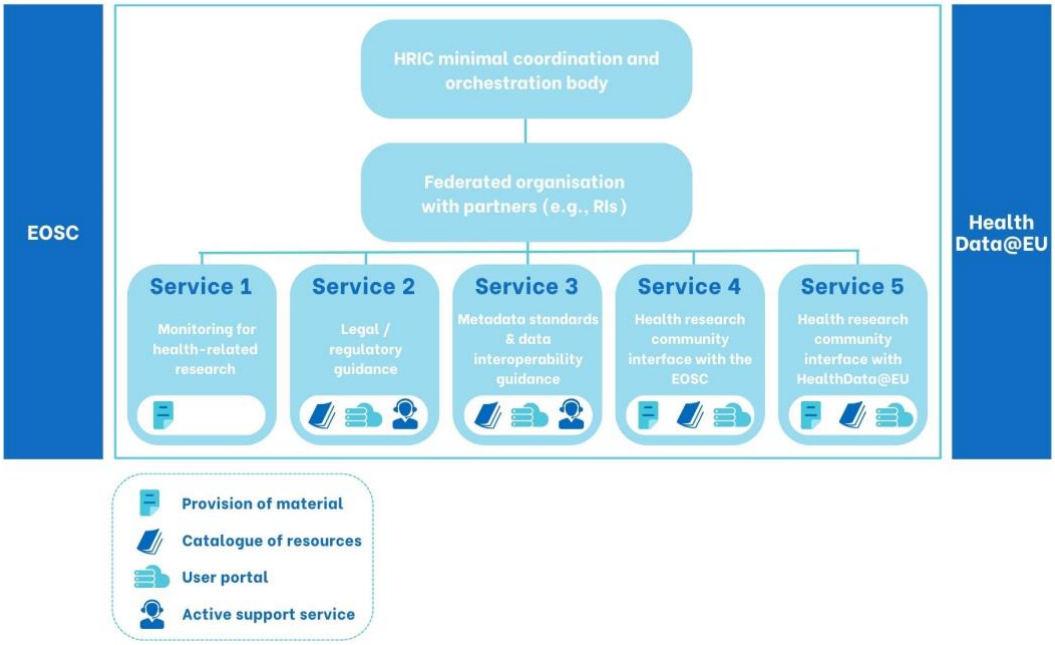

Figure 2: Organisation of the HRIC and its proposed five services

4 Implementation and sustainability

The five proposed HRIC services are derived from the needs and gaps identified and specified in this document. This includes proposals for the focus, conception, organisation, and implementation of the services. What is still missing is a concrete plan with respect to:

- Affiliation/organisation
- Governance
- Authorisation
- Funding

Here, no definitive decisions could be taken for the final Strategic Agenda due to the given uncertainties in the landscape (e.g., related to EOSC, EHDS) and the lack of a specific funding stream for the HRIC and its services. Nevertheless, implementation and sustainability issues were intensively discussed in the stakeholder workshops and within the HealthyCloud consortium. The main ideas and concepts put forward are presented below.

4.1 Affiliation / Organisation

To be able to provide an implementation plan, some fundamental decisions must first be made. A major question is whether the services proposed for the HRIC should be bundled in a separate organisation or affiliated to existing organisations (e.g., EOSC). This Strategic Agenda adopts an agnostic position in this regard. Options could be an affiliation to EOSC as, for example, “EOSC Health Research” or a research part in the EHDS as “HealthData@EU for research”. The main points of discussion can be summarised as follows:

- In initial discussions, the HRIC was usually (and often still is) referred to as “EOSC Health Research”, although to be fair, at that stage the EHDS proposal had not yet been published.
- Several of the initiatives within EOSC projects, such as the work on discovery metadata, already overlap with some of the services described for the HRIC.
- The perception that EOSC, with its broad remit within science, would be a more natural and flexible “home” for an interdisciplinary structure like a HRIC.
- The concern expressed by some HealthyCloud members (certainly not all) that the EHDS will inevitably be too focused on developing systems to manage routine health data to have sufficient capacity to handle a wide variety of research generated data.

That said, if it turns out that the EHDS has the funds to develop services and the EOSC does not, or if the EHDS development proceeds at a faster pace than the EOSC, we see no difficulty at all in embedding services within the EHDS, so that instead of being “EOSC Health Research”, the HRIC becomes “EHDS Research”. The requirement is that the identified services are developed and maintained, and the “banner” under which this happens is irrelevant. The assumption is that the various health-related research communities will also not care in any meaningful way how those services are funded, branded, or organised - their concern will be with the usefulness of the service.

However, it is clear that any work provided for a HRIC must be aligned with the work of both EOSC and EHDS and with other initiatives. This requires constant dialogue with these organisations or, better still, a joint action. A concrete plan for any kind of cooperation cannot be provided at this time, as EOSC is a moving target currently undergoing profound changes and the EHDS is still under construction. Competition between the EHDS, the EOSC and other initiatives should be avoided. Therefore, if a development and pilot phase is proposed for the HRIC, EOSC and EHDS representatives should participate in the project organisation and work plan. In such a project, the role of the EC, which proposed the concept of HRIC, could also be clarified.

