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Health Research & Innovation Cloud

WP8 “Developing the HealthyCloud Strategic Agenda with the involvement of all relevant European actors”

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Outline of session

1. Background and context
2. Developing a consensus
3. Ideas for services
4. Continued evolution of the idea of a HRIC
5. Voting on services

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)

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

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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

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The 2018 HRIC Recommendations

Provide and foster standards, good practices, and guidelines necessary to establish the European Health Research and Innovation Cloud (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 project under Horizon 2020. Kick-off in March 2021 with a 30-month duration. 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)

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

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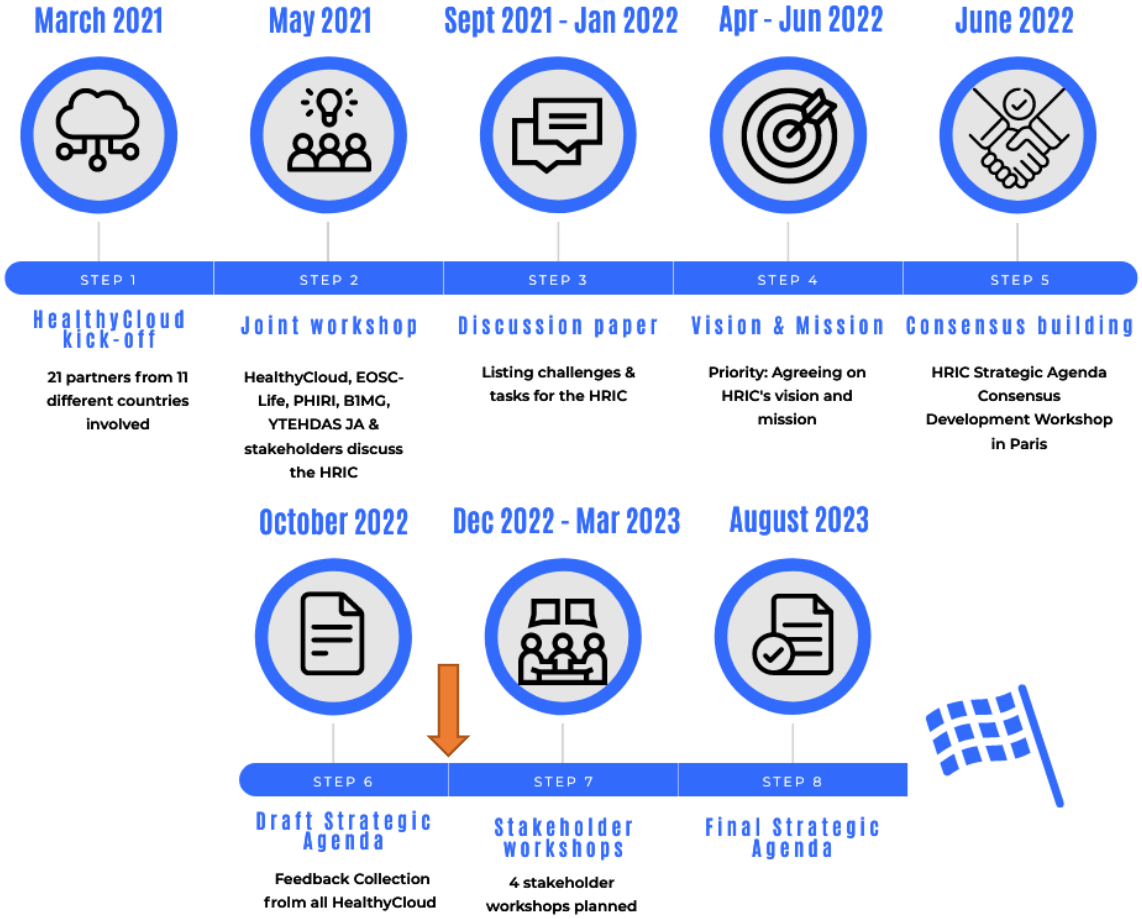
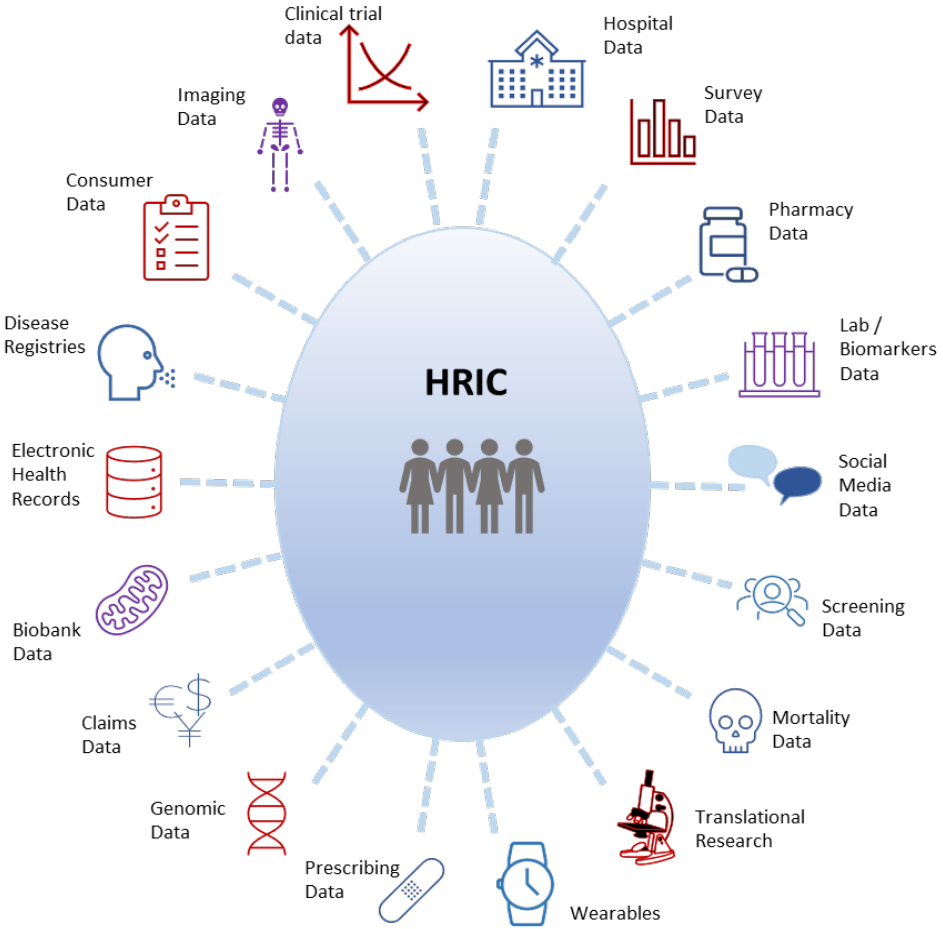


