

EUROPEAN HEALTH DATA SPACE
**SECONDARY USE OF DATA
AND DATA SUBJECT RIGHTS**
24-25 MARCH 2026
CONFERENCE ONLINE



UNIVERSIDAD
DE MURCIA



CSIC
CONSEJO SUPERIOR DE INVESTIGACIONES CIENTÍFICAS

Secondary Use of Health Data and the Protection of Individual Rights in Rare Diseases



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EHDS AND RARE DISEASES

In the European Union, rare diseases are defined as those affecting **fewer than 5 people per 10,000 inhabitants**. There are between **5,000 and 8,000 rare diseases** worldwide, and **between 6% and 8% of the global population may be affected**. Many are **serious, chronic, disabling** or fatal.

Main problems:

- Complex and lengthy diagnosis process.
- Lack of specific treatments for many rare diseases.
- Difficulties in obtaining integrated care and in gathering sufficient case studies.
- Difficulty in accessing specialised centres depending on the origin of the families.
- Lack of social and health care facilities geared towards treating chronic conditions or providing palliative care.
- **Much more to be resolved:** [EU rare disease action plan](#)



EHDS AND RARE DISEASES



The implementation of the European Health Data Space: a study on health data governance models applied to rare diseases

How does the European Health Data Space Regulation transform the legal framework governing the secondary use of rare disease health data in the EU, and what changes to EU and national law are required to ensure fundamental-rights protection, legal certainty and effective cross-border data sharing?



Collective benefit from biomedical research vs the protection of individual rights (personal data protection + patient autonomy)

Scarcity of patients in each EU member state (need of cross-data sharing) vs health as national-regional competences (different jurisdictions)

Local and small databases lack of sufficient statistical power vs break the silos and promote cross border data aggregation.

WORK IN PROGRESS AT EUROPEAN UNION LEVEL



Summary of Legal basis for EU action on rare diseases

EU action in the field of rare diseases is governed by the Treaties and is subject to strict limits. Under **Article 168 TFEU**, public health is a **supporting competence**: the EU may support, coordinate or complement national policies, but **may not harmonise** the organisation, financing or delivery of healthcare, nor require Member States to adopt specific health models. Member States retain full responsibility for defining their health policies and health systems.

Within these limits, the EU may adopt incentive measures, fund programmes, promote cooperation, issue guidance and facilitate the exchange of best practices. In addition, the EU may rely on other Treaty bases, **notably Article 114 TFEU (internal market)**, to adopt binding rules in areas closely linked to rare diseases, including the **authorisation and regulation of medicines** (e.g. Regulation (EC) No 141/2000 on orphan medicinal products; Regulation (EU) 726/2004), **clinical trials** (Regulation (EU) No 536/2014), **health technology assessment** (Regulation (EU) 2021/2282) and **health data governance** (Regulation (EU) 2025/327 establishing the European Health Data Space), provided that such measures genuinely improve the functioning of the internal market and do not circumvent the prohibition of harmonisation in health policy laid down in Article 168 TFEU.

The **Charter of Fundamental Rights** and the **European Pillar of Social Rights** reinforce the importance of health protection and access to care, but **do not extend EU competences** beyond those conferred by the Treaties. An EU Action Plan on Rare Diseases would therefore operate primarily through **coordination, guidance, funding and strategic alignment**, complemented where appropriate by binding measures adopted on other Treaty bases, fully respecting the principles of **subsidiarity and proportionality** (Article 5 TEU).

Source: Compiled by the author, 2026.



