

March 2024



# Interconnecting Innovation Ecosystems for Common European Data Space in Health



**Funded by the  
European Union**

**D4.3 Policy Input Report – Spanish Presidency**

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**Grant Agreement No. 101070811**



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## History of Versions

Version	Date	Status	Page (if applicable)
V0	16-2-24	Draft circulated among partners	
V0.1	15-3-24	Advanced version for final revision	
V1		Final version	

## Disclaimer

The content of this document represents the views of the authors only and it cannot be considered to reflect the views of the European Commission and/or the European Innovation Council and SMEs Executive Agency (EISMEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.

## Executive Summary

The present Deliverable 4.3 “Policy input report 1: Spanish Presidency of the EU” has been developed within the framework of WP4 “Fostering broad-scale dialogue linked with EU presidency agendas” of **EDAH**.

**EDAH** (Interconnecting innovation ecosystems for common European data space in Health) is a 2-year preparatory action funded by Horizon Europe that aims to contribute to the development of the European Health Data Space. The 4-partners-consortium seeks to establish close collaborations with the EU presidencies during the project’s lifetime, to help prioritise EHDA in their successive agendas. EDAH also seeks to engage a wide range of quadruple helix stakeholders from diverse innovation ecosystems across Europe in identifying barriers and enablers to EHDS, channelling the different Member States’ inputs into EU policy processes. By bridging the current digital health divide in Europe, EDAH contributes to the New European Innovation Agenda with more inclusive, dynamic, diverse and interconnected European innovation ecosystems.

**EDAH** aims to unlock the power of health data for innovative medicines and future healthcare by helping develop the European Health Data Space.

The project’s key milestones are:

1. Set an open dialogue to facilitate the agreement among Member States, Associated Countries and EU Regions about key aspects related to EHDS.
2. Advancing towards common legal, governance, data quality and interoperability framework to facilitate the advancement of EHDS.
3. Scaling up good practices and addressing important gaps in the regional and national innovation ecosystems, through a better understanding of the digital health innovation landscape.

The following report is the third of a series of four policy input reports in this project (including Policy Input Report 1: Czech Presidency of the EU, Policy Input Report 2: Swedish Presidency of the EU, Policy Input 3: Spanish Presidency of the EU and Policy Input 4: Belgian Presidency of the EU). The reports are connected to the EU presidencies happening during the timespan of this preparatory action, from September 2022 to August 2024, corresponding to the end of the Czech Republic’s, Swedish, Spanish and Belgian EU council presidencies.

# 1. Introduction to this report

## 1.1 Specific objectives of EDAH

The partnership implementing EDAH has five specific objectives:

- O1 – Ensuring a coherent overview of the (ongoing) strategic developments related to the European Health Data Space (EU level policy processes, important initiatives, and projects) and developing a deeper understanding of seven important EU ecosystems (innovation agendas and ecosystem stakeholders) represented by clusters/networks from Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria.
- O2 – Setting up a coordination mechanism to connect important stakeholders from innovation ecosystems all around Europe and engage them in focused dialogue around key challenges and opportunities related to advancing the EHDS.
- O3 – Scaling up the dialogue at the EU level via developing further collaboration pathways with EU presidencies.
- O4 – All of the above will be used for, step-by-step, developing, validating, and finalising the Joint Action Plan (JAP) for synergetic work in the interconnected ecosystems of EU health-related clusters/networks (facilitated by the dialogue mechanisms and collaboration frameworks developed in this project) to jointly advance the development of the EHDS.