Heterogeneity Issues



In data types

In data sources

In users

In terminologies

In data organisation

In jurisdictions

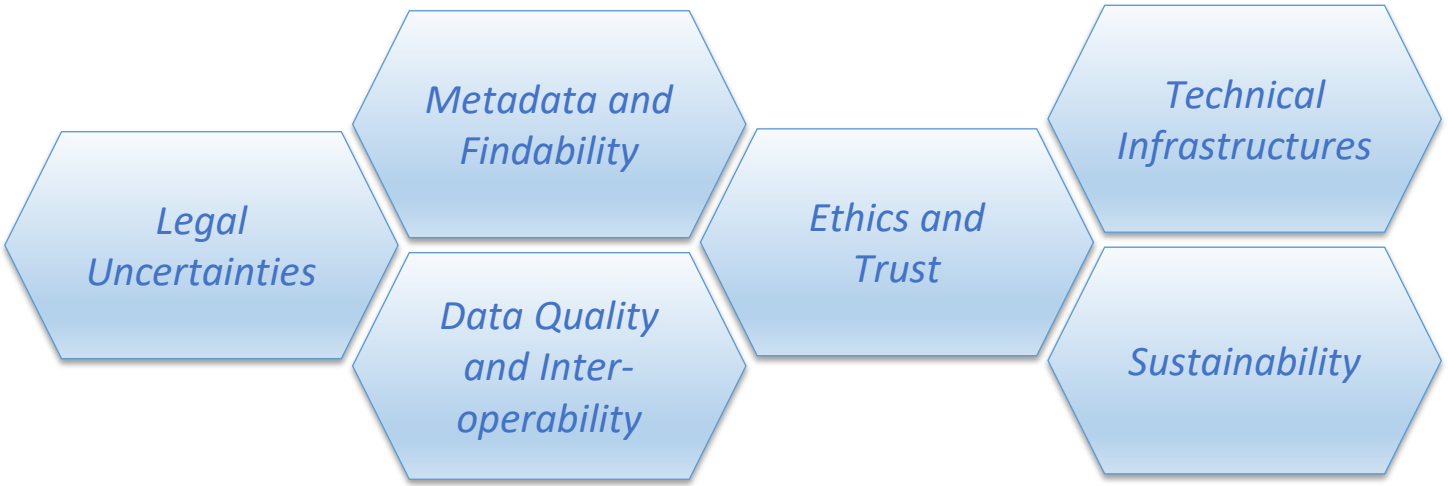
In regulations

In languages

In challenges

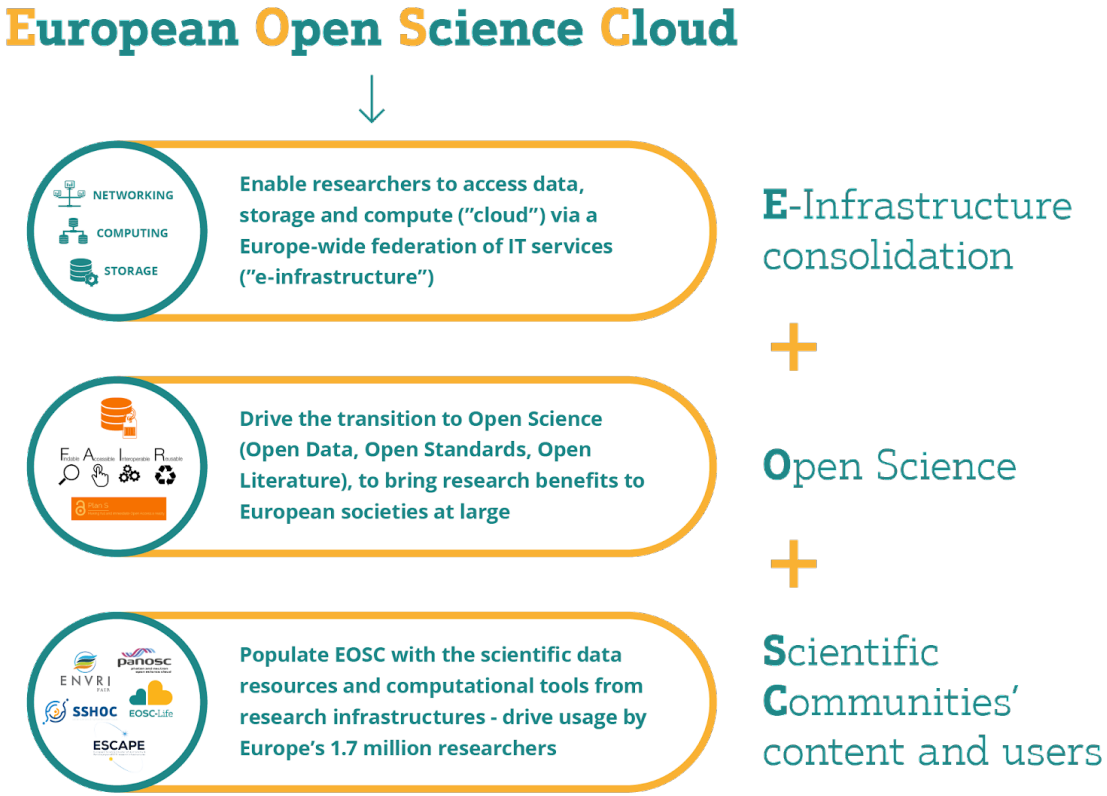
Discussion Paper – Scoping the Agenda

Developed September 2021 to January 2022, identified 6 main areas as in scope for development of a HRIC (input from all WPLs):



Dedicated session in the "All-Hands meeting" on 23 February 2022 to discuss with the HealthyCloud consortium also highlighted Incentives, and Access governance

