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# Interconnecting Innovation Ecosystems for Common European Data Space in Health



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## History of Versions

Version	Date	Status	Page (if applicable)
V0	27-9-23	Draft circulated among partners	
V1	28-9-23	Advanced version for final revision	
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V3	29-9-23	Final version	

## Disclaimer

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## Executive Summary

The present Deliverable 4.2 “Policy input report 1: Swedish 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 second 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 report 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.

## Introduction to this report

### 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.

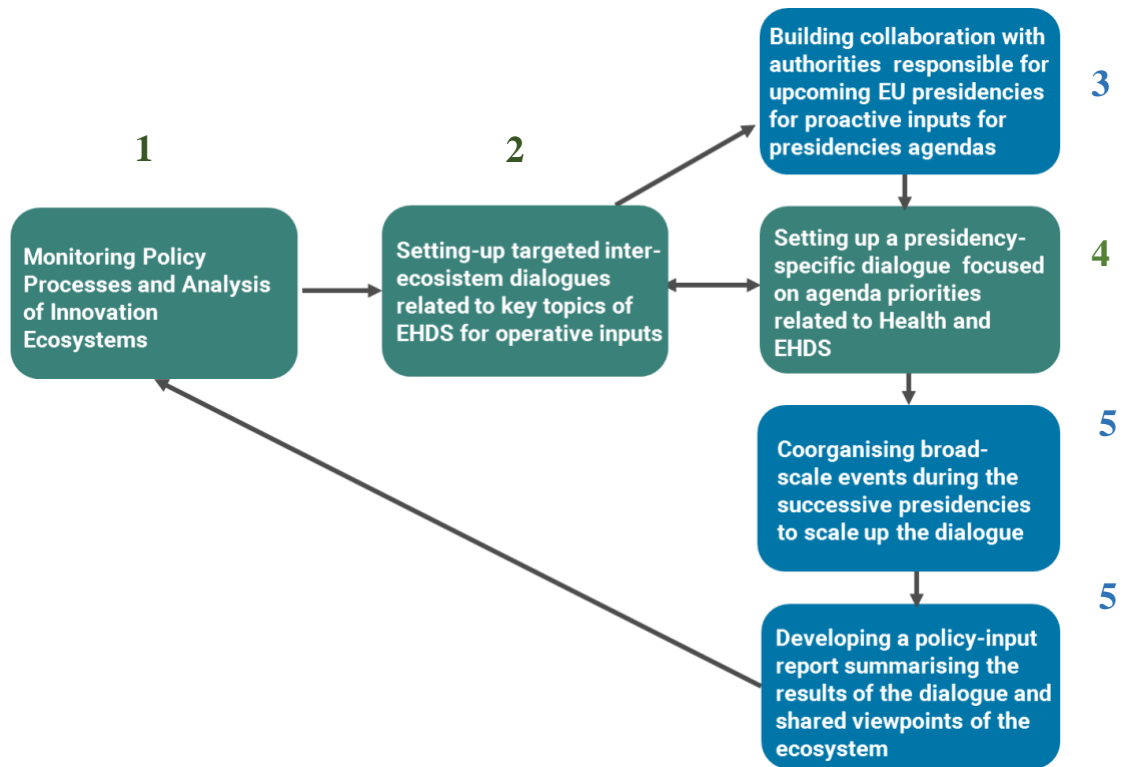


Figure 1: Workflow of the EDAH project: step 1 is the analysis of Innovation Ecosystems

## 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

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

#### Objectives

- Scaling up the dialogue processes started in WP 4 both 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.

#### Task 4.2 Providing inputs to the EU presidency agenda and co-organising the presidency-related event in Sweden.

The consortium is consistently tracking advancements in various important EU-level policy processes and monitors progress related to initiatives such as the follow-up of the TEHDAS project and GAIA-X (e.g., key milestones achieved), relevant new studies and analyses, etc. This information will be processed and analysed to identify potential synergies, needs for action and inputs by EDAH to support important developments in line with the idea of 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 will materialise into monthly Strategic Progress Updates (SPUs) prepared for the monthly EDAH Coordination Working Group meetings. The SPUs will cover the key developments as well as suggestions for related responses and actions in the context of the EDAH project.

