



HEALTHYCLOUD

Health Research & Innovation Cloud

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

HealthyCloud GAM, 2nd October 2023

Jacques Demotes - ECRIN



The HealthyCloud Strategic Agenda

The screenshot shows the Zenodo project page for the 'Final HealthyCloud Strategic Agenda for the Health Research Innovation Cloud'. The page features a blue header with the Zenodo logo, a search bar, and navigation links for 'Upload' and 'Communities'. On the right, there are 'Log in' and 'Sign up' buttons. The main content area includes the project title, authors (Canham, Steve; Ohman, Christian; Demotes-Mainard, Jacques; Panagiotopoulou, Maria; Rujano, Maria Alexandra), project leader (González-García, Juan; Capella-Gutiérrez, Salvador), project members (Matei, Mihaela; Bernal-Delgado, Enrique; García-Armesto, Sandra; Valencia, Alfonso; Jene-Sanz, Alba; Lopez-Cuesta, Lidia; Satagopam, Venkata; Gu, Wei; Schluender, Irene; Schutte, Nienke; Lekadir, Karim; Dietrich, Mark; Sipos, Gergely), supervisor (Martínez-Martínez, Ricard), and work package leader (Blomberg, Niklas; Merchant, Arshiya; Chatterjee, Anamika; Saunders, Gary; Portell-Silva, Laura; Thorogood, Adrian; Becker, Regina; Holub, Petr; Mayrhofer, Michaela Th.; Garcia-Alvarez, Eva; Kessissoglou, Irene; Cosgrove, Shona; Martínez-García, Alicia; C. Alvarez Romero; Parra-Calderón, Carlos Luis; Barysch, Sina; D'Altri, Teresa; Wagener, Harald). On the right side, there are statistics: 988 views and 628 downloads, with a 'See more details...' link. Below that, it says 'Indexed in OpenAIRE'. At the bottom right, the publication date is September 29, 2023, the DOI is 10.5281/zenodo.8389643, and there are no keywords listed.

September 29, 2023 Project deliverable Open Access

Final HealthyCloud Strategic Agenda for the Health Research Innovation Cloud

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González-García, Juan; Capella-Gutiérrez, Salvador

Project member(s)

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Supervisor(s)

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Keyword(s):



Pre-final, version 2: <https://doi.org/10.5281/zenodo.8389643>

March 2021



**HealthyCloud
kick-off**

*21 partners from 11
countries...*

May 2021



**Joint
Workshop**

*With EOSC-Life, TEHDAS
JA, B1MG, PHIRI...*

Sept 2021 – Jan 2022



**Discussion
Paper**

*Listing challenges & tasks
for the HRIC...*

Apr – June 2022



**Vision &
Mission**

*Priority: Agreeing on
HRIC's vision & mission...*

June 2022



**Consensus
Building**

*Internal workshop in
Paris...*

October 2022



**Draft Strategic
Agenda**

*Feedback collection
from all HyC...*

Dec 2022 – June 2023



**Stakeholder
Workshops**

*4 stakeholder workshops
planned...*

November 2023



**Final Strategic
Agenda**

*Based on stakeholder feedback +
internal Writing Groups...*



The HRIC and HealthyCloud – Genesis

In March 2018, the Health Directorate of the EC Directorate-General for Research and Innovation organized a workshop to discuss opportunities and challenges of establishing a pan-European **Health Research and Innovation Cloud (HRIC)**.