The European landscape: EOSC

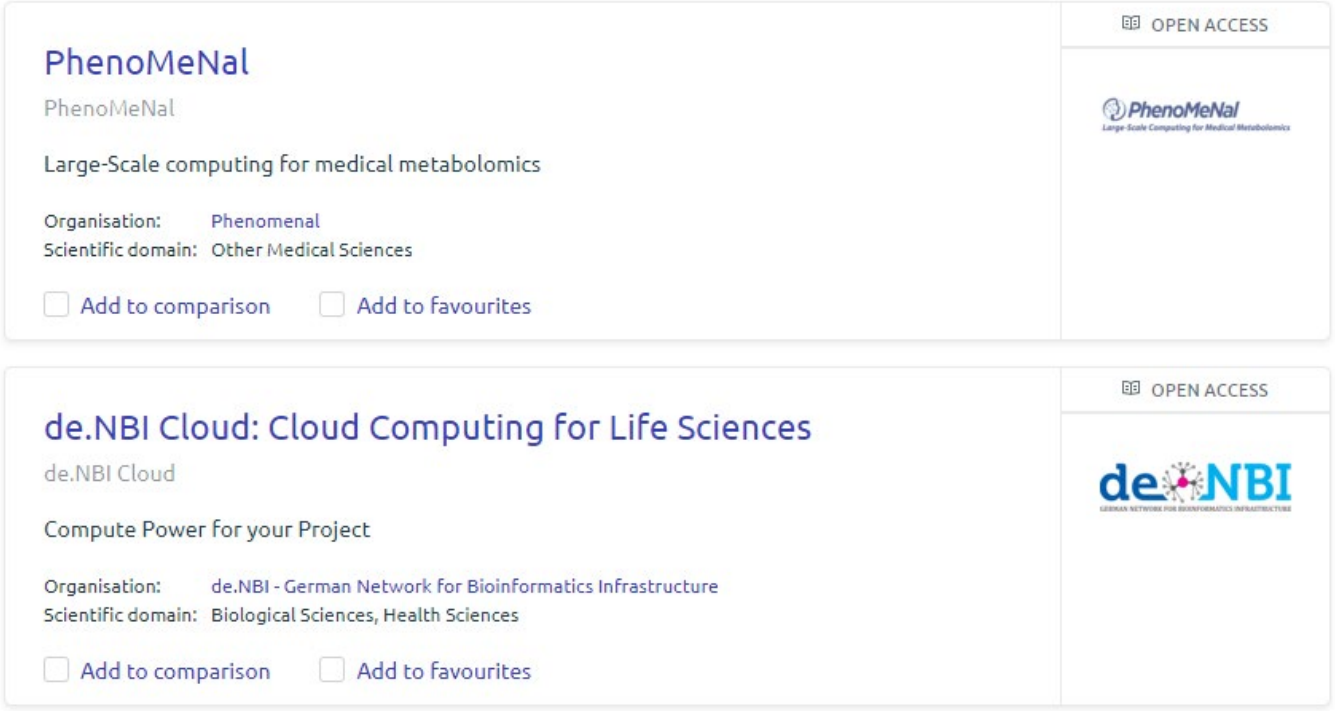


EC and Member State initiative that started taking shape in 2015.

Web of existing projects (EOSC-Life, EOSC Future, EOSC Enhance, BY-COVID, EOSC4Cancer…..)

The European landscape: EOSC

- EOSC portal implemented (https://eosc-portal.eu/) including an EOSC catalogue & Marketplace whose scope includes **“Medical & Health Sciences”**.

