

# Lo spazio Europeo della salute: strumenti, modelli, priorità e attori

Alessandro Amorosi – Regione Lombardia – DG Welfare  
20/04/2021



# Digital Transformation of Health and Care

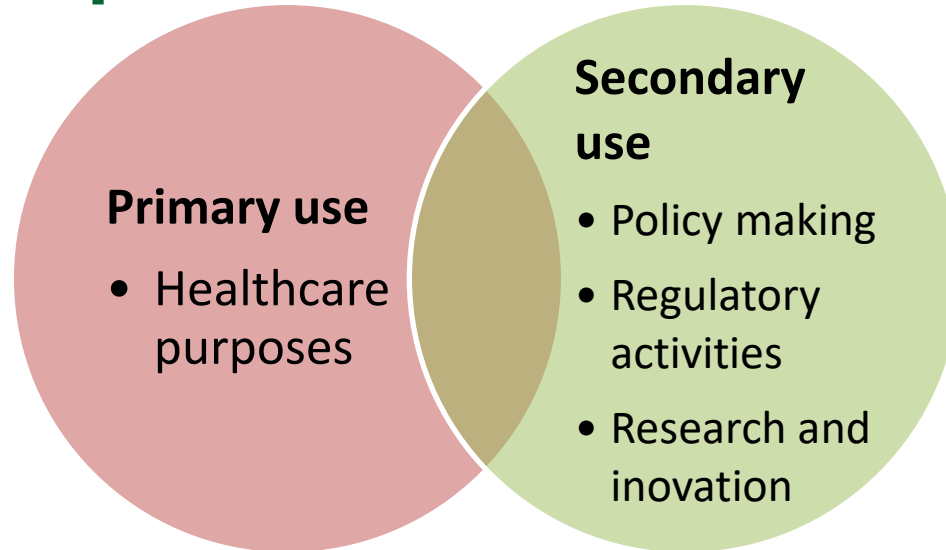


[2018 Communication on enabling the digital transformation of health and care \(COM\(2018\)23\)](#)

*Licinio Kustra Mano – DG for Health and Food Safety  
B3: Digital Health – European Reference Networks*

# Digital Transformation of Health and Care

## Health data purpose of use



[2018 Communication on enabling the digital transformation of health and care \(COM\(2018\)23\)](#)

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# EC Dir 2011/24 Art. 14: the eHealth Network

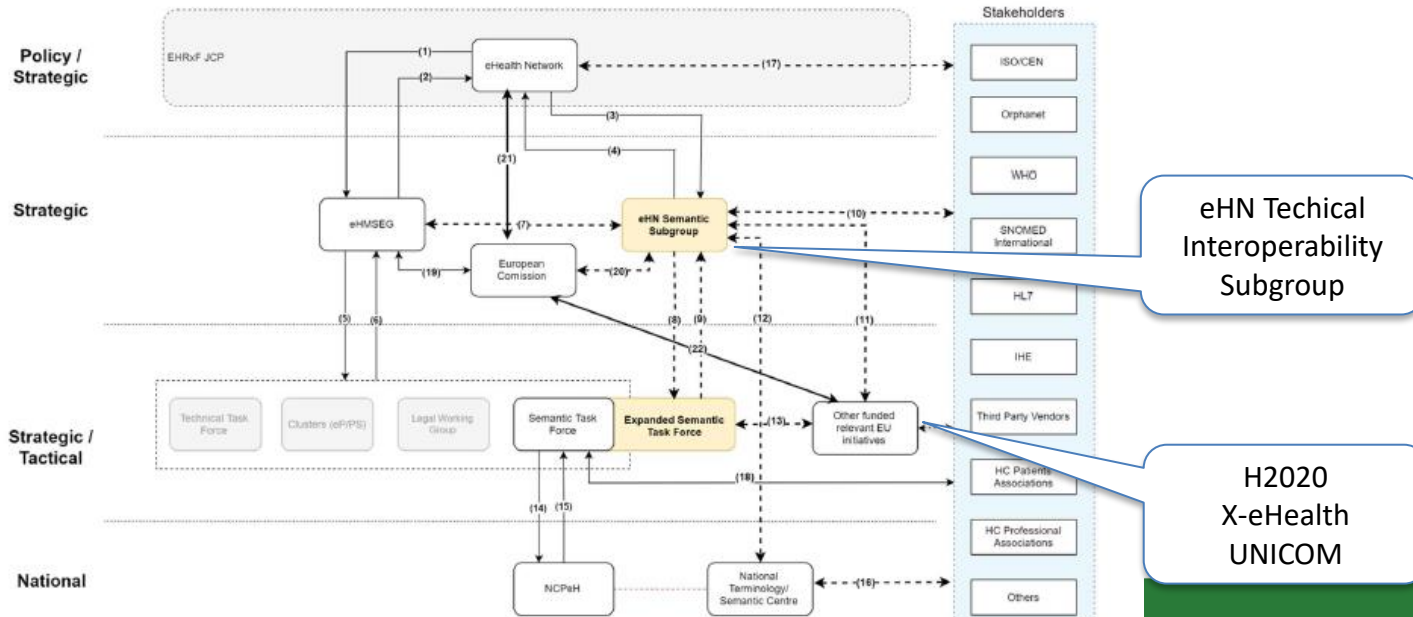


**My Health @ EU**  
 eHealth Digital Service Infrastructure  
 A service provided by the European Union



Co-funded by the European Union's Health Programme (2014-2020)