In addition, the consortium is constantly looking for opportunities to establish contacts with various key stakeholders to collaborate and provide input to the EHDS process.



# 1 – Overview of the outreach to relevant stakeholders in Sweden

## 1.1 Reaching out to the national authorities responsible for the presidency program.

Leading up to the Swedish Presidency, the consortium partners undertook several initiatives aimed at establishing positive relationships with local authorities and national institutions involved in the Swedish Presidency.

These efforts resulted in the establishment of favourable connections through conversations with entities such as the Swedish eHealth Agency (E-Hälsomyndigheten), LIF, Novartis Sweden, EIT Health Scandinavia, STUNS Life Science, Region Västra Götaland (VGR), and the Swedish innovation agency Vinnova. All of these organisations expressed their willingness to collaborate and contribute to the ongoing discussion on the EHDS. As a result of these connections, members of the EDAH consortium actively participated in various events and discussions related to EHDS during the Presidency period.

In preparation for the Swedish presidency, the consortium partners made efforts to find the appropriate contacts and used their networks to build links with relevant players at the local level to be able to connect the project activities to the presidency. The contacts initiated were useful to obtain information for case studies and to involve the consortium members in different discussions on EHDS.

## 1.2 Communication activities

- 1) Post about the session “Health data for better care” at Vitalis 2023 (24 May 2023) on EDAH webpage – [Link to post](#)
- 2) LinkedIn post about the session “Health data for better care” at Vitalis 2023 (24 May 2023) – [Link to post](#)



Figure 1 Panel (Michel Silvestri, Hille Hinsberg, Petronille Bogaert, Jodri Piera Jiménez, Montse Daban); booth at the Vitalis 2023 fair

- 3) LinkedIn post about the panel discussion “Digital transformation of health systems: towards health for all”(6 March 2023) in Tallinn, Estonia – [Link to post](#)





- 4) LinkedIn post about the panel discussion "Unlocking access to health data in Europe" organised by Biocat – [Link to post](#)



Amb la col·laboració de:

**INFORME biocat**

**ACCIO**

**Catalonia & HealthTech**

**farmapoints**

**Fenin**

**AMGEN**

**ESTEVE**

**Altrahealth**

**almirall**

Amb el suport de:

**eatris**

**BRIGHT**

**EDAHA**

**Innexa**

**Innexe**

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5) Introduction of the EDAH project at an event organised by Commissioner Mariya Gabriel – [Link to post](#)



## 2 – Overview of the EU presidency-related events to scale up the dialogue

### 2.1 – Participation in the events related to the presidency

Date	Event	Dialogue
26/01/2023	New Data Centre for European Innovation Ecosystems	Some of the members of the EDAH consortium had the opportunity to attend the launch of the new Data Centre for European Innovation Ecosystems. This event, organized by Commissioner Mariya Gabriel, took place at the European Commission headquarters in Brussels. Montse Daban, the Director of Science Policy and Internationalisation at Biocat seized the opportunity to introduce the EDAH project and explain its role in advancing the objectives of the New European Innovation Agenda.
06/03/2023	Panel discussion: Digital transformation of health systems: towards health for all!	Consortium members ScanBalt (Dr. Jaanus Pikani) and Biocat (Alba Jiménez) participated in a panel discussion on behalf of the EDAH project.
24/05/2023	Health Data for Better Care	The EDAH consortium co-organised a panel discussion at Vitalis 2023. The speakers exchanged insights regarding successful practice and developments in the context of EHDS, drawing from their respective countries experiences. Additionally, they touched upon the primary challenges and obstacles that could influence the smooth implementation of the EHDS.
27/06/2023	Empowering Patients through Health Data	The EDAH consortium member Dr Jaanus Pikani was invited to participate the seminar and a round table hosted by Swedish Medtech and EIT Health Scandinavia. Participation in this event provided an opportunity to actively engage and discuss opportunities for cooperation with both policy makers and local stakeholders to contribute to the development of the EHDS process.

