Draft concept note for a **High-level event on the European Health Data Space (EHDS)**

The European Health Data Space (EHDS) Regulation [1]is a landmark initiative within the European Health Union and the broader European Data Strategy. It represents a major step forward in creating a secure, trusted environment for accessing and sharing electronic health data across the EU, with the goal of fostering innovation, improving healthcare delivery, and enabling a single market for digital health services and products. Moreover, the EHDS is poised to strengthen Europe's global competitiveness in digital health, creating opportunities for European companies to innovate and lead in this rapidly evolving sector.

This high-level event, organized under the auspices of the Polish Presidency, will serve as a celebration of the final adoption and Official Journal publication of the EHDS regulation as well as a (re)statement of the Commission and Member States commitment to its successful implementation and a follow up of the lunchtime debate during the informal EPSCO under the Hungarian Presidency.

The event aims to highlight the transformative potential of the EHDS for the healthcare systems, emphasize the shared European vision for health data and provide a strong foundation for the successful implementation of the EHDS, ensuring that it delivers on its promise to enhance healthcare delivery and innovation across the EU for the health and wellbeing of European citizen.

1. Event Objectives

Primary objectives

- **Celebrate the Adoption of the EHDS Regulation**
  The event aims to mark the successful adoption and official publication of the EHDS as a major milestone within the European Health Union and the broader European Data Strategy. To achieve this, we will organize a high-visibility event that underscores the political and societal significance of the EHDS. This will include keynote addresses from key political figures including members from the European Parliament and a dedicated ministerial panel to highlight the collective commitment from Member States towards the EHDS.

- **Highlight the Promises and Benefits of the EHDS**
  This objective focuses on showcasing the potential of the EHDS to revolutionize healthcare delivery, foster innovation, and enhance the lives of European citizens. The event will use expert panels, and testimonials to demonstrate the tangible benefits the EHDS will bring, emphasizing how it will contribute to creating a more integrated and robust European health system.

- **Reaffirm the European Vision for Health Data**
  The event will position the EHDS within the broader context of the European Data Strategy, emphasizing its role in building a cohesive and interoperable European health data ecosystem. Discussions will be linked to the overarching goals of the European Data Strategy, including enhancing data sovereignty, driving innovation, and boosting competitiveness across the EU as well as potential synergies with other data space in development. This will underline the EHDS as a major milestone and critical component in achieving these goals.

- **Present the Commission's plans for EHDS Implementation**
  The event will be an opportunity to outline the necessary steps, milestones, and responsibilities involved in the successful implementation of the EHDS. To reinforce this, the event will conclude with a closing statement from DG SANTE who will detail the Commission's plans.

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[1] Texts adopted - European Health Data Space - Wednesday, 24 April 2024 (europa.eu)

Secondary objectives

- **Strengthen Collaboration Among Stakeholders and national authorities**
  The event aims to promote cross-sector partnerships and collaboration among Member States, industry leaders, and other stakeholders to support the EHDS implementation. This objective will be achieved by facilitating discussions on the roles and responsibilities of various stakeholders and different national authorities (e.g. health, digital, research) encouraging political synergies, joint initiatives, and fostering knowledge-sharing that is crucial for the EHDS's success.

- **Raise Awareness and Build Trust**
  Raising awareness on the EHDS among policymakers, healthcare professionals, and the public, while addressing concerns related to data privacy, security, and patient rights, is another key objective. The event will include a session focused on trust, transparency, patient engagement, and the ethical use of health data including in relation with AI applications, which are essential to building trust in the EHDS among European citizens.

2. Intended Outcomes

- **Increased visibility and awareness on EHDS**
  The ambition and complexity of the EHDS project will require continuous and strong political support. The event is expected to significantly enhance the visibility and political support towards the EHDS among Member states, European Parliament and Commission. It will also enhance the understanding among healthcare providers, and the general public. Through high-profile speeches, panel discussions, and media materials and outreach, the event will help build momentum for the EHDS implementation, highlighting its potential to transform healthcare in Europe.

- **Stakeholder engagement and political commitment**
  The event will foster a stronger engagement and commitment from various stakeholders. Industry leaders, healthcare organizations, and member states will be encouraged to express their support and readiness to contribute to the EHDS implementation. The goal is to create a collaborative environment where stakeholders are motivated to take active roles in the success of the EHDS.

- **Outline of the Commission's plans for implementation**
  The event will be an opportunity for the Commission to present its plans to fulfil its obligations under the EHDS Regulation. This will include a broad overview of the major steps and milestones in the implementation process. In its closing statement, DG SANTE will highlight the need for a long term sustainable implementation of the EHDS and call for Member State commitment in implementation at national level.

- **Foundation for future political discussions on implementation challenges:**
  After celebrating the adoption of the EHDS and generating enthusiasm for its potential, the event will pave the way for future political discussions on the key challenges of its implementation.