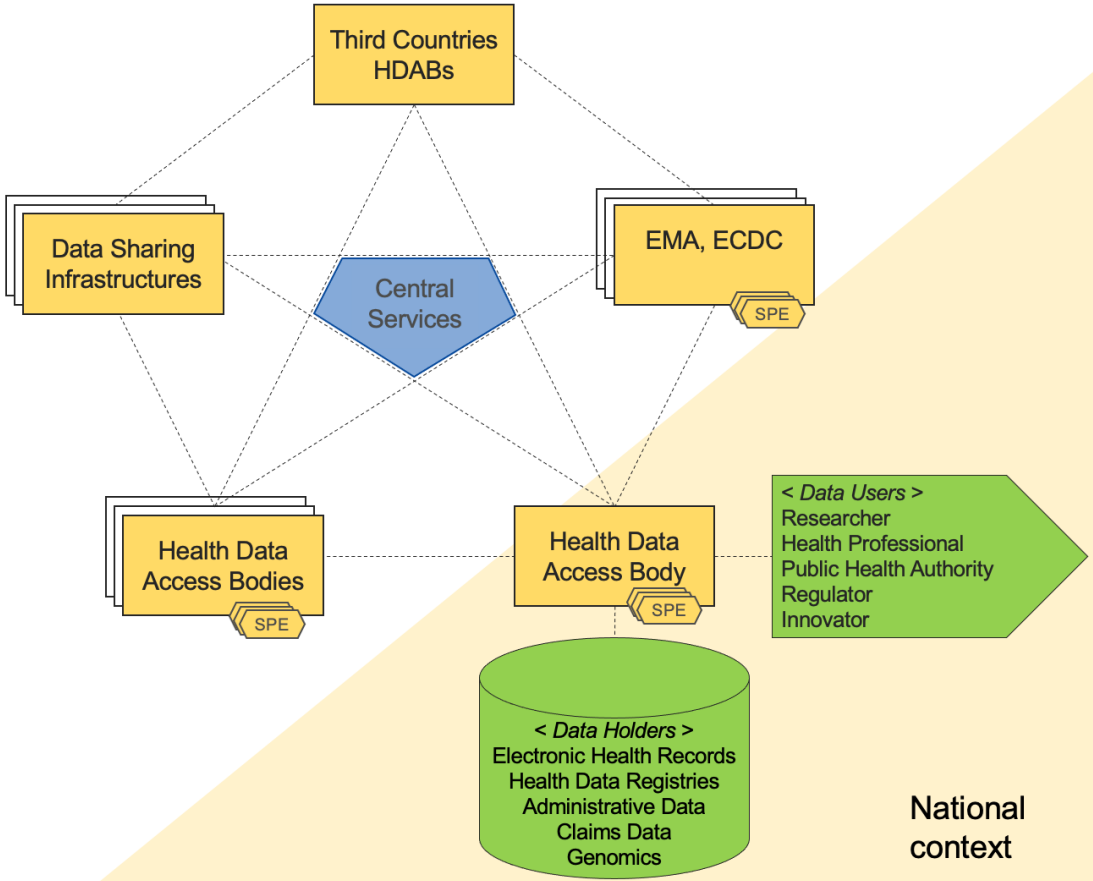


The European landscape: EHDS

The creation of a European Health Data Space one of “the European Commission’s key priorities for 2019-2025”. Proposals for EHDS legislation published in May 2022

MyHealth@EU	HealthData@EU
Primary use: Covers standardisation and mandatory certification of EHR systems, voluntary labelling of wellness apps, European Electronic Health Record Exchange Format Single health data and data protection landscape, supporting free movement of people	Secondary (re-)use: Covers Health Data Access Bodies, valid purposes for re-use and forbidden usage. Data permits, secure processing environments, de-identification. To facilitate research & innovation, better policy making, support regulatory decision making