### 2.1 – Ecosystem involvement

Type of interaction	Person	Organisation/position
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Presentation of EDAH project and discussion on the developments of the European Health Data Space	Michel Silvestri	Head of Unit at the Coordination Department of the Swedish eHealth Agency
Discussion on the developments of the European Health Data Space and the state of play of health data in Sweden.	Laurent Saunier	Head of precision health at Vinnova
Intro to the EDAH project and possible synergies	Fredrik Moen	Contact for the EU presidency activities at LIF
Discussion on potential collaboration during Swedish EU Presidency and input for the Swedish case study.	Björn Arvidsson	Managing Director at STUNS Life Science
Discussion on potential collaboration during Swedish EU Presidency and introducing the EDAH project and the activities related to the EHDS.	Monica Åberg Yngwe	Public Affairs and Stakeholder Relations Lead at EIT Health Scandinavia
Discussion on potential collaboration during Swedish Presidency and introducing the activities related to the EHDS.	Lotta Liljelund	Public Affair Director at Novartis Sweden and EU Policy Manager at LIF
Collaboration on joint session at Vitalis 2023.	Daniel Höglund	Patient Journey and Solutions Lead at Novartis Sweden
Collaboration and mediating contacts.	Lars Linsköld	VGR / AI SWEDEN / Center transdisciplinär AI Umeå University/ SFMI / EFMI

## 3 – Summary of the collaboration process

### 3.1 – The collaboration process with the national authorities

The project partners reached out to representatives Swedish eHealth Agency (a government agency) and established contact with the Head of the Unit at the Coordination Department, Michel Silvestri. The consortium made efforts to get feedback on the results of their case study by reaching out to their network in Sweden. The most valuable interactions occurred during their ongoing communication with representatives of eHealth Agency and EIT Health Scandinavia, which grew into fruitful cooperation in the framework of various events.

### 3.2 – The collaboration process with the national authorities

The positions and conclusions shared during various meetings and discussions in the frameworks of the Swedish Presidency are gathered in a Case Study on the digital health landscape of Sweden. The outcome of the Case Study was shared with the representatives of the eHealth Agency and other collaboration partners and the consortium is looking forward to continuous collaboration during the next EU Council Presidencies.

### 3.3 – The collaboration process with the national authorities

During numerous discussions with the representatives of the government agencies and local partners, the consortium members provided relevant information about the EDHS process in other member states and the EDAH project objectives including the EHDS debate on the EU Presidencies' agenda of priorities.

### 3.4 – The results of the presidency related to the EHDS

The Swedish Presidency led the discussion on the compromises to the proposal for a regulation on the European Health Data Space that ensures cross-border access to and exchange and use of health data.

Building on the work done under previous presidencies, the Swedish Presidency introduced updated texts for Chapters I and Chapters IV to IX9, embodying compromises shaped by discussions during meetings, feedback received from delegations in written form, and clarifications provided by the Commission. The compromises included several adjustments to the Commission proposal, such as replacing the advisory procedure with an examination procedure in all implementing acts (as already presented in the Czech compromise on Chapters II and III), deleting delegated acts to give greater influence to the co-legislators on essential elements of the proposal, introducing the term 'health' before 'data holder' and 'data user' to specify the concepts of data holders and users defined in the Data Governance Act and the Data Act, and clarifying the links with the General Data Protection Regulation (GDPR).<sup>1</sup>

The Swedish Presidency provided a good basis for future discussions and has given the Spanish Presidency a good foundation to build on the progress made so far.

September 2023

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<sup>1</sup> <https://data.consilium.europa.eu/doc/document/ST-9368-2023-INIT/en/pdf>