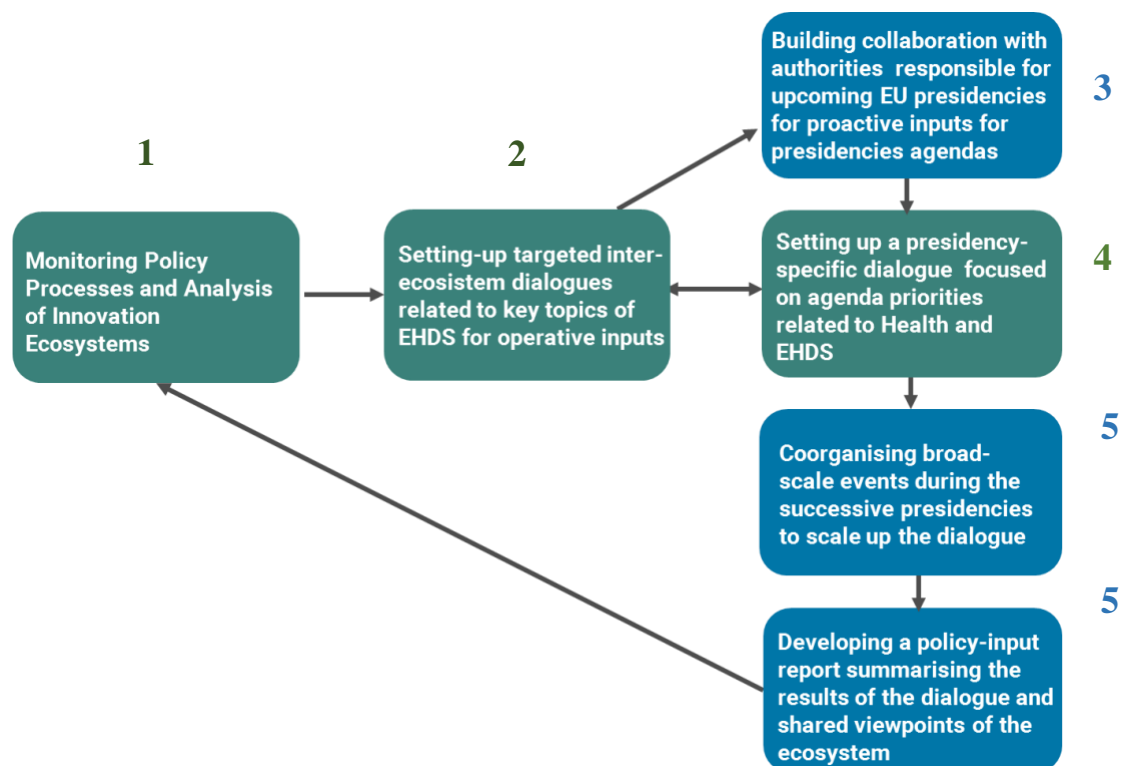


Figure 1: Workflow of the EDAH project: outputs from steps 3-5 are gathered in the present report

## 1.2 List of consortium partners and beneficiary numbers

Beneficiary #	Name	Acronym	Country
1	BIOCAT LA FUNDACIO BIOREGIO DE CATALUNYA	Biocat	ES
2	HEALTH CLUSTER PORTUGAL	HCP	PT
3	SCANBALT	ScanBalt	EE
4	COUNCIL OF EUROPEAN BIOREGIONS	CEBR	BE

## 1.3 Activities under Work Package 4 – Fostering broad-scale dialogue linked with EU presidency agendas.

This WP is aimed to:

- Scaling up the dialogue in terms of 1) the audience/participants in the dialogue process and 2) linkages with high level EU policymaking (via inputs to the EU presidency agendas).
- Providing proactive input to the agendas of the EU presidencies in the project period based on complementarities/synergies identified with the priorities of the specific presidency framework regarding topics relevant to advancing the EHDS.
- Co-organising four EU-wide events linked with the upcoming four presidencies to scale up the dialogue and gather further input relevant to the Joint Action Plan.

Four impactful types of actions have been implemented during this period, connected to tasks 4.3: **Inputs to and from the EU presidency and co-organising the Spanish presidency-related event.**

1. Strategic Progress Updates (SPUs)
2. Dialogue with National and Regional authorities responsible for Health Data strategies or involved in the official presidency program
3. Presidency-related events
4. In the same period, the **Spanish case study** (deliverable 2.5, WP2) was also published, providing additional inputs and synergies to this period activities for the consortium.

### 1.3.1 Strategic Progress Updates (SPUs)

The consortium has continued to consistently track advancements in various important EU-level policy processes and monitor progress related to initiatives such as the follow-up of the TEHDAS project, EP Permed (kicked-off during this Presidency period) and GAIA-X, among others (gathering useful connections and key outcomes that can be connected to EDAH), as well as relevant new studies and analyses and other valuable information for the consortium and for EU policy makers.