Reported in 2020, as <https://doi.org/10.1186/s13073-020-0713-z>

Opinion | [Open Access](#) | [Published: 19 February 2020](#)

Towards a European health research and innovation cloud (HRIC)

[F. M. Aarestrup](#), [A. Albeyatti](#), [W. J. Armitage](#), [C. Auffray](#) , [L. Augello](#), [R. Balling](#), [N. Benhabiles](#) , [G. Bertolini](#), [J. G. Bjaalie](#), [M. Black](#), [N. Blomberg](#) , [P. Bogaert](#), [M. Bubak](#), [B. Claerhout](#), [L. Clarke](#), [B. De Meulder](#), [G. D'Errico](#), [A. Di Meglio](#), [N. Forgo](#), [C. Gans-Combe](#), [A. E. Gray](#), [I. Gut](#), [A. Gyllenberg](#), [G. Hemmrich-Stanisak](#) ... [H. Van Oyen](#)  Show authors

Genome Medicine **12**, Article number: 18 (2020) | [Cite this article](#)

8806 Accesses | **24** Citations | **48** Altmetric | [Metrics](#)

Abstract

The European Union (EU) initiative on the Digital Transformation of Health and Care (Digicare) aims to provide the conditions necessary for building a secure, flexible, and decentralized digital health infrastructure. Creating a European Health Research and Innovation Cloud (HRIC) within this environment should enable data sharing and analysis for health research across the EU, in compliance with data protection legislation while preserving the full trust of the participants. Such a HRIC should learn from and build on existing data infrastructures, integrate best practices, and focus on the concrete needs of the community in terms of technologies, governance, management, regulation, and ethics requirements. Here, we describe the vision and expected benefits of digital data sharing in health research activities

The 2018 HRIC Recommendations

Provide and foster standards, good practices, and guidelines necessary to establish the European HRIC

Develop and certify the infrastructure and services required for operation of the HRIC

Enable the HRIC to operate within an ethical and legal framework that is adequate for health systems

Establish a proper environment for the training of a new generation of data and medical scientists

Fund public and private initiatives for the development of the HRIC through EU Framework Programmes (Horizon 2020 and Horizon Europe)

The HealthyCloud project

Coordination & Support Action under Horizon 2020.

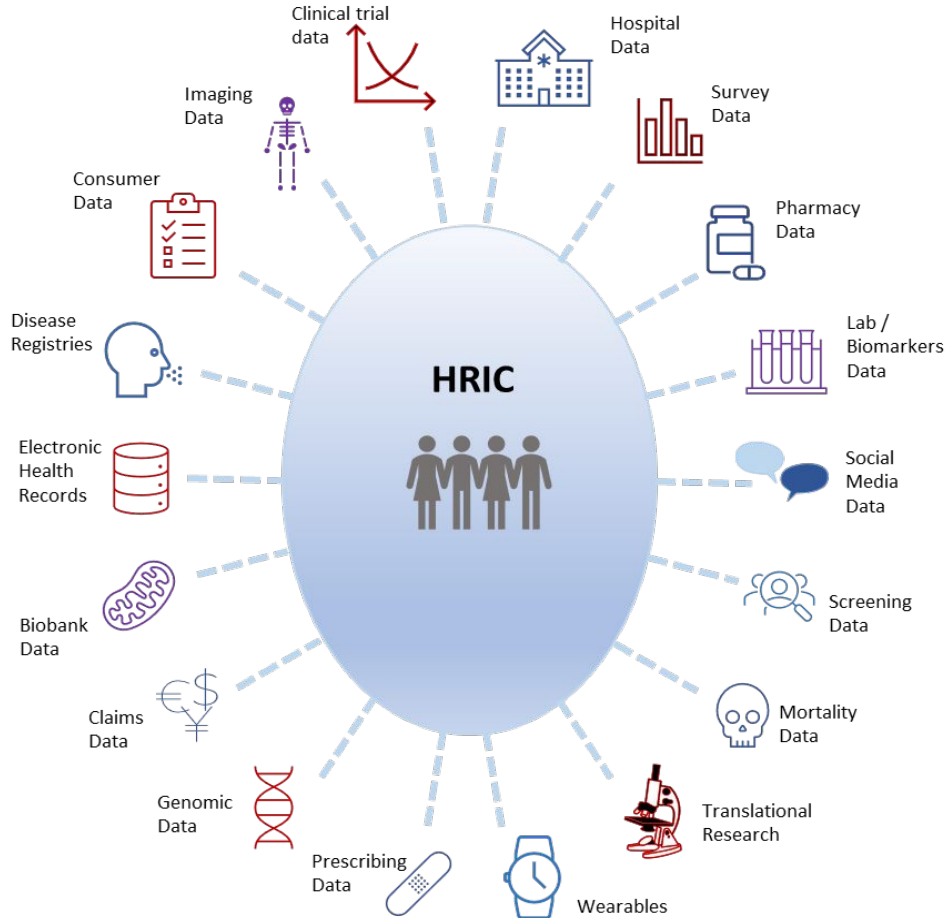
Kick-off in **March 2021**. End in **November 2023**.

