



Junta de Andalucía

Consejería de Salud y Familias

SERVICIO ANDALUZ DE SALUD



European Data Spaces Initiatives: working on trustworthy health research data infrastructures for the success of data spaces

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Disclaimer

- The author declares that he has no commercial interest in the content of this presentation, nor does his family.
- The content of this presentation is based on the author's knowledge, experience, and opinion; it is not intended to be an exhaustive state-of-the-art description of all the elements to be taken into account concerning the challenges and needs of the European Research Data Space, nor of all the possible answers to these challenges.

Objective

To show a landscape of the security and data protection aspects that will have to be taken into account in the data spaces for health and biomedical research, taking into account:

- *the current regulations,*
- *the responsibilities of the treatment, and the risks involved,*
- *in time to be foreseen in the design of the infrastructure and,*
- *taking into account as a critical aspect the deep needs of trustworthiness towards healthcare data providers.*

Reference projects in progress.

IMPACT | Data 



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IMPACT Data

PRECISION MEDICINE INFRASTRUCTURE associated with SCIENCE and TECHNOLOGY

IMPACT MISSION


Establish the pillars to facilitate the effective deployment of Precision Medicine in the Spanish National Health System, assuring the scientific-technical quality, equity, and efficiency while using the available scientific resources to respond to society's needs.

IMPACT Pillars



Data Science Pillar: IMPaCT-Data

- The pillar focuses on developing an environment for data analysis and integration. It proposes a life cycle of testing, evaluating and implementing computational systems in healthcare settings.
- IMPaCT-Data aims to create the infrastructure for secondary use of data from the Spanish healthcare systems - electronic health records, medical imaging and genomic repositories- and contribute with the knowledge and methodology produced to the healthcare system.

IMPACT	
DATA 	
Budget	4.5€
Institutions	47
Autonomous Communities	15
Period	2021-23

Recommendations on sensitive data in IMPaCT Data

- IMPaCT Data has developed throughout the project a deep discussion and revision of the legal, ethical, organizational, and technical aspects for the correct, safe treatment of sensitive data in use for health and biomedicine research purposes, specifying the difference that involves the use of anonymized and pseudonymized data sets as well as the varied nature and origin of the same.
- The need for **informed consent of patients** as a legal basis is covered, as well as the exception situations that may arise.
- Regarding the responsibilities of the treatment, the specifications set by **the National Security Scheme and the CCN-STIC 801 Guide** are being taken into account, as well as the different roles that must be present.

Data Risk at IMPaCT Data

- Illegitimate access to data,
- Unauthorized modification of data,
- Deletion of data,
- Re-identification from data,

Preventive, corrective and mitigating actions have been identified to minimize exposure to the different risks.

From the data flow to the responsibility flow.

- The work is challenging, addressing the security issue while designing the infrastructure.
- An exhaustive definition of data flows is fundamental, since it conditions **the flow of responsibilities over the data** and, therefore, **“the map of data processing agreements”** necessary to avoid responsibility gaps in these flows.
- From the basic components identified, **role-based access control policies** and the authentication system to be implemented by IMPaCTData are outlined.
- Advanced anonymization and pseudonymization techniques have been reviewed. However, it is an open issue for **the anonymization of data BEFORE it is shared for research use**, with the complexity of the inclusion in healthcare systems environments (EHRs).

IMPACT Data's Approach to the Spanish National Security Scheme - ENS

- The IMPACT Data infrastructure defines 3 types of nodes regarding data:
 - Sensitive data provider node,
 - Computational provider node,
 - Both types of nodes.
- A comprehensive survey was addressed to the different participating nodes to evaluate the ENS security measures implemented as well as those to be recommended.
- 24 of the 76 ENS measures have been evaluated.

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Towards the European Health Research and Innovation Cloud (HRIC)

Overview

HealthyCloud

Grant agreement ID: 965345

Status

Ongoing project

Start date

1 March 2021

End date

31 August 2023

Funded under

H2020-EU.3.1.5.

Overall budget

€ 2 999 975

EU contribution

€ 2 999 975



Coordinated by

INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD

 Spain



HealthyCloud Vision

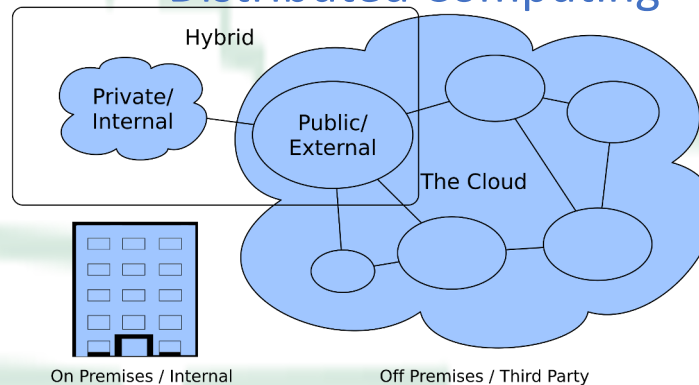
- Paving the way for an effective health-related data sharing across Europe to maximise the impact of health research
- Helping conform the future European Health Data Space by defining **the Strategic Agenda for the European Health Research and Innovation Cloud**

Health Data



Health

Distributed Computing



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Cloud

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Towards the European Health Research and Innovation Cloud (HRIC)



Stakeholder Forum

- Exchanging views on the future HRIC ecosystem
- Identifying challenges & opportunities



Roadmap

- Recommendations
- Specifications



Strategic Agenda

- Good practices for ethical & legal use of health data in EU
- Sustainable use of EU capabilities on computational systems

Gaps, needs and uncertainties taken into account in the H&C Strategic Agenda

- Concerns about appropriate resourcing of data sharing in the research sector may result in underutilized infrastructures such as HealthData@EU and EOSC.
- The number of services listed in the EOSC Marketplace focusing on sensitive data management is still quite limited.
- EOSC focuses primarily on open data and metadata, so it lacks inherent access control systems.
- **Additional management requirements and costs** are discovered in the data lifecycle, which must be recognized and integrated into funding processes.

HRIC Core visión and 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.

- A fundamental aim of the HRIC is to **reduce barriers** between different health-related research domains and data sources.
- The HRIC must **uphold the protection of privacy and promote the safe use of citizens' health data.**

HRICS Strategic Agenda Features

- Defines a set of services, including a legal/regulatory guidance service, with three components:
 1. HRIC Legal/Regulatory Community Resources
 2. HRIC Legal/Regulatory Support
 3. HRIC Legal/Regulatory Policy Monitoring
- Includes common components among services.
- Defines an implementation and sustainability model.

HealthyCloud Final Event



HEALTHYCLOUD
Health Research & Innovation Cloud

FINAL EVENT



9:00 - 14:30 CEST
6 OCT 2023



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CONFERENCE ON
PERSONALISED MEDICINE

**The evolution of
healthcare to improve
people's lives**



VALENCIA



4-5 OCT

<https://healthycloud.eu/event/healthyclouds-final-event/>

Thank you for your attention

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