



Council of the European Union
General Secretariat

Brussels, 04 July 2023

**Interinstitutional files:
2022/0140 (COD)**

WK 9070/2023 INIT

**REDACTED DOCUMENT ACCESSIBLE
TO THE PUBLIC (27.03.2025).
ONLY MARGINAL PERSONAL DATA
HAVE BEEN REDACTED.**

LIMITE

**SAN
PHARM
COMPET
MI
DATAPROTECT
CODEC**

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (Attachés) Working Party on Public Health (European Health Data Space)

Subject:	Working Party on Public Health on 04 July 2023 - Presentation by the Presidency on the European Health Data Space
----------	--

Delegations will find enclosed the presentation given by the Presidency during the Working Party on Public Health held on 04 July 2023.



PRESIDENCIA
ESPAÑOLA
CONSEJO DE LA
UNIÓN EUROPEA

Working Party on Public Health on 04 and 05 July 2023

Tuesday, 4th of July 2023
14:00-18:00

Wednesday, 5th of July 2023
10:00-13:00 & 14:30-18:30

ES EHDS Team

- ✓ [REDACTED] (chair) / [REDACTED] (back-up)
- ✓ [REDACTED] (vice-chair)
- ✓ [REDACTED] (senior expert)
- ✓ [REDACTED] (expert)
- ✓ [REDACTED] (expert)
- ✓ [REDACTED] (expert)

EHDS regulation

- Wrap-up (what has been done)
- Goals & scenarios
- Working methodology
- Conference on Personalised Digital Healthcare (León, Spain)
- Today's meeting: agenda and contents

EHDS wrap-up

May 2022:

Commission's proposal published

January - June 2022: French presidency of the EU Council

5 meetings devoted to EHDS

- preliminary meetings
- kick-off of first reading
- approval of European Ethical Principles for Digital

Health

EHDS wrap-up

July-December 2022: Czech presidency of the EU Council

17 meetings devoted to EHDS

7 October 2022:

- First Presidency compromise text
(Chapters II and III & Annexes)
[document number ST 13318 2022]

EHDS wrap-up

January 2023-June 2023: Swedish presidency of the EU Council

13 meetings devoted to EHDS

16 January 2023:

- First Presidency compromise text (Chapters I and IV)
[document number ST 5302 2023]

28 February 2023 :

- First Presidency compromise text (Chapters V-VIII)
[document number ST 6627 2023]

15 March 2023 :

- First Presidency compromise text (articles 66, 66A, 70 and 72)
[document number ST 7353 2023]

EHDS wrap-up

January 2023-June 2023: Swedish presidency of the EU Council

13 meetings devoted to EHDS

17 April 2023:

- Second Presidency compromise text (Chapters I-IV, VI-VIII & Annexes)

[document number ST 8171 2023]

8 May 2023:

- Second Presidency compromise text (all Chapters)

[document number ST 8171 REV 1 2023]

EHDS pending topics (1/3)

Primary use of health data

- Clarifications about scope (national vs cross-border) of digital health services and rights of natural persons.
- Approach for assessment of EHR systems (Chapter III).
- Wellness applications in primary use (articles 31-31A).

EHDS pending topics (2/3)

Secondary use of health data

- Definition of health data holder (article 2(2)(y))
- IP rights & trade secrets (article 35(A))
- Opt-out (article 35F)
- Fees (article 42)
- Merging of data access applications and data access requests (articles 45 & 47)
- Revision of rights of natural persons in the context of secondary use of health data (articles 35D, 35E, 35G)
- Revision of article 58 (current wording may give a broader implementing power to COM than the original text)

EHDS pending topics (3/3)

Governance

- **Governance at the national level:**
 - digital health authority: arts 10, 10A & 11
 - HDAB: arts 36, 37 & 39
- **Governance at the EU level:**
 - EHDS board & steering groups: arts 64-66
- **Third countries**
- **EU central services:**
 - Validation environment for EHR systems provided by the EU Commission?
 - HDAB for EU institutions?

Goals & Scenarios

Main goal: General approach (GA)

- **GA in October 2023 & begin trilogues**
- **BE finishes trilogues.**
- **This implies a compromise text by the end of September 2023.**

Working methodology

- Identification of MS' **red lines**.
- **Efficiency** of meetings:
 - Comments in **written form**, using **common format** for text proposals.
 - Cleaning of non-substantial elements.
 - **Avoid** long technical interventions and circular discussions.
 - **Avoid** “*nice to have*”.

Working methodology

We will continue working with the Swedish presidency compromise text, document number ST 8171 2023 REV1 (herein after “compromise text”).

Working methodology

At your disposal:	involve all MS identify red lines reach agreements
Before WP meeting:	informal contacts documents in advance
During WP meeting:	efficient meetings focused interventions
After WP meeting:	written comments on specific issues cleaning of non-substantial elements

Flexibility is needed to reach an agreement!