8 different WPs, including WP1: Coordination.

- WP2 Ethical, Legal and Societal impact of cross-border health data access for cloud analysis
- WP3 Health data landscape analysis
- WP4 Experiences on health data management: national, regional and domain-specific data hubs
- WP5 Designing a decentralized cloud for health data research
- WP6 Reference architecture for a FAIR health data portal
- WP7 2 real world use-cases (cancer and atrial fibrillation)

Aim of WP8: To produce a **Strategic Agenda** to advance the establishment of the European HRIC, that can be up-taken by the EC and the Member States.

Heterogeneity Issues



- In data types
- In data sources
- In users
- In terminologies
- In data organisation
- In jurisdictions
- In regulations
- In languages
- In challenges

The changing landscape (I)



Strategy for data
(2020)

AI Act
(2021)

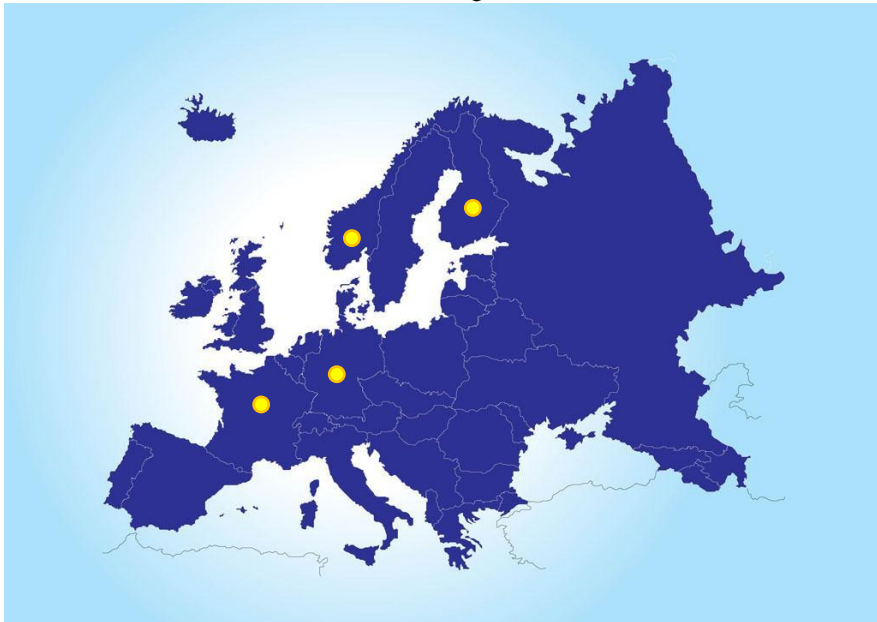
Data Act
(2022)

Proposal for a regulation on the EHDS
(2022)

Digital Decade Policy Programme 2030
(2023)

Data Governance Act
(2023)

The changing landscape (II)



France:



Finland:



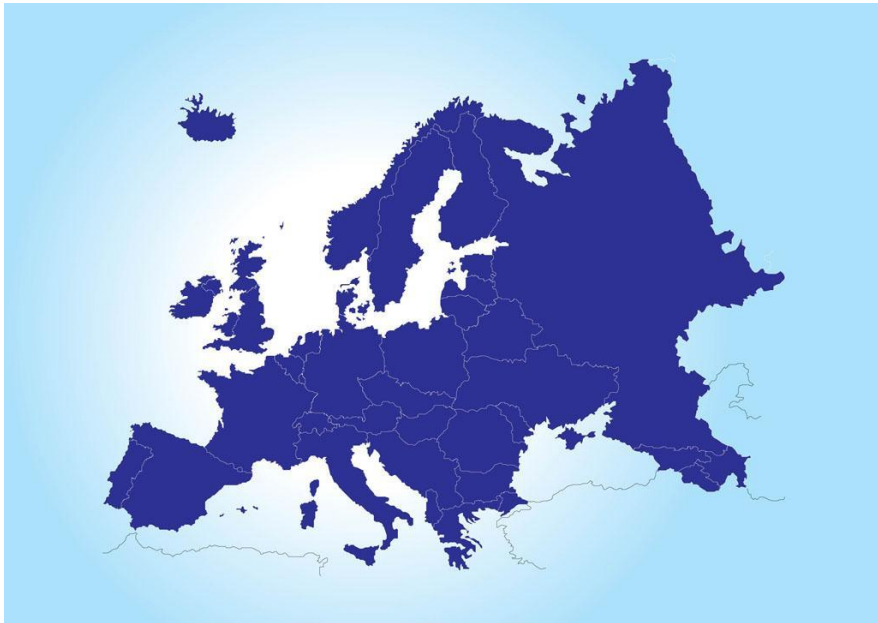
Germany:



Norway:



The changing landscape (III)



The changing landscape (IV)

<p>European Open Science Cloud (EOSC)</p>	<p>Increasing number of provided services to support open science and FAIR data management, including in the life-sciences domain.</p>
<p>European Health Data Space (EHDS) and HealthData@EU</p>	<p>Specifically includes provisions for the secondary use of health data for research, innovations and the support of policy making</p>



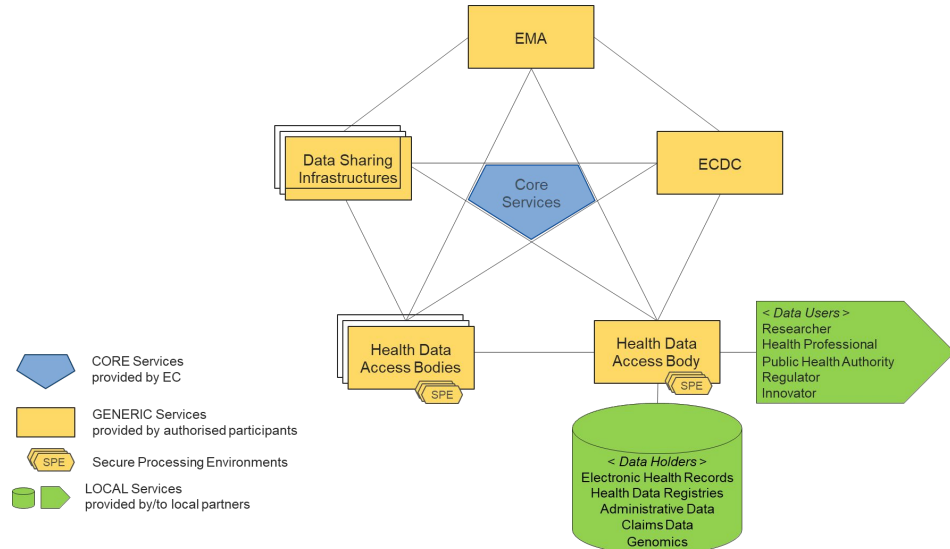

EUROPEAN OPEN SCIENCE CLOUD

Your unified access to the European hub of research data, tools and services for innovation and education

Search... Marketplace

3m+ Assets in the marketplace

300+ Content providers



Gaps + Uncertainties = Needs

For...