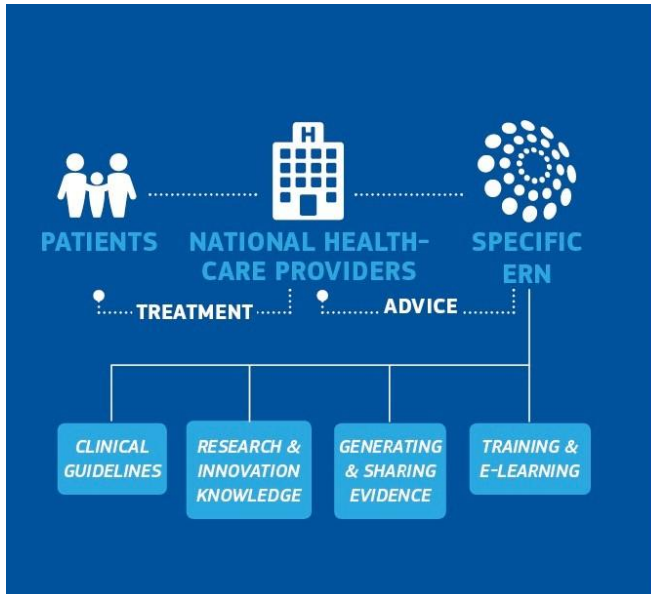
EU rare disease
action plan

European Added
Value Assessment

- Public health is a supporting competence: EU's role is to support → Member States lead + responsibility
- Internal Market (114 TFEU)
- Prohibition of harmonization in health policy (168 TFEU)
- Strategic alignment and principles respect (Art.5 TFEU)

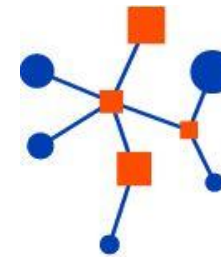
I) THE CRITICAL NEED FOR DATA SHARING IN RARE DISEASES

- **Genotype-Phenotype Studies:** Large volumes of clinical and biosample data are essential to understand how specific genetic changes (genotype) result in clinical characteristics (phenotype).
- **Overcoming the "Diagnostic Odyssey":** Integrating fragmented records into registries, such as those within European Reference Networks (ERNs), allows expertise to "move" rather than the patient, accelerating diagnosis and the development of orphan drugs.
- **Altruism and Solidarity:** Patients with rare diseases often act as "data altruists," voluntarily sharing their data because they recognize that the utility of these "gifts" must be maximized for the public good.



EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW-PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

2) PROTECTION OF INDIVIDUAL RIGHTS AND THE RISK OF RE-IDENTIFICATION

- **Complex balance of values:** autonomy, the right to know (or not know) medical findings, and the right to personal data protection (Article 9 GDPR)
- **The Granularity Paradox:** Research into rare diseases often requires high-resolution, fine-grained data to remain scientifically meaningful. However, the smaller the patient population, the higher the residual risk of re-identification, even after state-of-the-art anonymisation.
- **Privacy vs. Utility:** If data are fully anonymized to remove all risk, they may become scientifically unusable. Conversely, a breach of confidentiality can lead to discrimination in insurance or employment.
- **Potential solutions:** unique encrypted identifiers (UUIDs) → To mitigate these risks, researchers use tools like Global Unique Identifiers (GUIDs). These allow for the merging of data sets from different studies (e.g., biobanks, hospitals, and labs) to follow a specific patient's journey without exposing their direct identity.



3) LEGAL FRAMEWORK AND SAFEGUARDS UNDER EHDS

The EHDS (Regulation (Eu) 2025/327) complements the **GDPR** by establishing specific rules for health data.

- **From Consent to Opt-Out:** The EHDS shifts the legal basis for secondary use from explicit consent to **public interest**, granting citizens a **right to opt-out** from having their data reused.
- **The Rare Disease Exception (Override):** Crucially, the Regulation allows Member States to establish mechanisms to **override an opt-out** when the research serves an "important public interest," → ensures that datasets for rare conditions remain as complete and representative as possible? Is public interest the solution for data processing?
- **Health Data Access Bodies (HDABs):** These bodies act as "gatekeepers," evaluating requests to ensure they meet legitimate purposes (Art. 53) and do not fall into prohibited categories, such as using data to increase insurance premiums or for marketing.
- **Secure Processing Environments (SPE):** To prevent unauthorized access, researchers never receive raw personal data. Instead, they must perform their analysis within a **Secure Processing Environment** provided by the HDAB.

4) ETHICAL AND PRACTICAL DATA GOVERNANCE CHALLENGES



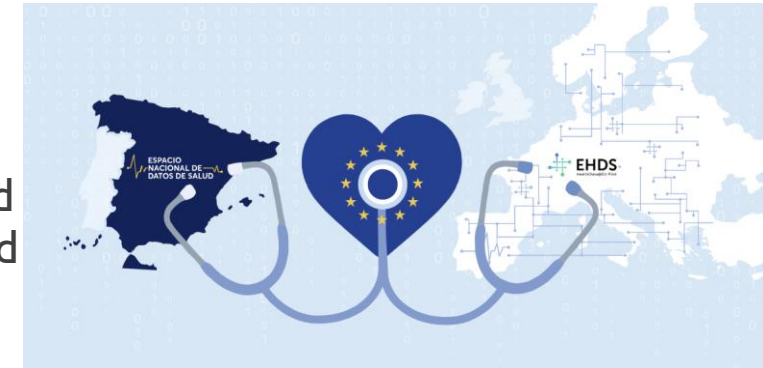
The transition to a "culture of data sharing" requires maintaining public trust through transparent governance.