Common Semantic Strategy for health in EU  
 For Adoption  
 Revision 2.1 – 12/11/2019





## My Health @ EU

### eHealth Digital Service Infrastructure

A service provided by the European Union

**My Health @ EU**  
Electronic cross-border health services in the EU

e-prescription    patient summary

**My health @ EU**  
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**ePrescription - PHARMACIST**

What does this mean for a pharmacist working in the country of travel?

**Patient Summary - PATIENT**

What does this mean for a patient in their country of travel?

[https://ec.europa.eu/health/ehealth/electronic\\_crossborder\\_healthservices\\_en](https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en)

*Licinio Kustra Mano – DG for Health and Food Safety*  
*B3: Digital Health – European Reference Networks*

## EUROPEAN HEALTH DATA SPACE

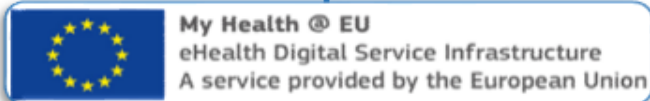
Use of data for healthcare (primary use of data)

Give citizens **better access** to their **health data**, everywhere in EU



## My Health @ EU

eHealth Digital Service Infrastructure  
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From 2019 exchange of:

- ePrescriptions
  - Patient Summaries
- in healthcare professional language  
25 MS joined

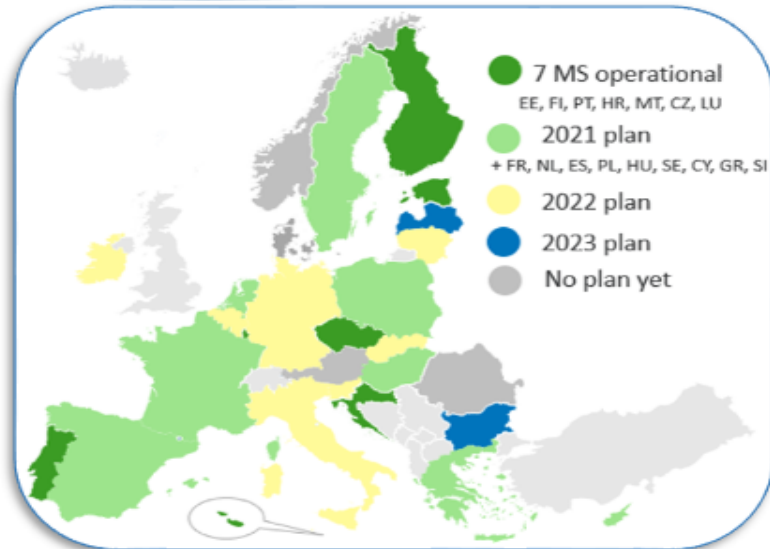
From 2022 exchange of:

- Original Clinical Documents

From 2023 exchange of:

- Laboratory reports
  - Medical images and reports
  - Hospital discharge letters
- in healthcare professional language  
As in Recommendation on an  
Electronic Health Record exchange format  
in cooperation with DG CNECT

- Extension to Rare Disease Networks



*Natalia Zilinska Puta – DG for Health and Food Safety  
B3: Digital Health – European Reference Networks*

# Network, sistemi di rete e partenariati

All'interno di alcune progettualità, Regione Lombardia ed Aria svolgono un ruolo di supporto alla “Governance” partecipando a diversi tavoli di lavoro per confrontarsi con vari stakeholder su tematiche di interesse per la comunità

Tavoli attivi



## My Health @ EU

eHealth Digital Service Infrastructure

A service provided by the European Union

- **CEF eHDSI Italia: Min. Salute, MEF//SOGEI, AgID/CNR, Regione Emilia-Romagna/LEPIDA, Regione Veneto/Azienda Zero,/Arsenal, Regione Lombardia/ARIA**

**Su mandato Ministero Salute:**

- **eHMSEG Semantic Task Force**
  - **Coord. Organisational WG**
  - **Coord. Sematic WG**
- **eHN Subgroup of Semantic**
  - **Patient Summary Guidelines**
  - **Vaccination Proof for clinical use Guideline**
  - **Digital Green Certification Value Set**
- **eHN Subgroup Technical Interoperability**
  - **Extended EHR Services strategies & architectures**
  - **Digital Green Certificate Trust Framework**