- Better coordination between development, over extended time periods
- Specific support for sensitive data management
- Better legal and regulatory guidance
- Good support for multinational research, especially using Real World Data (RWD)
- Greater data interoperability – amidst huge data diversity
- Improved data findability, especially across traditional domains, and RWD
- Clarifying roles of EOSC and HealthData@EU, and their interaction
- Provision of Secure Processing Environments (SPEs)
- Retaining public involvement and trust
- Good links to and interactions with existing Research Infrastructures (RIs)
- Adequate training

HRIC's vision & key values

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.

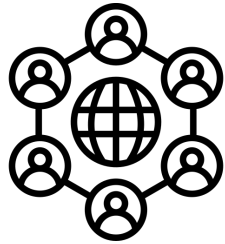
The HRIC must:

- Be **collaborative** and have a **multi-stakeholder approach**.
- Retain a European focus but be **global** in scope.
- Be demonstrably **useful to research communities**.
- Promote the application of the **FAIR principles** and commit to **Open Science practices**.
- Uphold the **protection of privacy** and promote the **safe use of citizens' health data**.
- Be **integrated with existing systems** where possible.



HRIC services

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



1. A monitoring service for health-related research

High-level monitoring functionality, providing **periodic reports** to the health-related research communities, and the EC, about the “**state of play**” of health-related research data and the **progress** towards goals that had been previously identified (‘check point’)

Targeted issue

- Problems and needs arising from **inadequate, delayed or uncoordinated implementation** of health-related research initiatives/programmes in Europe.

Service conception

- High-level **expert group** with adequate representation of health-related research communities.
- Co-development of service **with EOSC/EHDS** to ensure adequate orchestration.
- Forum representing **all relevant stakeholders** from health-research (**all health determinants**, including general public representatives, industry).

Potential benefit

- **Oversight** and transparency on health-related research initiatives/programmes.
- Cross-project / initiatives **evaluation**, with proposals to **adjust** accordingly
- Sustained effort to **inform ALL stakeholders**

Resources needed

- Another **CSA** or a **Joint Action** to implement the service (involvement of EHDS & EOSC).
- An expert group with a **secretariat** & ToR
- An **EU Mission** on “Health Research and Innovation” ?

2. A legal/regulatory guidance service

Centre of **expertise and resources** around **legal and regulatory issues** (provide material to help researchers interpret and comply with regulations), ensure that the views of researchers on these issues are known and fed into the broader **debates on the evolving legal and regulatory framework**.

Targeted issue

- Existing ELSI Services (local and pan-European level) **address some but not all** ethical, legal and societal needs relevant to the HRIC ecosystem.
- The health-related research community is insufficiently represented in the **policy-making, regulatory, and legislative discussions** taking place at the European and Member State levels.

Potential benefit

- Provide material, guidance and support to researchers willing to **share and/or access** health-related data for research purposes.
- Represent the collective interests of the HRIC community in the **policy-making, regulatory, and legislative process**.

Service conception

Component 1: HRIC Legal/Regulatory **Community Resources**

Component 2: HRIC Legal/Regulatory **Support**

Component 3: HRIC Legal/Regulatory **Policy Monitoring**

Hybrid organisation: Central coordination + Outsourcing to existing service providers (e.g. BBMRI ELSI services)

Resources needed

- Component 1: Possible **in-kind** contributions of RIs.
- Component 2: **Public funding** due to equity and accessibility concerns.
- Component 3: benefit for the **community as a whole**

3. Metadata standards and data interoperability guidance service

Centre of **expertise and resources** to support the development, promotion and application of more **consistent metadata and data standards** within health-related research

Targeted issue

- **Different metadata schemas**, do not always consider the same objects and attributes to describe a dataset
- Data integration requires **interoperability** based on common data / metadata standards

Service conception

Involvement of **data standardization bodies** (CDISC, OMOP).

Hybrid:

Central for coordination, expert group, guidance documents
Federated for training (local branches, different languages)

Potential benefit

- **Findability** of datasets, **interoperability** for efficient **reuse and integration** of datasets.
- Indirect benefit on **reproducibility** of research.
- **Capacity building** for data providers and data users.