3. Target Participants

- Ministers (health, Research, Digital) and high-level representatives from EU Member States.
- Health Commissioner, Officials from the Commission and other EU institutions.
- Stakeholders from the healthcare industry, including technology providers, as well as healthcare professionals (nurses, medical doctor) ad providers (European University Hospital Alliance); patient organisations.
- Experts in digital health, health data management, and cybersecurity.

- Representatives from supporting actions in MS (joint actions, pilots communities, eHN)

4. **Draft Agenda**
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- **Opening Session** (45 min)
    - Welcome address by the Commissioner for Health.
    - Keynote speech by the Polish health minister or a high-ranking official from the Polish Presidency, highlighting the importance of the EHDS.
    - Keynote speech from a high ranking Commission official : providing an overview of the EHDS Regulation, its objectives, expected benefits, and its role within the European Health Union and the European Data Strategy .

- **Panel discussions – Morning (150 min)**

Panel Discussion	Participants	Discussion Points	Questions for Discussion
1 - The Promises of EHDS – A person centric initiative - Benefits for European Citizens	*Ministerial panel* : Health Ministers from selected EU Member States.	The anticipated benefits of the EHDS for citizens, focusing on both primary and secondary uses of health data. How the EHDS will enhance patient care, improve public health outcomes, and drive innovation.	How will the EHDS transform healthcare delivery for European citizens? What are the critical steps to ensure the EHDS achieves its full potential?
2 - Building Trust : Privacy, security and patient engagement	Representatives from patient advocacy groups, healthcare professionals, and digital health experts	Strategies to build and maintain trust in the EHDS, focusing on data security, privacy, and transparency. The importance of patient engagement and the ethical use of health data	How is the EHDS setting new standards ensuring that patients feel secure and confident in the use of their health data? In what ways does the EHDS empower patients by enhancing transparency and involving them more actively in the management of their own health data? What are the key benefits for patients in terms of trust and engagement that the EHDS will bring ?

- **Panel discussions – Afternoon -** *75 min each*

Panel Discussion	Participants	Discussion Points	Questions for Discussion
3 – The Promises of EHDS – Driving Innovation and Competitiveness in the Health Sector	Industry leaders, innovation experts, patient representatives, EU bodies (EMA, ECDC), AI office ? and ministerial representatives	Exploration of future digital health innovations enabled by EHDS. Opportunities for industry and healthcare providers. Case studies on AI applications and real-world use cases.	What innovations are on the horizon for digital health? How can the EHDS framework support and accelerate these innovations?

- **Closing Session** *(45 min)*
    - Summary of Key Takeaways:
    - Closing Statement by DG SANTE focused on confidence in success, Commission's implementation actions and looking ahead.
    - Final Remarks by the Polish Presidency:

5. Logistics

- **The Polish Presidency will lead the organization of the event, ensuring alignment with their digital health agenda and providing necessary logistical and strategic support.**
- **Venue:** Brussels, Le Plaza - to ensure high visibility and accessibility for EU officials and stakeholders + online attendance possible
- **Date:** 18 March 2025, TBC – with set up on the 17/03
- **Duration :** one day event max, with the possibility of a social event on the evening before or after the event.
- **Budget:** TBC with (possible) financial support from EU4Health/DG SANTE
- **Suggested timing :** The opening session and the first panel are ministerial, with the remaining panels being more technical in nature.

Time	Session	Type of Session
09:00 - 09:45	Opening Session	Ministerial
09:45 - 11:00	Panel 1: The Promises of EHDS—A Patient-Centric Initiative—Benefits for European Citizens	Ministerial
11:00 - 11:15	Morning Coffee Break	Break
11:15 - 12:30	Panel 2: Building Trust—Privacy, Security, and Patient Engagement	Technical
12:30 - 13:30	Lunch Break	Break
13:30 - 14:45	Panel 2: The Promises of EHDS – Driving Innovation and Competitiveness in the Health Sector	Technical
14:45 - 15:00	Afternoon Coffee Break	Break
15:00 - 16:00	Closing Session	Technical

6. Speakers

Session	Proposed speakers
Opening Session	- Health Commissioner - PL MoH - DDG1 or Dir C (SANTE)
Panel 1: The Promises of EHDS—A Patient-Centric Initiative—Benefits for European Citizens	- PL MoH - Upcoming Pcy : DK + CY - Advanced Member State : FI - MEP : Tomislav SOKOL / Tilly METZ
Panel 2: Building Trust—Privacy, Security, and Patient Engagement	- EPF : Marco GRECO - Eurordis : Valentina Bottarelli - Healthcare professionals representatives - CPME Dr Christiaan Keijzer - Past MEP : Sara CERDAS - SANTE - DDG1 or Dir C - + Chair eHN ?
Panel 3: The Promises of EHDS – Driving Innovation and Competitiveness in the Health Sector	- EFPIA Nathalie Moll - Digital Europe Ray Pinto - Germany : Nick Schneider - Estonian rep Jaanika Merilo - CNECT – Dir H / RTD ?
Closing Session	DG SANTE + PL Presidency