This information is processed to identify needs for action and inputs by EDAH consortium partners, to support and strengthen more dynamic, inclusive, gender-diverse, and connected innovation ecosystems for the joint development of the European Health Data Space, fostering innovation in industry and the public sector.

The work under this task has been materialising since the beginning of the project into monthly reports, prepared and shared among consortium members by partner CEBR, and discussed in the monthly EDAH Coordination Working Group meetings, to explore further opportunities. The SPUs cover the key developments as well as suggestions for related responses and actions in the context of the EDAH project.

The consortium is constantly looking for opportunities to establish contacts with various key stakeholders to collaborate and provide input to the EHDS process, also advised by the Advisory Board.

### 1.3.2 Dialogue with National, Regional and European authorities

By end of June 2023, Biocat, the Spanish partner of EDAH and coordinator of the project, held a series of meetings with representatives of different national and regional authorities and organisations and with EU-wide institutions. The partner met with representatives of Spanish Ministries and Catalan Government to discuss updates from SPUs reports, gather insights about Spanish Presidency's priorities related to Health data, for the period, and request support to prepare EDAH's events linked to the Spanish EU Council Presidency. These meetings enhanced the already existing cooperation between Biocat and the Spanish Government and paved the way for events that took place during the 6 month-Spanish Presidency of the EU (July-December 2023).

#### *With the Spanish Government*

As stated in [the Spanish Case Study](#) delivered in July 2023, the Spanish National Health System (SNS) is a decentralized structure, with two main actors: the **Ministry of Health** and the Departments of Health in the 17 Autonomous Communities (ACs), in line with the territorial organization of the State. Related to that is relevant to highlight the multiplicity of providers of health services. Therefore, we aimed both at the Central and Autonomous governments for support and advice. Within the Ministry of Health, the General Secretariat of Digital Health, Information and Innovation of the National Health System is the governing body responsible for addressing projects for the modernization, innovation, improvement and transformation of the National Health System, particularly those related to digital health and information systems.

As also states our Spanish Case Study, other interested ministries have specific roles related to the health system (innovation and digitalisation):

- The **Ministry of Science and Innovation**, with the [Institute for Health Carlos III](#) (Instituto de Salud Carlos III, ISCIII). The ISCIII combines health technology assessment, research centres, public health services, and the coordination and financing of biomedical research.
- The **Ministry of Economic Affairs and Digital Transformation**, with the State Secretariat of Digitalisation and Artificial Intelligence, responsible for the Spanish Health Data

#### *With Catalonia Government representatives and policymakers*

Additionally, regarding Catalonia's Government, Biocat has participated in a regional program to support the Catalan Health system in the definition and implementation of the necessary processes for the secondary use of health data following the EEDS Regulation Proposal. Regarding EDAH it's been instrumental to support a further analysis of the existing literature regarding the EHDS Proposal, in particular the Articles referring to the 'secondary use of data', of reference cases at European level, and of the Catalan health system in relation to Catalonia's health data policy. On the other hand, the responsible agents of the main Catalan health entities have been involved, including the Department of Health, CatSalut, TIC Salut Social, the Health Council of Catalonia, Biocat and AQuAS among others. The members of the different entities participated in three activities based on the exchange of ideas: 1) semi-structured interviews; 2) a day and workshop to co-create a potential EEDS with professionals in the sector; and 3) a presentation session of the EEDS Regulation Proposal to the vocal assistants within the Health Council of Catalonia.

Some of the conclusions of the interviews performed with the participation of Biocat have been included as main take home messages in this report.

### With other Spanish regions

Biocat met with Government officials from **other Spanish Autonomous Communities**, in a special meeting of the National Research and innovation Platforms, organised by Fenin, the Association of Healthtech Industries (Madrid, 23 may 2023).

### With EU-wide organisations: EIT Health

To evaluate the feasibility of the application of the EHDS in different regions and Member States of the EU, EIT Health has carried out a multi-stakeholder, pan-European initiative focusing in particular on provisions relating to secondary use of health data. This EIT Health Think Tank initiative collected real experiences and points of view of EIT Health Partners and other relevant agents of the EU healthcare innovation ecosystem. Biocat was invited as an expert organisation in this initiative, synergistically with EDAH works. Biocat participated in the panel of experts held on June 14, 2023 in Malaga, and provided inputs that served to elaborate the report [“Implementation of the European Health Data Space in Spain, is it really feasible?”](#), presented to the media on 15 February 2024, also with EDAH coordinator in the panel.

