



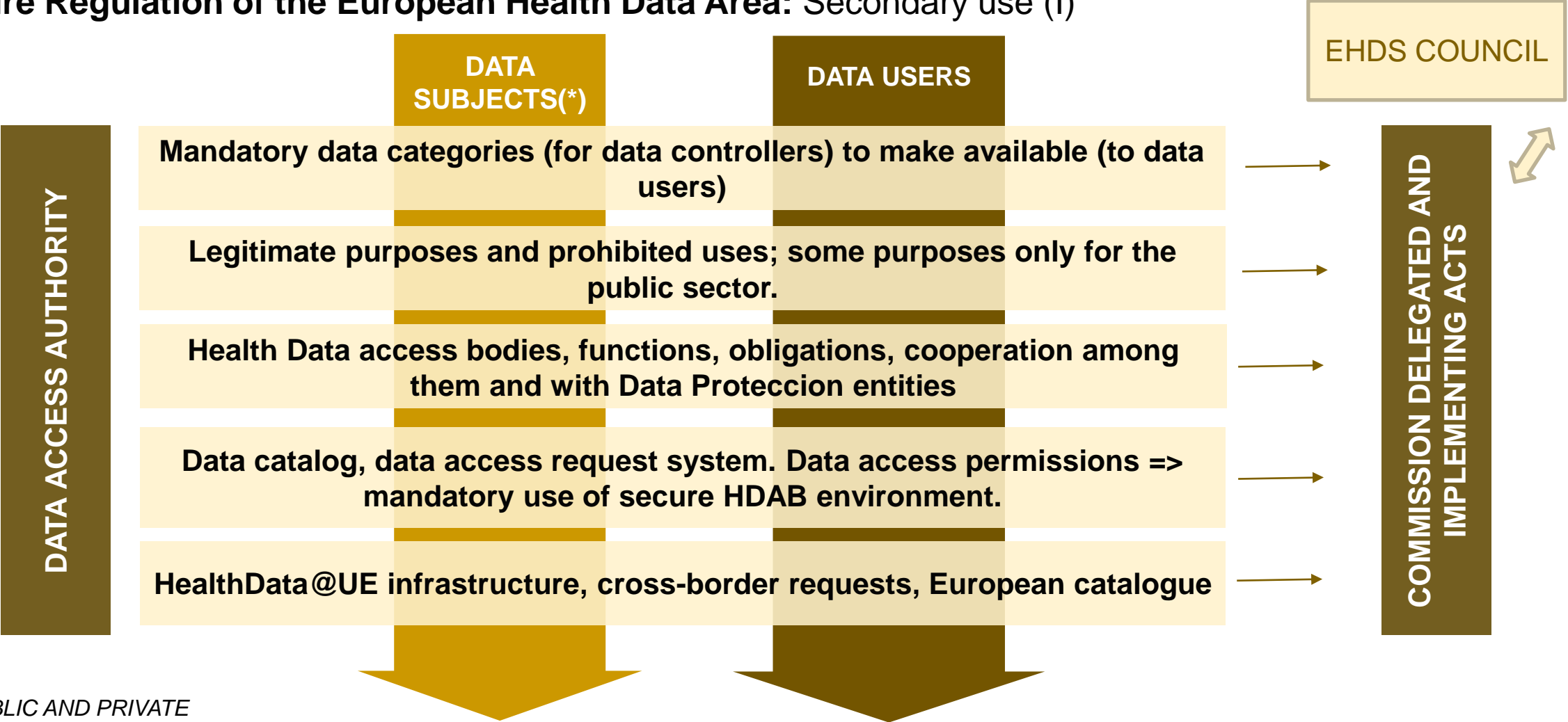
**REMAINING  
CHALLENGES LINKED TO  
RESEARCH INTO RARE  
DISEASES**



## The future Regulation of the European Health Data Area: Primary use

Field	New features introduced
<p><b>People rights</b></p>	<ol style="list-style-type: none"> <li>1. Access, <b>add</b>, and transfer their data between healthcare providers</li> <li>2. Authorize <b>representatives</b> manage their data</li> <li>3. <b>Know</b> access to their data</li> <li>4. Obtain copies and transfer between healthcare systems in EU-HER format</li> </ol>
<p><b>Obligations of states</b></p>	<ol style="list-style-type: none"> <li>1. Free Access service, with the possibility of representation</li> <li>2. Establish access by <b>types of professionals</b></li> <li>3. Include eIDAS electronic identification</li> <li>4. Join MiSalud@UE</li> <li>5. Onboard all healthcare providers</li> </ol>
<p><b>Public and private professionals and care providers</b></p>	<ol style="list-style-type: none"> <li>1. Use compliant EHR systems and have updated data</li> <li>2. Join the <b>national</b> MiSalud@UE system</li> </ol>
<p><b>Market</b></p>	<ol style="list-style-type: none"> <li>1. Manufacturers, representatives, importers =&gt; compliant EHR systems, self-declaration</li> <li>2. Includes well-being apps, health products and high-risk AI systems, which declare interoperability with EHRs (self-declaration and voluntary label)</li> </ol>
<p><b>Entities</b></p>	<ol style="list-style-type: none"> <li>1. <b>Digital Health Authority</b> as National contact point for connection to MyHealth@EU</li> <li>2. Market Surveillance Authority (verification, risks and non-compliance, sanctions regarding the conformity of EHRs) with functions closer to the field of Consumer Affairs</li> </ol>

# The future Regulation of the European Health Data Area: Secondary use (I)



(\*) PUBLIC AND PRIVATE EXCEPT FOR Micro SMEs



# The future EHDS Regulation: Secondary use (II)

Field	New features introduced
<p><b>People rights (natural and legal)</b></p>	<ol style="list-style-type: none"> <li>1. Data Access requests</li> <li>2. Within the scope of the Regulation (applications via HDABs, permitted purposes, evaluation of applications, pseudonymised or anonymized data), <b>consent is not necessary</b></li> <li>3. Information process is carried out through general publication on a website</li> </ol>
<p><b>Health Data access Bodies</b></p>	<ol style="list-style-type: none"> <li>1. Application management system and <b>national data catalogue</b></li> <li>2. Annual report to the Commission</li> <li>3. <b>Examination, processing and authorization of applications</b></li> <li>4. Obligation of a <b>safe treatment environment</b></li> <li>5. Transnational <b>collaboration</b> (with other HDABs)</li> <li>6. <b>Mutual recognition of requests</b> between HDABs</li> </ol>