The European landscape: EHDS

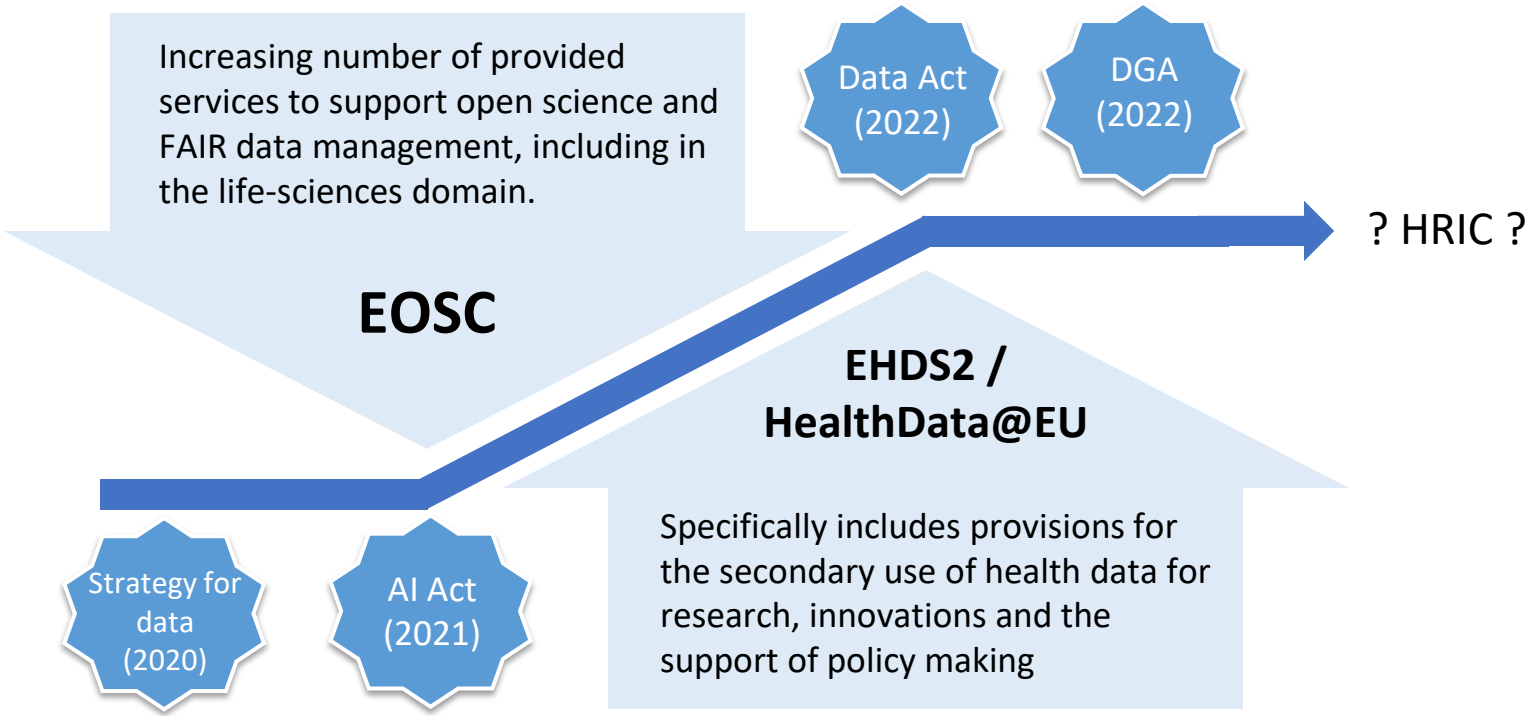


The envisaged HealthData@EU (or EHDS2) ecosystem

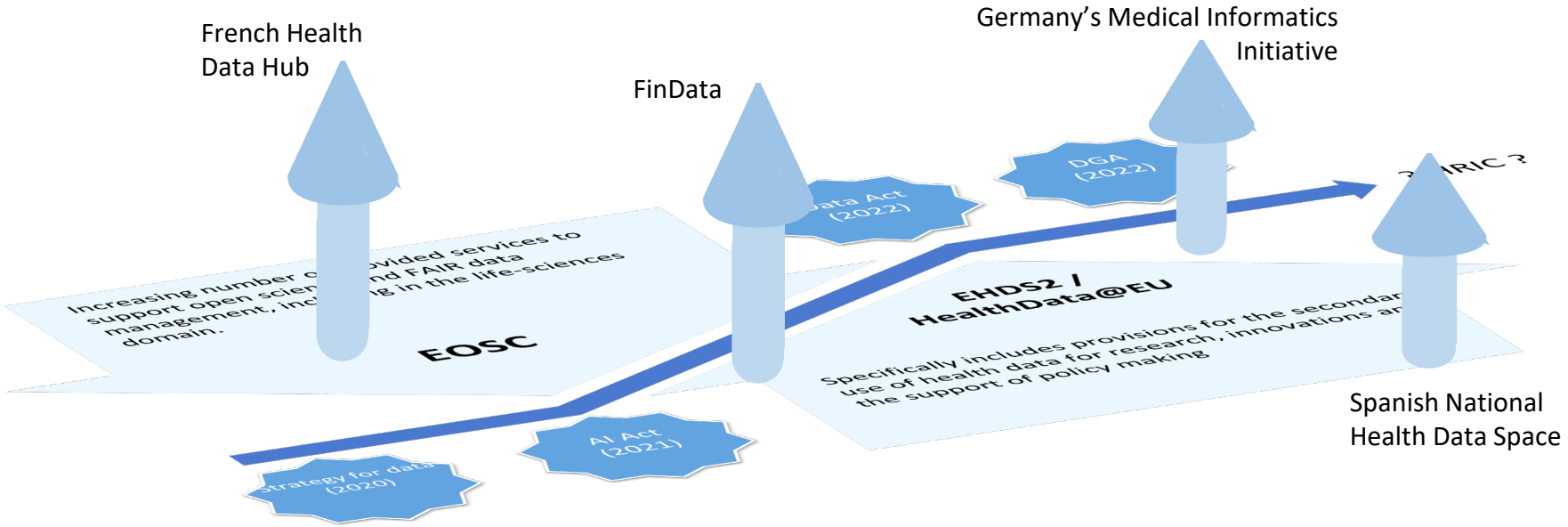
is being defined with the help of EC projects (e.g. TEHDAS Joint Action towards the EHDS, EHDS2 pilot).