Conference on Personalised Digital Healthcare

Dates:

September 27: Personalised Digital healthcare + eHN Semantic SG

September 28: Personalised Digital healthcare + eHN Technical SG

September 29: joint session at the national conference

Venue:

León, Spain

(320 km from Madrid)



Expenses:

Transportation: Spain / EU Commission (*)

*Airplane ticket to Madrid + speed train from Madrid to León
speed train from León to Madrid + Airplane ticket from Madrid*

Accommodation & meals & cultural activities: Spain

Up to 2 persons per MS for September 27-29:

1 representative for the eHN Semantic SG

+ 1 representative for the eHN Technical SG



WEDNESDAY 27 OFFICIAL OPENING AND WELCOME (9:00 – 9:30) (AUTHORITIES FROM MINISTRY OF HEALTH /REGIONAL GOVERNMENTS TBC)	
SESSION	PARTICIPANTS
The European Health Data Space and 5P medicine (9:30 -10)	DG SANTE
The Strategy of Digital Health of the National Health System (10:00 -10:45)	Secretary General of Digital Health, Information and Innovation (Ministry of Health of Spain)
10:45 – 11:15 Coffee break	
Digital transformation of National Health Systems through Europe (Denmark, Belgium, Hungary and Estonia) (11:15 – 13:15)	Round table with representatives of the Health Ministries of Denmark, Belgium, Hungary and Estonia Moderator: DG Digital Health, Ministry of Health of Spain
13:15- 15:00 Lunch	
Digital Health: data, rights, privacy and ethics. (15:00 – 16:00)	Round table with AEPD (Spanish Agency of Data Protection), Director of the EDPS (European Data Protection Supervisor), PhD Ricard Martínez, PhD M ^a Belén Andreu Moderator: Data Proteccion Officer of the Ministry of Health
Cybersecurity and digital health (16:00 -17:00)	Round table with representatives from the Health Departments of the regional governments of Baleares and Castilla La Mancha, INCIBE (National Institute for Cibersecurity) and ENISA (tbc) Moderator: Under Director of Health IT infrastructure, Ministry of Health
18:30 - TOURISTIC VISIT AND DINNER	

PARALLEL AGENDA FOR THE E-HEALTH NETWORK TECHNICAL AND SEMANTIC GROUPS MEETING



THURSDAY 28	
SESSION	PARTICIPANTS
Secondary use of health data: the experience of Finland, France and Sweden (9:00 – 10:00)	Round table with representatives from the Finland, France and Sweden data access organizations. Moderator: TBC
Challenges and opportunities of HealthData@UE (10:00 – 11:00)	Round table with representatives from the Spanish Agency of Medicines and Medical Devices, the European Medicines Agency, ASEBIO (Spanish Association of Biocompanies) and Foundation 29 (non-profit organization, expert in artificial intelligence applied to health). Moderator: TBC
11:00 – 11:30 Coffee break	
“Comprehensive treatment of rare diseases” / Únicas: raras pero no invisibles (11:30-12:30)	Round table with representatives of the General Directorate of Basic Services and Pharmacy Portfolio of the Ministry of Health of Spain, the Health department of the regional government of Catalonia, FEDER (Spanish Federation of Rare Diseases) and the chair of the ERN Board. Moderator: TBC
Gobernanza, calidad y evaluación de algoritmos y datos (Governance, quality and evaluation of algorithms and data) (12:30-13:30)	Round table with representatives of SEIS (Spanish society of health informatics) and of the Health department of the regional governments of Andalucía, Navarra, Cantabria and Murcia. Moderator: Under Director of Information systems for the NHS (Ministry of Health)
13:30- 15:00 Lunch	
La atención digital personalizada de la cronicidad (Personalized digital care for chronicity) (15:00 – 16:00)	Round table with representatives the Health department of the regional governments of Galicia, Comunidad Valenciana, Aragón, Extremadura and Asturias. Moderator: TBC
Ciber resiliencia en Sanidad (Cyber resilience in Health) (16:00 – 17:00)	Round table with representatives of CCN (National Cryptology Centre), AMETIC (Association of Electronics, IT, Telecommunication and Digital Contents Companies), ASLAN (Association of IT companies) and ISMS Forum (Spanish Association for the Promotion of Information security). Moderator: TBC
18:30 - TOURISTIC VISIT AND DINNER	

PARALLEL AGENDA FOR THE E-HEALTH NETWORK TECHNICAL AND SEMANTIC GROUPS MEETING



PUBLIC

FRIDAY, 29	
SESSION	PARTICIPANTS
Primary use of Health Data: the E-Health Network experience (9:30 – 10:30)	Round table with e-Health Network representatives of Portugal, Croatia, Luxembourg and Malta and of the Health department of the regional governments of Canary Islands and Madrid Moderator: TBC
10:30 – 11:00 Coffee Break	
New standards and data models for primary use health data: EHDS & EHR (11:00-12:00)	Round table with e-Health Network representatives of Greece and Cyprus and of SEIS (Spanish society of health informatics) and FACME (Federation of medical scientific associations) Moderator: TBC
Digital devices and health systems (wellness apps, medical IoT devices...) (12:00 – 13:15)	Round table with representatives of the Health Ministries of Germany and the Netherlands, Farmaindustria (National Association of the Pharmaceutical Industry in Spain) and FEP (Spanish Forum of Patients) Moderator: TBC
13:15- 13:30 OFFICIAL CLOSING (MINISTER OF HEALTH OF SPAIN)	
13:30-15:00 LUNCH	