- Clinically Significant Findings → Data users are obligated to inform HDABs of any significant medical findings discovered during research that could impact a patient's health. The patient, however, retains the "right not to know".
- Ethics Committee Oversight → While the EHDS centralizes access through HDABs, it leaves Member States the discretion to involve Research Ethics Committees, in the assessment process.
- Solidarity as a Duty → Some scholars argue that in the context of solidarity-based healthcare systems, there is an ethical duty to contribute data to research that benefits the general interest, provided safeguards are robust.
- **What about patients?** Should we create specific rights or exceptions for rare diseases context?

EHDS AND SPAIN

Spanish National Health Data Space: [ENDatosSalud](#) | Inicio

- **An initiative of the Spanish Government.** The ENDS is a joint initiative of the Ministry of Health and the Ministry for Digital Transformation and Public Administration, which are working in coordination to build a national infrastructure that facilitates the responsible use of health data for the benefit of society.
- **The autonomous communities are key players in the ENDS.** Each one maintains control over its data, participates in governance bodies and contributes to the integration of information from the National Health System.
- **An ecosystem based on quality and trust.** Organisations and entities that manage health data — such as health services, research institutes, public agencies and other data holders — participate in the ENDS by contributing expert knowledge and ensuring that the information used meets quality, security and traceability standards.
- **Research and open collaboration.** Universities, research centres, public institutions and private entities can develop use cases within the ENDS, subject to prior evaluation and approval. This collaboration makes it possible to promote projects that generate public value, scientific knowledge and improvements in citizens' health.



RARE DISEASES DIGITAL HEALTH PROJECTS



- **ÚNICAS:** The **ÚNICAS Network** was created with the aim of establishing an ecosystem of partnerships to improve the Spanish National Health System's response to patients with complex rare diseases throughout their entire care process (from start to finish), seeking to offer a new model of personalised networked care within the Spanish National Health System, so that all children with rare diseases have the same opportunities for care and treatment.

Other objectives of the ÚNICAS project are:

- To provide comprehensive care through specialised centres.
- To focus on pediatric patients with rare diseases.
- To provide all nodes of the ÚNICAS Network with tools, processes and protocols to establish a Personalised Network Care Model.
- Initially, the project focuses on pediatric diseases, given the special characteristics of pediatric patients, in four main disease categories: mitochondrial diseases, neuromuscular disorders, epileptic encephalopathies and neurodevelopmental syndromic disorders.

<https://unicas-fhir.sanidad.gob.es/proyectoRedUNICAS.html>

PROYECTO ÚNICAS

Objetivo
Atender a los pacientes de EEMM pediátricas en cualquier nodo de la red ÚNICAS como si estuvieran en el centro de referencia de su patología, sin importar dónde residan (que viajen los datos y no los niños). Este proyecto complementa la red actual de CSUR en aspectos como la visión holística del paciente y su apoyo integral, así como parte asistencial de los profesionales no-CSUR.

Información General del Proyecto
El proyecto ÚNICAS prestará una atención integral a través de una red de 30 nodos especializados repartidos por todas las Comunidades Autónomas participantes e INGESA. Estos 30 nodos de la red ÚNICAS estarán dotados de herramientas, procesos y protocolos comunes para establecer un Modelo de Atención Personalizada en RED. El proyecto impulsado por el Ministerio de Sanidad, está liderado por Cataluña y la Comunidad de Madrid. Los componentes de la plataforma ÚNICAS serán desarrollados por Cataluña y el nodo central de intercambio por el Ministerio de Sanidad, utilizando arquitecturas tecnológicas consensuadas entre todos.