from ec.europa.eu

Positioning the HRIC I

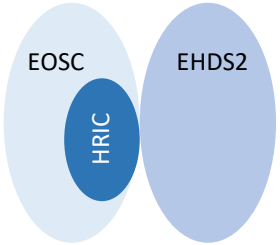


Positioning the HRIC II

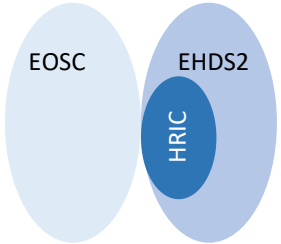


Positioning the HRIC III

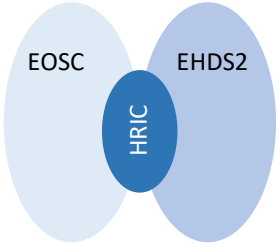
Inevitably, different views in the consortium on perceived gaps and how and these might be covered within the EOSC and / or EHDS2 infrastructures



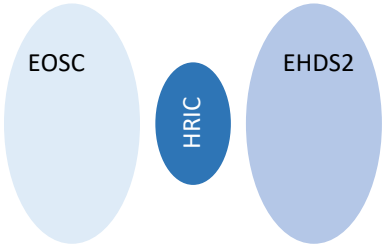
The HRIC as 'EOSC health'



The HRIC as 'EHDS research'



The HRIC as an 'EOSC / EHDS2 interface'



The HRIC as an independent entity

Developing a Consensus, Paris, June 2022

Participants: HealthyCloud WP8 Task leads (ELIXIR, ECRIN, EATRIS), HealthyCloud WPLs, HealthyCloud coordination (IACS & BSC).

Main objective: To bridge the different views expressed within the consortium around the HRIC, to find a consensus for the Draft Strategic Agenda (D8.1)

Gaps + Uncertainties = Needs

For…

- Better co-ordination between developments, over extended time periods
- Specific support for sensitive data management
- Better legal and regulatory guidance
- Good support for multi-national research, especially using RWD
- Greater data inter-operability – amidst huge data diversity
- Improved data findability, especially across traditional domains, and RWD
- Clarifying roles of EOSC and EHDS2, and their inter-action
- Provision of Secure Processing Environments
- Retaining public involvement and trust
- Good links to and interactions with existing RIs
- Adequate training

Possible HRIC Services

- A monitoring service for health related research
- A legal / regulatory guidance service
- A training service for researchers
- A metadata standards service
- A data interoperability service
- An EOSC sensitive data users service
- An EOSC Health catalogue service
- An EOSC Health resource service
- A research community interface service, with HealthData@EU
- A research community interface service, with the general public

Monitoring and Advocacy Services

3.1 A monitoring service for health related research

High-level monitoring functionality, providing periodic reports to the health-related research communities, and the European Commission, about the “state of play” of health-related research and the progress towards goals that had been previously identified. A periodic HC WP8 ‘check point’.

3.6 An EOSC sensitive data users service

Possibly a special interest group within EOSC. Such a group, selected to represent researchers working in health-related areas, would try to ensure that EOSC systems properly supported the needs of health-related research, in particular relating to processing of sensitive data, and could lobby for the inclusion of specific services if they were felt to be missing.