In all cases, the meetings to prepare the involvement of EDAH in the Spanish Presidency took place between May 2023 and November 2023. The policymakers and officials, the dates and places and the matters and outcomes are indicated in the table below:

Name and role	Date and place	Meeting subject
Miguel Ángel Armengol, Head of the Big Data	23 May Government of Andalusia, Madrid. Event of National Platforms coordination, Fenin, Madrid.	Discussing regional approaches to EHDS.
Javier González, Director Market and Health; Joseba Laka, Director of Digital	23 May, Tecnalia, Basque Country Tech Center. Madrid.	Discussing regional approaches to EHDS.
Marian Ibarrondo, General Director	23 May. Directorate general Health Research and Innovation, Health Department, Basque Country. Madrid.	Discussing regional approaches to EHDS.
Lorea Mendoza, Scientific coordinator	23 May. Bioef, the Health Agency Basque Country	Discussing regional approaches to EHDS.
Sergio Muñoz, FENIN	26 June 18.00, Madrid	Preparation of an industry-linked event in Barcelona
Javier Colás, BioMadrid, CEO of Madrid Life Sciences Cluster	26 June, Madrid	Discussion of main challenges in health data for Spanish Ecosystems
Director general, Salvador Esteban, and Deputy director, Antonio Alcolea	27 June, General Directorate of Digitalisation and Artificial Intelligence, Ministry of Economic Affairs and Digital Transformation, Madrid	Sharing EDAH’s SPU, discussing needs and involvement of the Industry in Secondary use of health data, requesting for support for a large-scale event
Cristobal Belda	27 June National Institute of Health Salud Carlos III, Madrid	Discussing the role of research infrastructures
Noemi Cívicos, Deputy director Digital Services	27 June Ministry of health, General Directorate of Digital Health and Information Systems for the National Health System, Madrid	Discussing the creation of a Spanish health Data Lake
Pol Pérez, CIO Catalan Health Services	Several meetings, and 11 July event CIO of the Catalan Health Services, Barcelona	Focus group, and Participation in a EDAH event organised by Biocat.
Juan Ignacio Coll, director general for Digital Transformation,	11 July 2023 Government of Aragon, Barcelona	Participation in a EDAH event organised by Biocat.



Innovation and User Rights		
Ramón Rodríguez, head of Advanced Analytics in the Sub-Directorate General for Information Technology	11 July 2023 Murcia Health Service, Barcelona	Participation in a EDAH event organised by Biocat.

### 1.3.3 Organising and participating in Presidency-related events

#### Events

Date	Event	Main stakeholders involved	Format
11 July 2023	<a href="#">Building the European Health Data Space of the Future (EHDS)</a>	Catalan Health Services, Biocat, PredictBy, TIC Salut, Tech Barcelona, Biocat	Full day session, keynotes and panels, coorganised by Biocat under EDAH project
20 July 2023	<a href="#">Will there be and EHDS for everyone? Secondary use of health data</a>	Biocat and Barcelona Health Hub	Half a day session, keynotes and panels, coorganised by Biocat under EDAH project
27 September 2023	<a href="#">BioSpain Conference: "Health Data for Innovative Medicine and the Health of the Future"</a>		Panel
29 - 30 November 2023	<a href="#">Matchmaking event, personalised Medicine</a>	Fenin, Biocat, Eurecat	
5 October 2023	<a href="#">High-level conference on Personalised Medicine</a>		Panel on National examples of data infrastructures, chaired by EDAH coordinator.
10 October 2023	<a href="#">Next Generation Innovators Summit</a>	Spanish Presidency of the EU, EC, Spanish Ministry of Science and Innovation, CDTI and FECYT	EDAH coordinator as speaker in a panel moderated by Anna Panagopoulou, Director for European Research Area and Innovation, DG RTD.

#### Experts' and policymakers' involvement

The following experts have been co-organisers or speakers in panels organised by EDAH in the framework of the Spanish Presidency (July-December 2023).