<p><b>Obligations of the owners</b></p>	<ol style="list-style-type: none"> <li>1. Describe, label data and communicate to Health Data Access Body data and access</li> <li>2. Manage the own requests in a secure environment</li> <li>3. Provide the <b>data requested by HDAB</b></li> <li>4. <b>Provide elaborated data received</b></li> <li>5. Do not provide non-personal data.</li> <li>6. The possibility of charging fees is contemplated</li> </ol>
<p><b>Obligations of the users</b></p>	<ol style="list-style-type: none"> <li>1. Submit and justify requests, <b>make results public</b>, and return elaborated data</li> <li>2. Become co-responsible for the treatment</li> <li>3. Avoid prohibited uses, de-anonymization and transfer to third parties</li> </ol>
<p><b>Entities</b></p>	<ol style="list-style-type: none"> <li>1. A <b>national Health Data Access body(ies)</b> is contemplated</li> <li>2. Authorized participants are considered in HealthData@EU</li> <li>3. The connection to MyHealth@EU is included for the national contact point</li> </ol>

## 1) The future European Health Data Space

- Primary use => patient control over their data and add other data held by the patient, continuity of care, data sharing among healthcare professionals.
- Secondary use => new capabilities for research, a consistent framework for data usage throughout the EU, secure processing environments.

## 2) The digital transformation of healthcare

- Bringing healthcare closer to patients, especially the most vulnerable.
- Facilitating collaboration among professionals and care levels.
- Incorporating new technologies like AI supported by data in research, diagnosis, and personalized and continuous treatment (IoMT telemonitoring).

**Personalized Digital Care Plan → UNIQUES Network, for pediatric rare diseases care.**



# Objectives and scope plan (Pending final approval Addendum Spanish recovery plan)

## Areas

### Data Capture

Ingestion, storage and interpretation of patient data from activity monitoring devices and **IOMT**.

### Monitorization



### Diagnostic Support



### Information Generation

Alerting, monitoring and **diagnostic support tools** and utilities for professionals based on monitorin patient and EHR data

### Personalized Digital Care (PDC)

Definition and implementation of **care processes** for patient groups and pathologies with **collaboration** among professionals.

### Health Assistance



### Performance Measurement



### Impact

Analysis of the impact of the processes and tools for care and change management on the implemented use cases.