In this context, the possible creation of an EU Mission on "Health Research and Innovation" should also be explored. EU Missions [85] are a coordinated effort by the Commission to pool the necessary resources in terms of funding programmes, policies, and regulations, as well as other activities. They also aim to mobilise and activate public and private actors, such as EU Member States, regional and local authorities, research institutes and will engage with citizens to boost societal uptake of new solutions and approaches. An EU-mission or "mission-like" approach for "Health Research and Innovation" could be a useful instrument to refine the HRIC strategy and to support implementation through a series of calls and projects. The EU Cancer Mission [86] is a successful example of this. Another point to clarify is whether the HRIC and its services need a specific branding or whether they can be integrated into the infrastructures it may be affiliated to.

It should be clear that, from a long-term perspective, the HRIC should bring together all relevant communities and stakeholders. The involvement of the EOSC, the EHDS, the health-related RIs and the EC is essential. Also, patients and the public should play a major role. National developments related to the proposed services should be adequately reflected in the work of the HRIC, and existing national mirror groups (e.g., as formed in the 1+MG initiative) were proposed to support communication and alignment. Regular feedback with standardisation bodies and other related stakeholder groups is also necessary. The HRIC and its services should take a broad perspective with a cross-domain approach, covering all health-related areas, including life sciences, social sciences and humanities, and environmental sciences. All health-related research domains need to be represented in the expert groups and boards to be set up.

4.2 Governance

In the Strategic Agenda, the needs and technical requirements for the services have been captured, and it was agreed to deal with the governance aspects in a second phase. A possible governance model for the HRIC depends on the envisaged organisational structure. If a HRIC is affiliated to another organisation (e.g., EOSC), it must be embedded into the governance of that organisation. It remains to be determined whether such an integration is possible in principle, whether adaptations are necessary, and whether the existing governance models should be reviewed. In any case, if such a model is feasible, existing structures can be used and administrative overheads can be minimised. At least for the monitoring service, integration into an existing organisation is not foreseen, to keep independence of major projects and initiatives. For other services, hybrid models with a minimum central coordination and provision of the services by the individual RIs are preferred. How to embed such a concept in existing

infrastructures or initiatives (EOSC, HealthData@EU) and who should be responsible for the services is a matter of negotiation and available resources, which should be extensively explored, discussed, and decided during the development and pilot phase of the HRIC.

The role of the health-related RIs in a HRIC must be clearly specified. The idea is to connect the planned services to existing services in the RIs. A reasonable approach could be to define and share the governance of a HRIC with the RIs and relevant research networks. Embedding the planned services into health-related RIs may have major advantages. Services could rely on permanent infrastructures, an existing legal framework could be used, experiences with similar services are already available and the administrative overload could be reduced compared to implementing new infrastructures.

4.3 Authorisation

The five planned services cover different types of service components with certain areas of overlap. A major element in all but one of the services is the creation of expert/focus/interest groups. How the members of these groups are selected and appointed, and how the work of these groups is authorised to enable them to fulfil their responsibilities remain to be defined. It should be explored whether implementation as an EC Expert Group is feasible and useful. If that is the case, the service should be authorised, and the members of the expert group appointed by the EC. The selection of expert group members could then be established as a permanent Open Call for applications. If the HRIC is affiliated to existing organisations, such as the EOSC, the needed expert groups could be integrated into the governance structure of these organisations and could use their power and reputation to fulfil their work (e.g., EOSC boards or task forces). In the stakeholder meetings it was suggested that experts involved in providing the services could be mandated by an RI health-related subgroup. The situation may become more difficult when expert groups have no specific authorisation for their work and function primarily as advisory boards. Then specific measures must be undertaken to foster uptake of the material and guidance developed for the health-related research community by the expert groups and to facilitate capacity building for the scientific community.

4.4 Funding

With respect to funding, the following two phases should be distinguished:

1. Development and pilot phase
2. Maintenance and sustainability phase

The development and pilot phase should be limited to 2-3 years and should be supported by project-based EC funding (e.g., another CSA). The Open Call methodology of the OSCARS project offers a potential route for the continuation of some activities of HealthyCloud, and the development of the HRIC before definitive funding is assured. OSCARS brings together RIs organised into five "Science Clusters" along the ESFRI thematic research domains and will support new Open Science projects, that together will drive the uptake of FAIR data intensive research across the European Research Area.

However, the OSCARS Open Calls are expected to award projects of ca. €100,000, and last for ca. 12 months. It is therefore essential to explore other avenues to ensure the generation of a sustainable HRIC.

The development and pilot phase should provide the procedures and tools needed for technical implementation of the services based upon the Strategic Agenda developed by the HealthyCloud project. During this phase the services will be implemented and tested. Furthermore, during this phase, a stable business and sustainability plan should be provided for the period following the development and pilot phase. This requires a detailed costing and financial plan, working out the costs for the individual service components, ranging from resource-intensive and costly services (e.g., active legal/ethical support by experts) to services where the resource input may be limited (e.g., catalogue of resources). In the design, consideration should be given to whether existing RIs could and should be involved to provide the services to minimise administrative overload or whether alternative approaches are necessary. To support decision-making, different models should be developed, ranging from minimum to maximum implementation of the five proposed services.