- Carlos Sisternas  
Director of FENIN (Spanish Federation of Healthcare Technology Companies) in Catalonia
- Xavier López  
Corporate and Operations Director of EURECAT ( Technology Centre of Catalonia).
- Felip Miralles

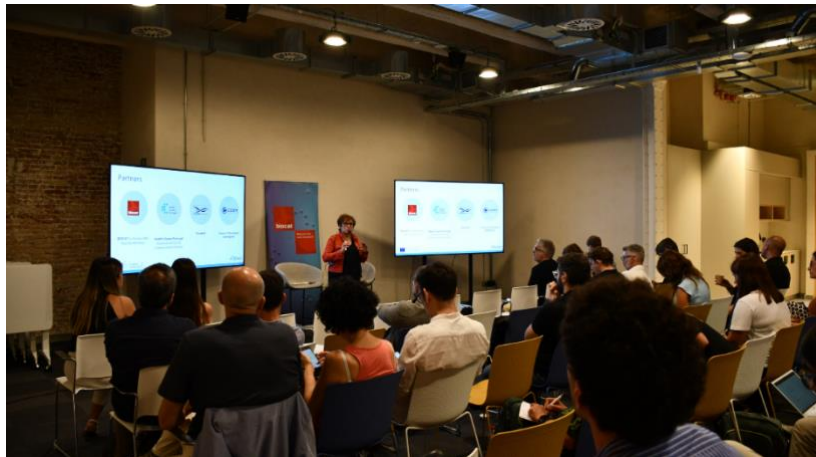




- Director Health Unit, Eurecat, Tech Center and Digital Innovation Hub Catalonia
- Jordi Piera  
Director of the Digital Health Strategy Office at Catalan Health Services
- Sergio Muñoz  
Director of Innovation at Fenin and coordinator of the spanish platform for innovation in healthcare Technology
- Rosa Vivancos  
Innovation Director at AQuAS
- Miguel Angel Armengol  
Big Data Area coordinator at the progress and health Foundation
- Vincent Ribas-Ripoll  
Scientific Coordinator of Digital Health and Artificial Intelligence at Eurecat
- Alfredo Vellido  
Founding Member of the Spanish Society of AI in Biomedicine
- Francisco Vázquez  
President of the Clinical Technologies and Systems Sector
- Xavier Garcia  
Representative of the Digital Health sector at Fenin.
- Arcadi Navarro  
Director of the Pasqual Maragall Foundation, ICREA Research Professor, and Director of the EGA (European Genome-Phenome Archive) at the CRG
- Lluís Blanch  
Director of the Parc Taulí Research and Innovation Institute - I3PT and Coordinator of the ITEMAS-ISCIII Platform
- Manuel del Castillo  
Director of the Vall d'Hebron Research Institute
- Enriqueta Felip  
President of the Spanish Society of Medical Oncology (SEOM).
- Laia Arnal  
General Director of Transfer at the Department of Research and Universities of the Generalitat de Catalunya.
- Luis Badrinas  
CEO Barcelona Health Hub
- Pol Pérez  
Director of Health Information Systems, Catalan Health Services
- Joan Guanyabens  
Director of TIC SALUT Social and of AI Health Program, Catalonia
- Ramon Maspons Bosch  
Director of Innovation Strategy, Ministry of Health, Catalonia, and director of innovation at AQuAS, the HTA agency
- Zaira Benítez  
Head of Vall d'Hebron Hospital Data Architecture Unit

## Communication and media impact

- Post on EDAH website about an event on “Building the European Health Data Space of the Future” (11 July 2023): [Link to post](#)



- LinkedIn post about an event on “Will there be a European Health Data Space (EHDS) for everyone? Secondary use of health data.” (20 July 2023): [Link to post](#)

- Youtube video about the panel on National examples of data infrastructures (5 October 2023, Valencia): [Link to video](#) Min 1.45-3.06)



- LinkedIn post about the roundtable on “Innovation in the making; Innovative Europe’s success stories” (10 October 2023) at Next Generation Innovators Summit: [Link to post](#)



- LinkedIn post about the session on “Health Data for Innovative Medicine and the Health of the Future” (27 September 2023) at BIOSPAIN organized by EDAA: [Link to post](#)