**UNIQUES Network**  
**Pediatric rare diseases care network**

**Caring for pediatric rare diseases patients in any care node of the UNICAS network as if they were treated in the reference center for their pathology, regardless of the Autonomous Community in which they reside .**

## GOALS

- Provide **comprehensive care through a network of 27 Hospitals**
- Focused on **pediatric patients with rare diseases**
- Provide these 27 UNIQUE network nodes with **tools, processes and protocols** to establish a Personalized Care Model on the NETWORK.
- Coordinates Ministry of Health, **co-leads** Catalonia and Madrid.
- Catalonia will develop **components for all Regions** on agreed tech architectures
- **Participating Regions=> more than 150 experts in functional groups and ICT**
- Ministry of Health =>
  - ✓ **Governance and data quality,**
  - ✓ **information exchange services,**
  - ✓ **Terminology and ontology servers,**
  - ✓ **advanced analytics**

## 2 PERSPECTIVES

**Healthcare profesional perspective**  
**UNICAS 360**

**Patient / family / caregivers perspective**  
**UNICAS CHANNEL**

And focused on **4 types of diseases:**



Syndromic neurodevelopmental disorders



Neuromuscular disorders



Mitochondrial diseases



Epileptic encephalopathies

Project

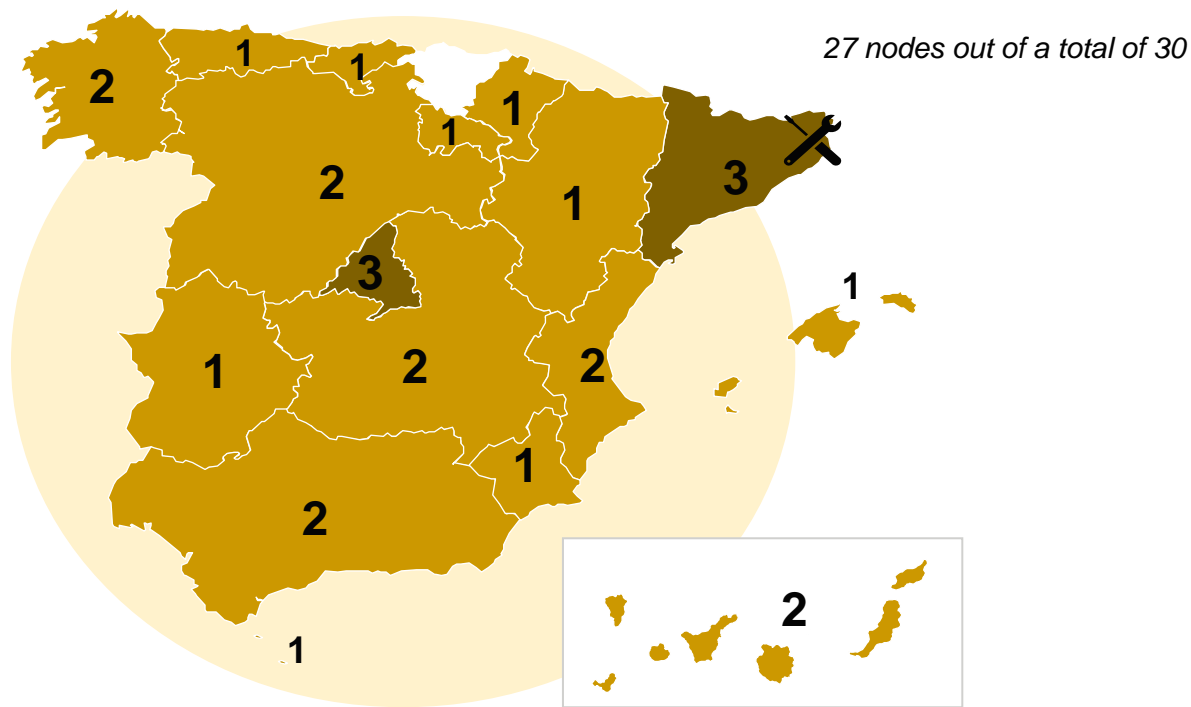


Única2  
Raras pero no invisibles

PAC Plan use case

(Pending Addendum signing to the PRTR)