La red está inicialmente centrada en 4 tipologías de enfermedades:

- Trastornos síndromicos del neurodesarrollo
- Trastornos neuromusculares
- Enfermedades mitocondriales
- Encefalopatías epilépticas

Aspectos clave del proyecto
Este proyecto proporcionará un nuevo servicio para el Sistema Nacional de Salud

- ✓ Normalización: estandarizar y protocolizar la forma de trabajar.
- ✓ Proximidad: prestar apoyo a las familias/cuidadores a lo largo de todo el proceso.
- ✓ Accesibilidad/Ubicuidad: poder atender de forma remota a pacientes desde cualquier nodo de la red.
- ✓ Modelo asistencial: proporcionar una visión integral del paciente (de principio a fin) y de la enfermedad atendido por un equipo multidisciplinar (sin importar la ubicación geográfica).
- ✓ Sostenibilidad: enfoque de permanencia, posibilidad de ampliación y de mejora continua
- ✓ Proceso común: conseguir de forma consensuada un proceso básico común para toda la red Únicas.

Grupos Funcionales
Para la definición de proyecto contamos con más de 150 expertos de todas las Comunidades

- Asistencial
- Paciente
- Soporte al diagnóstico
- Codificación y estandarización
- Farmacia / Terapias avanzadas

Fases del proyecto

Organización → Definición → Desarrollo, demostración e implantación

2023 → 2024 → 2025 → 2026

Diciembre 2025: Instalación de software e infraestructura
Junio 2026: Puesta en operación

Financiado por la Unión Europea | ERDF 2020-2024 | Estrategia de Salud Digital | Plan de Recuperación, Transformación y Resiliencia | Para más información: Grupo Coordinación Únicas: gc_unicas@sanidad.gob.es



Reglamento UE (2025/327) sobre el Espacio Europeo de Datos de Salud



Uso secundario de los datos de salud electrónicos



El tratamiento de datos de salud electrónicos para los fines distintos de los fines iniciales para los que se recogieron o produjeron.

¿Cómo participar?

- 1 Se recluta a los participantes y se les envía Consentimiento Informado y la hoja de información
- 2 Una vez se obtiene el acuerdo y consentimiento se fija hora y día para la entrevista (45 min)
- 3 Se realiza la **entrevista individual** que será **grabada** y posteriormente seudonimizada para detectar ideas, oportunidades y retos que serán objeto de análisis y publicación académica e institucional de resultados agregados.



¿Dónde?
En su organización o en las Oficinas CSIC-CCHS

¿Qué fines?

- Investigación científica,
- Salud pública, políticas y estadísticas públicas
- Desarrollo e innovación de productos sanitarios.
- Entrenamiento, la prueba y la evaluación de algoritmos, diagnóstico in vitro, sistemas de IA y aplicaciones sanitarias digitales.

CAMBIOS EN LA FORMA DE COMPARTIR DATOS DE SALUD EN EL SISTEMA SANITARIO ESPAÑOL Y EUROPEO. DESAFÍOS LEGALES, ORGANIZACIONALES, ÉTICOS, CIENTÍFICOS Y TÉCNICOS QUE NECESITAN RESPUESTA

¿Qué perfiles queremos entrevistar? especialmente en EERR

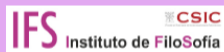
¡Tu voz y tu opinión cuenta! Si deseas participar en el estudio contacta con nosotras: laura.centeno@csic.es o sara.degli.esposti@csic.es



Laura Centeno Casado Investigadora Predoctoral CSIC-IFS- Universidad de Murcia



Sara Degli-Esposti Investigadora Científica CSIC-IFS



Advancing EHDS Implementation: HALO Project

Approved by CSIC and University of Murcia Research Ethics Committees. N.º 189/2025

Interviews to assess existing experiences, practices and protocols across the entire chain of actors involved in health data processing, with a particular focus on those working with patients with rare diseases. These experiences from the current situation will help to understand the willingness to share data and how the implementation of the European Health Data Space can change and improve current challenges and promote the opportunities proposed by the various actors affected by this regulation.

9 Profiles that form part of the EHDS ecosystem.

- Software and Digital health services companies.
- Health Managers (Public authorities and health and research system).
- Pharma companies
- Researchers (biomedical researchers, biobanks)
- Rare Diseases Patient Advocacy Associations.
- Research Ethics Committee.
- DPOs
- Bioinformatics and engineers.
- Medical professionals.

¡THANKS FOR YOUR ATTENTION!



Q&A



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