- Event "Matchmaking personalised medicine" [Link to tweet](#)



## 1.4 Outputs from the actions implemented

### 1.4.1 Meetings with National authorities

Ministries are launching initiatives to boost the digitalization digital skills in the private sector and to face the AI challenges in the industry and the business value chains and supporting new initiatives like National Neurotech Center, and some CSAs with networks between Catalonia, Murcia and Valencia, as some of the

most advanced regions in the subject. The Health Datalake project is not mature enough. The Government is providing training in digitalization. The different Ministries are promoting synergies among their initiatives: The Government is promoting the AI Regulation, still poorly legislated in Europe. Spain is pioneering a regulatory sandbox to see how companies can adopt the EC regulation.

There is a major area of concern: how to harmonize innovation with regulation on medical devices. Use cases within the private sector are needed, where digital native companies in the health sector and companies that can generate data work together. A B2b between companies for the provision of health services is a good model. There's a need to better define business models for companies.

As for the healthcare data lake, it is complex in terms of governance, as the objective is secondary use.

They want to enhance the fact that the system can fluidly share data, the concept of European data spa in the health sector. The Government is allocating RRF funds to the data lake, and will be launching programs to develop projects on that subject. However, it is not clear which Ministry is mainly responsible for the Data Lake. The Health Ministry stressed that Spain is a leader in primary use of health data and not in secondary use, and regarding the health system, Spain is more interested in how other countries have advanced in this primary use. In general, as the Spanish presidency was beginning at the moment of the visits, the officials wanted to be cautious regarding public statements.

#### 1.4.2 Meetings with Regional authorities

There are account for challenges such as technical complexity in the standardization of the data, training and capacity building for the proper functioning of the EEDS, the governance and leadership of the transition, investment and sustainability of the ecosystem, and interpretation of the regulatory aspects.

Catalonia currently has 27 different hospital information systems and the Government has been working on syntactic interoperability, so other stakeholders can interpret the data, and now they have to move onto semantic interoperability: exchanging not just data but also content and context.

#### 1.4.3 Discussions with experts and involved stakeholders

The stakeholders and policymakers participating in the interviews and meetings highlighted:

- need for strategic planning and vision by the leading entities: a definition of the rights and obligations of all the stakeholders involved is required through clear political leadership.
- Collaborative and contribution-based vision among stakeholders: the importance of creating an ecosystem of secondary data use based on the generosity of the data compartment, which includes citizen participation, health professionals, research institutes and universities, and other institutions in the public and private sectors
- Dissemination and training: training and pedagogy for the public and health personnel regarding the potential of the EEDS, and in particular to collect qualitative evidence from the public to ensure that the proposed regulation does not fail at a political level
- Alignment at European level: the interviewees note the importance of an implementation that can be scaled at European level and based on the principle of decentralization and autonomy in order to be competitive at international level.

#### 1.4.4 Main outputs from the Spanish presidency of the EU

On September 2023, the Ministry of Health expressed support to the digitalization process as a basic tool to provide and guarantee quality healthcare, personalized and equitable, adapted to the circumstances and needs of each person. This was defended during the closing of the High Level Meeting on Digital Health held in León within the framework of the Spanish Presidency of the European Union. The Ministry also highlighted the cross-border collaboration of the digital health network (E-Health Network) as a crucial tool and thanks





to it, Spanish and European Union citizens can allow access medical history to professionals in other countries and obtain your medicines from them when you travel. The Ministry states the necessary protection of privacy and the ethical commitment that accompany this process.

In the Spanish Presidency EPSCO meeting in November, progress was also made on the European Health Data Space, with Spanish Minister stating that managing health data on a large scale will enable the development of new services and products for the prevention and treatment of diseases.

On December, Spain pushed the Artificial Intelligence Regulation, a pioneering law to boost its development and adoption in Europe.

#### 1.4.5 Spain Case Study

Since 2020 there has been a significant progress in Spain towards EHDS, with the creation of specific Government units for digital health, launching of funds and instruments like the “Vanguard Health” PERTE (special strategic projects of interest) and the proposal for a creation of a Spanish Data Lake. The [report](#) published in the EC and EDAH’s sites reviews the main assets, needs and opportunities towards EHDS for Spain as a case study for EDAH.