Guidance and Training Services

3.2 A legal / regulatory guidance service

In conjunction with expert, authoritative groups, the creation of a centre of expertise and resources around legal and regulatory issues, partly to provide material to help researchers interpret and comply with regulations, but partly also to ensure that the views of researchers on these issues were known and fed into the broader debates on the evolving legal and regulatory framework.

3.3 A training service for researchers

The co-ordination of expertise and the development of materials, including possibly courses, to help people identify and use new or developing services, for example schemas, catalogues, data resources, procedures, and secure and / or federated processing environments, in the most effective and efficient way.

FAIR Data Services

3.4 A metadata standards service

To support the development, promotion and application of more consistent identifiers and discovery metadata schemas within health-related research, including full description of sensitive data available under controlled access. And the creation of supporting tools and resources.

3.5 A data interoperability service

Encouraging and supporting the use of the major data standards within both clinical research and healthcare. Identifying and helping to apply incentives and resources for promoting interoperability. Developing infrastructures, systems, and tools that can be used to promote *syntactic* interoperability, and exploring the best ways to tackle the *semantic* interoperability problem.

Resource Services

3.7 An EOSC Health catalogue service

Helping to identify and recruit resources to EOSC that are relevant to health-related research, and then to coordinate, characterise and catalogue those services, providing where appropriate supplementary service such as specialised access portals, storage for controlled access data and support tools for data access and data processing.

3.8 An EOSC Health resource service

The creation of new infrastructure services to researchers, especially, but not limited to, secure processing environments and other forms of specialist data repositories. The development and application and validation of innovative techniques (e.g. involving encryption, or federated analysis, or NLP) that can be applied to existing or new data resources.

Research Community Interfaces

3.9 A research community interface, with HealthData@EU

There will need to be ongoing debate between researchers and HealthData@EU to maximise the utility of EHDS RWD resources for research purposes (e.g. with systems and policies for appropriate data location, access, aggregation, de-identification, restructuring etc.). Existing RIs likely to have a central role in this two-way dialogue.

3.10 A research community interface, with the general public

Helping to provide greater understanding of why personal data is important for research, how it is used and the safeguards employed, and helping to build trust around the secondary use of data, by (for example) providing educational material and initiatives, developing ethical frameworks, ensuring transparency in secondary use of data, and engaging patient groups and the general public.

How do we fund any of this?

Discussion extensive but conclusions at this stage difficult – *no money has yet been allocated.*

Ultimately, the general consensus is that we are ***agnostic*** about the branding, and / or the organisational umbrella(s) under which services are developed.

The key requirement is for the services identified as required to be implemented, and implemented as infrastructure – not as a project

Where are we?

- WP8 has been a ‘check point’, an opportunity to discuss the further development and support of health-related research
- We have identified gaps and uncertainties => Needs => Services and resources
- We have to be flexible about a ‘HRIC’ – the important thing is the services
- Services and resources need wider discussion but more detailed specification, perhaps also prioritisation

Planned stakeholder workshops

December 2022	Group 1: Technical stakeholders
January 2023	Group 2: Patient representatives, ethics committees and data protection authorities and policy makers
February 2023	Group 3: User communities
March 2023	Group 4: EOSC governance and partners, and EOSC funders

And where next?

- The agenda is not likely to be ‘an implementable road map for a HRIC’. Nothing is implementable without allocated funding or a robust business model, and there may not be ‘a’ HRIC, branded as such.
- Models for sustainability need to be developed – perhaps not within HealthyCloud itself, but in conjunction with funders such as the commission.
- To focus future discussion better, should we and the commission set some ‘boundaries’?
- Should and could commercial interests be more involved?
- Intensive work over the next six months

Voting!

Please select the three services you think are most important to be fully implemented

1. A monitoring service for health related research
2. An EOSC sensitive data users service
3. A legal / regulatory guidance service
4. A training service for researchers
5. A metadata standards service
6. A data interoperability service
7. An EOSC Health catalogue service
8. An EOSC Health resource service
9. A research community interface service, with HealthData@EU
10. A research community interface service, with the general public

Thanks

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Comments or questions?

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