Resources needed

Provided within/by:

- **HealthData@EU** central services
- **RIs**
- **EOSC Health Research**

Technical, personnel & experts, **financial** (e.g., incentives to data providers)

4. A health research community interface service, with the EOSC

“**EOSC Health Research**” acts as a proxy for the interaction of EOSC service providers and researchers in the health-related realm, connecting with the rest of the proposed HRIC services. **Services within EOSC** that address community needs are identified and **new services co-designed and deployed**.

Targeted issue

- Need of a **health research component in EOSC**. Health-related service providers/users are under-represented.
- Align relevant **EOSC service providers with the health-related research community** (e.g., raise awareness).
- Monitor **SPE development within EOSC** to enable

Service conception

- Community-driven **portal** providing guidance to stakeholders (e.g., tutorials, workshops, reports, etc.)
- Federated **meta-catalogue** : existing health-related services, data and computational infrastructures, including SPEs.

Potential benefit

- Reference point for service providers and health researchers : **how to engage with EOSC and benefit from it** (e.g., embed core services).
- **Gateway for EOSC to the health-related community** of service providers and researchers (e.g., for identification of needs).

Resources needed

- **EOSC** - dedicated focus group or similar structure
- Connected to **EHDS** governing body
- **EDICs** or **Health RIs**.
- Aligned with the **Data Spaces Support Centre**.
- **EC** special interest group.

5. A health research community interface service, with HealthData@EU

Strategy group to facilitate **the exchange between the health-related research community and the HealthData@EU** to inform its **design, implementation and adoption**.

Targeted issue

- EHDS will be a disruptive actor / **accessing health data for research purposes**.
- Need for a direct communication channel to health-related researchers to inform about its **capabilities** and maximise its **uptake**.

Service conception

- **Central** service for **monitoring the EHDS evolution** and **generating materials** for the data users/data providers.
- **Federated** components to tackle aspects on **national level** such as interactions with local HDAB.
- Dedicated groups/task forces to **capture and analyse requirements** and translate them to the different levels of interoperability (e.g., legal, technical, semantical).