### NUMBER OF NODES BY AUTONOMOUS COMMUNITY AND THEIR ROLE



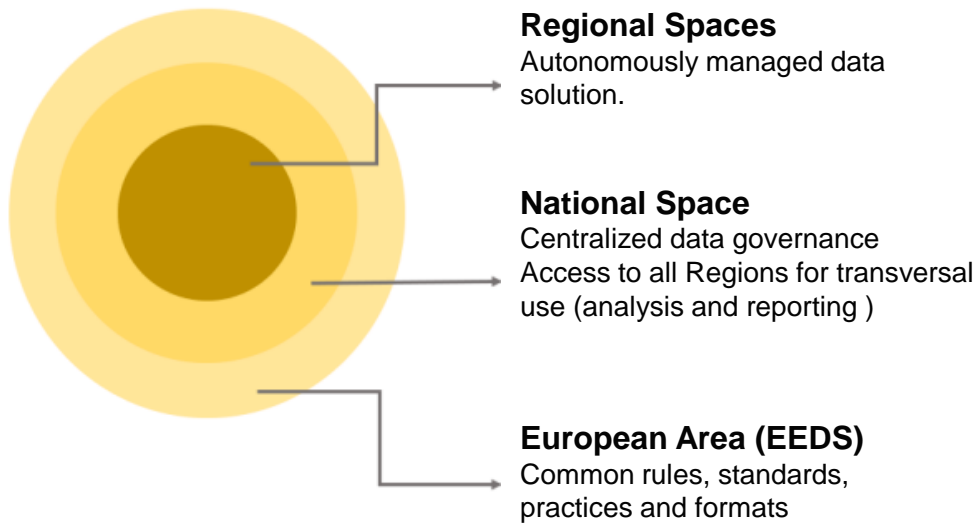
Legend:   
 ■ Leader   
 ■ Competitor   
 ✂ Leader responsible for tools development



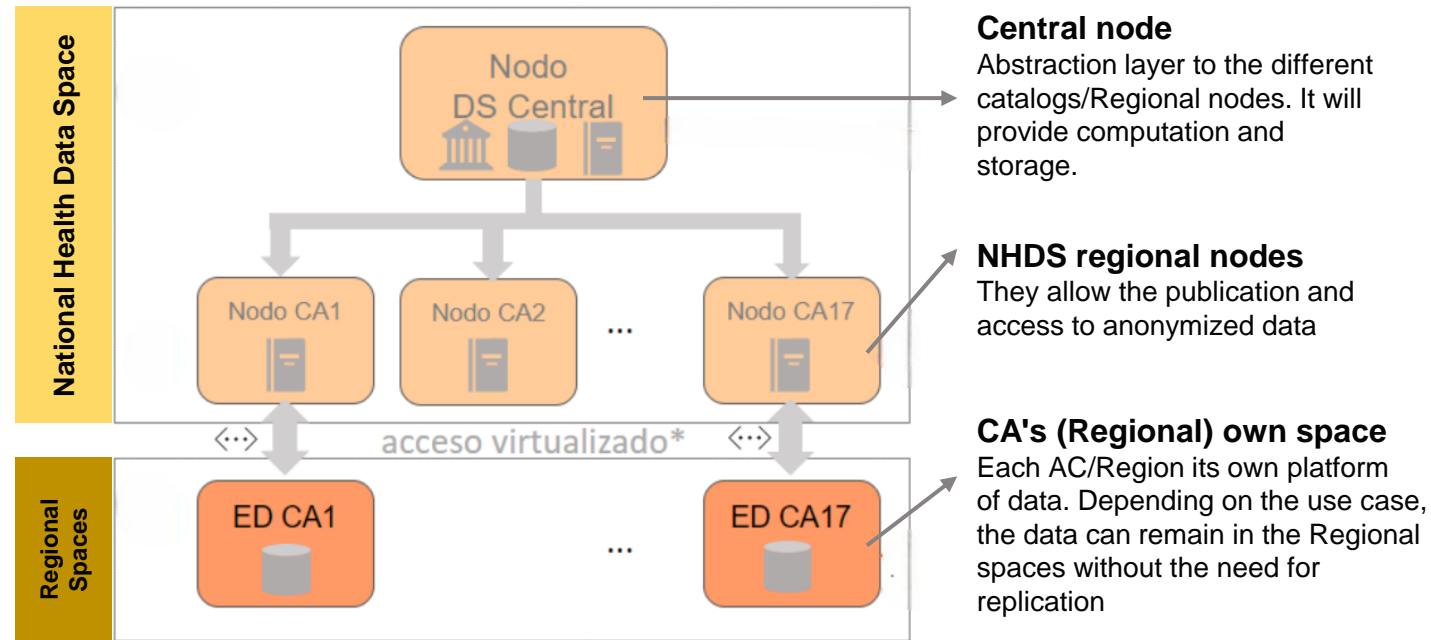
The main **objective** is to provide resources that facilitate the **development and implementation of massive data processing projects** by **Autonomous Communities, Ministry, research centers and units.**

## Reference model

A scheme of **federated data spaces** is proposed:



Architecture overview of the National Health Data Space at a high level:





*Juan Fernando Muñoz Montalvo*  
*Secretario General de Salud Digital, Información e Innovación para el Sistema Nacional de Salud*  
***Ministerio de Sanidad***