Different types of financing should be carefully explored and decisions for long-term funding should be taken. Time-limited project funding may help to technically specify and launch the services, but project-based funding will not work in the long term and durable funding is needed for maintaining the services. During the stakeholder workshops, different options were discussed, such as “fee for services”, in kind contributions from existing RIs, funding by contributions from the Member States and funding by the EC by making use of the services an eligible category in EC funding of projects. A possible approach could be to combine several of these or other funding streams. Of relevance here could be the discussion on funding of data sharing activities. Data sharing is highly promoted by the EC and many other organisations, but the funding model is still unclear. Three major options are being discussed, such as taking over the costs by the data providers as part of research grants, requiring fees for reuse from potential data users (e.g., as the pay-per-use model adopted by EHDS) or providing sustainable funding from (possibly different) funding bodies. It turns out that fees or any other type of direct costs to data providers and data users may create major hurdles, slowing down or even preventing the implementation of open research and open science. Therefore, any kind of “fees for service” model does not seem promising for the implementation of the HRIC and its services.

From the stakeholder workshops it can be concluded that for the HRIC, a low cost-solution should be aimed at, building upon what is already existing and running, and avoiding too much administrative overhead. New infrastructures are not necessary, and the services envisaged could be provided by existing RIs and in alignment with EOSC, EHDS and other organisations. If carefully designed and implemented, it could become a cost-efficient model for similar activities of the EC in the future.

A good example of how this could work and lead to durable services are the ESFRI infrastructures. For example, ECRIN, the European Infrastructure on Clinical Research, was created in 2004 with seed funding from the EC (CSA). Thereafter, three projects were successively funded by the EC from 2006 to 2011 to prepare a sustainable infrastructure with stable services for the research community. Finally, in 2013, ECRIN

obtained the legal status of European Research Infrastructure Consortium (ERIC), enabling member and observer country contributions that sustain the core of the organisation. Today, ECRIN and a number of other RIs in the life sciences are well established, some of them with an ESFRI landmark status. Given the severe gaps and needs identified in HealthyCloud and the time pressure to implement solutions, such a process is certainly too long and needs to be streamlined for the HRIC if it is to be realised sooner rather than later.

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6 Acronyms and Abbreviations

AAI	Authentication and Authorization Infrastructure
AI	Artificial Intelligence
BBMRI	Biobanking and BioMolecular resources Research Infrastructure
BSC	Barcelona Supercomputing Center
BY-COVID	Beyond COVID (*project acronym*)
CDISC	Clinical Data Interchange Standards Consortium
COVID	Coronavirus disease
CRG	Centre for Genomic Regulation
CSA	Coordination & Support Action
DARWIN	Data Analysis and Real World Interrogation Network (*project acronym*)
DCAT AP	Data Catalog Vocabulary Application Profile
DG RTD	Directorate-General for Research and Innovation
EATRIS	European infrastructure for translational medicine
EC	European Commission
ECRIN	European Clinical Research Infrastructure Network
EDIC	European Digital Infrastructure Consortium
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EGI	European Grid Infrastructure
EHDEN	European Health Data Evidence Network (*project acronym*)
EHDS	European Health Data Space

EHR	Electronic Health Record
ELIXIR	European life-sciences Infrastructure for biological Information
ELSI	Ethical, Legal and Social Issues
EMA	European Medicines Agency
EOSC	European Open Science Cloud
ERA	European Research Area
ERIC	European Research Infrastructure Consortium
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
EU-AMRI	European Alliance of Medical Research Infrastructures
EUCAIM	European Federation for Cancer Images
FAIR	Findability, Accessibility, Interoperability, and Reusability
FHIR	Fast Healthcare Interoperability Resources
GDI	Genomic Data Infrastructure
GDPR	General Data Protection Regulation
GXDCH	Gaia-X Digital Clearing House
HDAB	Health Data Access Body
HL7	Health Level Seven International
HRIC	Health Research and Innovation Cloud
IACS	Health Sciences Institute in Aragon
1+MG	1+ Million Genomes Initiative
IT	Information Technology
NIHR	National Institute for Health and Care Research
OHDSI	Observational Health Data Sciences and Informatics
OMOP	Observational Medical Outcomes Partnership
OSCARS	Open Science Clusters' Action for Research and Society (*project acronym*)

PHIRI	Population Health Information Research Infrastructure (*project acronym*)
PNED	Luxembourg National Data Service
RDF	Resource Description Framework
RI	Research Infrastructure
RWD	Real World Data
SAS	Andalusian Health Service
SME	Small and medium-sized enterprises
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SPE	Secure Processing Environment
TEHDAS JA	Towards the European Health Data Space Joint Action (*project acronym*)
TMF	Technology, Methods, and Infrastructure for Networked Medical Research
TRE	Trusted Research Environment
TSD	Service for Sensitive Data
U.S.A.	United States of America
VRE	Virtual Research Environment
WHO	World Health Organisation
WP	Work Package