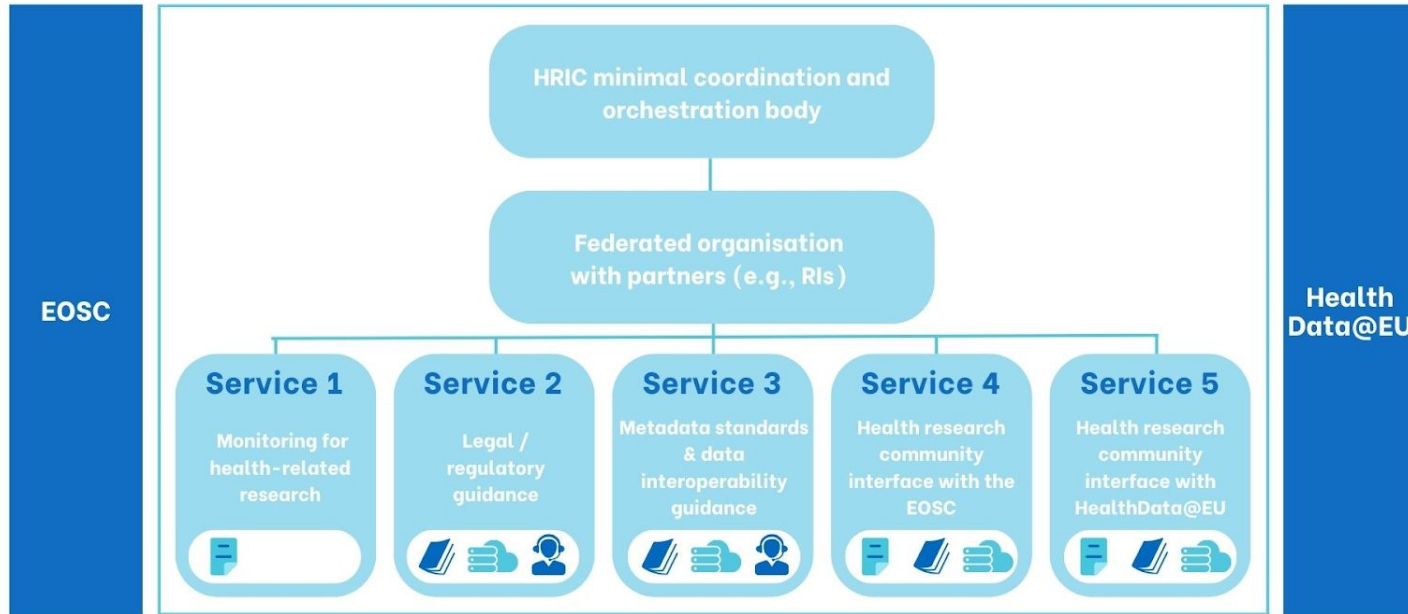
Potential benefit

- Guarantee the **alignment of the requirements** of the health-research communities represented.
- Increase the **use of the HealthData@EU infrastructure** by these communities.

Resources needed

- **Interest groups**, incl. different **RIs**/research domains.
- **EOSC** (capacity provision).
- **EHDS** (legal framework, data discovery and provision, capacity provision for analysis).
- **Health-related RIs** (capture community needs, curate high quality data resources, guarantee interoperability)

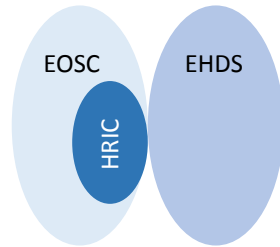
Organisation of the HRIC services



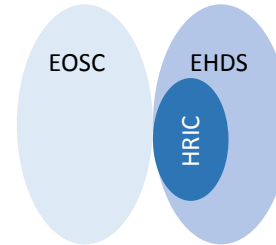
-  Provision of material
-  Catalogue of resources
-  User portal
-  Active support service

Implementation and sustainability - Affiliation

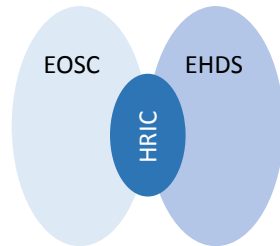
Different views on perceived gaps and how and these will be covered by EOSC/HealthData@EU.



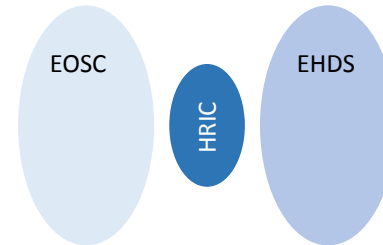
The HRIC as 'EOSC Health Research'



The HRIC as 'HealthData@EU for research'



The HRIC as an 'EOSC / HealthData@EU interface'



The HRIC as an independent entity

Conclusion: Agnostic approach

Implementation and sustainability - Organisation



EU Missions are a **coordinated effort** by the Commission to pool the necessary resources in terms of policies and regulations, as well as other activities. They aim to **mobilise and activate public and private actors**, such as EU Member States, regional and local authorities, research institutes, entrepreneurs and investors to create a real and lasting impact. Missions engage with citizens to boost societal uptake of new solutions and approaches.

EU Missions support Europe's transformation into a greener, **healthier**, more inclusive and resilient continent.

Could the HRIC become a Health Research and Innovation Data Mission ?

Implementation and sustainability - Funding

Two phases are recommended:

1) Development and pilot phase: Supported by **EC project funding** (e.g. CSA) and limited to 2-3 years. The aim will be to provide the necessary **procedures, tools, secretariat** for the implementation of the services described in the Strategic Agenda of the HRIC.

2) Maintenance and sustainability phase: Recognising that EC project funding can only be a time-limited solution, engage all relevant actors (e.g. EOSC, EHDS, EC, Member States, RIs, health-research stakeholders) to discuss sustainability options (e.g., fees for services applied to data providers/users, in-kind contributions of RIs, Member State contributions, data sharing costs as eligible cost category in projects).



Thank you



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Comments or questions?

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