**Partecipazione a tavoli di lavoro** per portare oltre i confini regionali l'esperienza lombarda

**Stesura di documenti tematici** (Es. Position Paper, pubblicazioni, ...)

**Network** per partecipazione a nuove progettualità





# European Reference Networks



[Clinical Patient Management System \(CPMS\)](#)

ERN Specific projects

RD-CODE  
Orphacode

X-eHealth:  
extension of  
eHDSI to Rare  
Diseases



# Secondary Use of Data

## Not enough data available for reuse

- More public sector data can be made available
- Low uptake of voluntary data sharing among companies
- No clarity on the use of private sector data for the common good

## No real user empowerment

- imperfect data portability mechanisms



Lack of European data processing & storage solutions

Absence of comprehensive data governance approaches

- To address legal and technical barriers within and across sectors (e.g. standardisation & interoperability)

Skills shortage and low data literacy

Fragmentation of the single market

*Saila Rinne*

*Head of Sector for eHealth in CNECT.H3*

# European Strategy for Data

A common European data space, a single market for data



*Saila Rinne*

*Head of Sector for eHealth in CNECT.H3*

# Deploying the data strategy through 4 Pillars



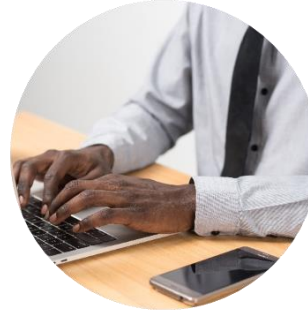
## A cross-sectoral governance framework for data access and use

including a legislative framework for the governance of European data spaces and other cross-sectoral measures for data access and use



## Enablers

Total investments of € 4-6 billion in a High Impact Project on European data spaces and federated cloud infrastructures



## Competences

Empowering individuals, investing in digital skills & data literacy and in dedicated capacity building for SMEs.



## Rollout of common European data spaces

in crucial economic sectors and domains of public interest, looking at data governance and practical arrangements.

International Aspects

*Saila Rinne*

*Head of Sector for eHealth in CNECT.H3*

# Lombardy Region / ARIA Data as a Service (DaaS) 2.0

## DaaS Data Bases

DB-COVID-19, Infectious and diffusive diseases; Vaccinations; Basic medical care; Outpatient and rehabilitation specialist care; Home care; Mental health; Addictions; Hospital care; Medical emergency; Residential, semi-residential, hospice care;...

## Stipulation of agreement

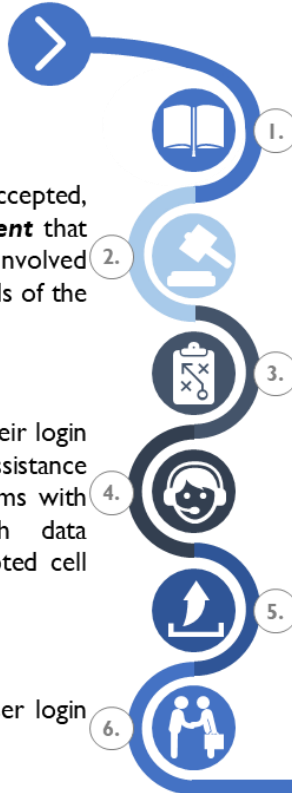
Once the accreditation and the project proposal are accepted, the institution and Lombardy Region sign an **Agreement** that states the aims of partnership, the duties of each sides involved and the duration of the partnership based on the needs of the project.

## Service application and Assistance

When the environment is set up, the users receives their login information to access the service. ARIA gives an assistance service for support request (e.g.: changes or problems with login information, library installation, in depth data interpretation) through an email address and a devoted cell phone line ([daas@ariaspa.it](mailto:daas@ariaspa.it); +39 023933 1729).

## End of service

When the research is done, ARIA removes all the user login information and the filing and/or erasing of the data.



## Accreditation and Project proposal

The interested institution, which wants to partner with the Lombardy Region free of charge, must present a **formal request of accreditation** to the General Director of the Lombardy Region. After acceptance, a **project proposal** will be examined by a **Commission**, composed of health professionals identified by the Crisis Unit.

## Environment Predisposition

After the agreement is signed, the environment will be set up (VM installation, software, upload of database, set up of user login information). The main characteristics are defined together by the institution and ARIA S.p.A. through the subscription of **operative DaaS KIT**.

## Request and output validation

When the institution needs to make a midterm or final output, it fills out a **Declaration of elaboration of research output/ end of the research**. After the validation of this declaration, ARIA makes the outputs available to the legitimate owner.

# Progetti Europei in ambito WELFARE

- DG Welfare ed ARIA cooperano in progetti su tematiche in linea con strategie Regionali

