

eHealth Network's work plan 2025

Approved on 13 January 2025 after written consultation

At its 27th meeting, the eHealth Network agreed to focus its 2025 workplan on two priorities:

1. supporting Member States in getting prepared for the EHDS' implementation;
2. preparing for the EHDS governance and services needed.

The 2025 eHN workplan is based on the same methods and principles than previously applied as they proved effective, that is: working together, sharing info and experiences freely, having clear and ambitious objectives and delivering frequent incremental achievements.

The 2025 eHN workplan focuses essentially on the major common next challenge: implementing the EHDS, with special attention to primary use.

The present document details the actions foreseen for each of the two priorities.

Priority 1: Prepare Member States for EHDS

Action 1.1 - Legal work

Redefine the eHMSEG Legal work group's role to provide a space for MS to exchange on national legal issues raised by EHDS Regulation (with no aim to substitute to or interfere on the official procedures for the adoption of implementing acts or the official interpretation of the EHDS Regulation, and with a clear understanding that LWG's outputs remain non-binding advice).

The scope of LWG should be broadened in order to encompass:

- Legal expertise role: Providing a forum for exchange of expert legal interpretations on the national implementation of the EHDS Regulation and its Implementing Acts. The focus should be on identifying areas that require (legal) guidance for implementation at national level;
- Providing a forum for sharing experiences and best legal practices between MS, including for instance but not limited to data protection and privacy compliance;
- Development of legal tools and materials useful for MS such as sharing legal solutions that some MS might have found to tackle issues related to the national implementation of the EHDS.

The LWG is expected to:

- Engage with Member States: Collaborate closely with national eHN/ digital health authorities, health data access bodies, and legal experts from Member States to help with coherent legal approaches;
- Suggest consulting Stakeholders about legal issues which may specifically affect them (e.g. regarding MS' leeway in implementing chapter 3): the LWG could suggest, in close coordination with the eHN, to consult other relevant and interested parties such as patient groups, healthcare providers, industry representatives, and data protection authorities to consider diverse perspectives and address legal concerns;
- Coordinate with other EHDS related Groups on legal matters: Work alongside technical and operational groups within the EHDS governance structure, as well as with groups active within the framework of Xt-EHR and TEHDAS2 joint actions which are working or will work on legal aspects too, to integrate legal considerations into all aspects of the EHDS as well as collaborating as needed with the EHDS2 Community of Practice.

The revamped LWG – as revised following above-mentioned points - should start its work and propose some specific topics to address and a timeline. For example, for the next two years that are focused on preparing MS for EHDS implementation those topics could be:

- Sharing – on a voluntary basis - National Legal Gap Analysis: eHN members who want, could share their national assessment of discrepancies between the EHDS Regulation and their national laws, identify areas requiring legal adaptation and share solutions and best practices;
- Development of Legal Tools and Guidelines based on existing documents coming from the eHN/eHMSEG ecosystem to assist Member States in evaluating the legal impact of the EHDS regulation: Draft guidelines on data protection and cross-border data exchange;
- Support Member States: Provide legal expertise to Member States for implementing EHDS requirements where requested, organise dedicated workshops, webinars, and training sessions on legal aspects of the EHDS where relevant.

Action 1.1: Expected deliverables

- The LWG is expected to continue sharing its work with eHN members, for instance at CA meetings on a regular basis – at least every 3 months to be sure there is no overlap with ongoing legal works in other groups.
- Confluence pages dedicated to sharing legal practices between MS that are available in eHN space should be used more effectively and evolve to provide a specific workplace, opened to LWG members, on a read-only basis, e.g. as a practical case repository.

Action 1.1: Responsibility

Action 1.1 to be led jointly by:

- | | |
|---------------------------|---|
| • eHMSEG Legal work group | Vanja Pajić, vanja.pajic@gmail.com
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| • France | Emilie Passemard, emilie.passemard@sante.gouv.fr |
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Action 1.2 - Implementation follow up

Define key milestones for EHDS implementation (for each chapter of the regulation, including implementation of the ethical principles) and share our progress and key challenges among MS and set up a mechanism or process so that the network is able to handle pre-consultations regarding documents related to the implementation of the EHDS.

Action 1.2: Expected deliverables

- Share a common simplified visual model to follow up EHDS implementation at MS level, using EC presentation on EHDS implementation phases made at the 27th eHN meeting.
- Build and share a macro-retro planning of decisions needed to be taken at MS level to secure EHDS implementation within the requested timeframe.
- In particular, when it comes to interoperability, keep all MS informed at eHN meetings and CA meetings about the deliverables and progress of the JA and participation in the consultation process for Xt-EHR Joint Action (JA).

Action 1.2: Responsibility

Action 1.2 to be led jointly by:

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Action 1. 3 Funding needs

The considerable amount of work carried out collectively on the joint paper (priority 1 of WP24) has led to an operational version of the joint paper, which Member States will be able to draw upon at the national level, for example to support their impact assessments of the EHDS regulation. Nevertheless, this document will continue to evolve as work progresses on implementing the regulation.

Action 1.3: Expected deliverables

It is proposed to schedule two dedicated online workshops during 2025 to:

- enable Member States to share any developments at the national level and their detailed technical methodology of cost calculations, taking into account national impact assessments or best practices from MS perspective;
- be informed of new developments from EC perspective, including the timeframe of the different relevant EU funds (EU4Health, DEP...);
- assess potential need for any updates to the paper.

Action 1.3: Responsibility

Action 1.3 to be co-led by:

- Hungary Orsolya Székely, orsolya.szekely@bm.gov.hu
- France Aline Conchon, aline.conchon@sante.gouv.fr

Action 1. 4 - Communication tools

Share common key messages, communication tools and communication strategies to raise awareness about the EHDS regulation and its impact towards the public (to build up trust, especially about how safe and secure is data sharing across borders) and the industry (e.g. vendors, EHR manufacturers); coupled with explanations related to data governance.

Action 1.4: Expected deliverables

Share information at CA meeting on existing work and initiatives, including:

- Report from the eHMSEG's Communication Task Force;
- Report about MS' contribution to the "country pages" of the eHMSEG's Communication Task Force on Confluence
- Report about the communication activities of the EHDS2 Community of practice;
- Follow-up of the EC communication toolkit which is being prepared with the support of a subcontractor;

Action 1.4: Responsibility

Action 1.4 to be led by:

- France

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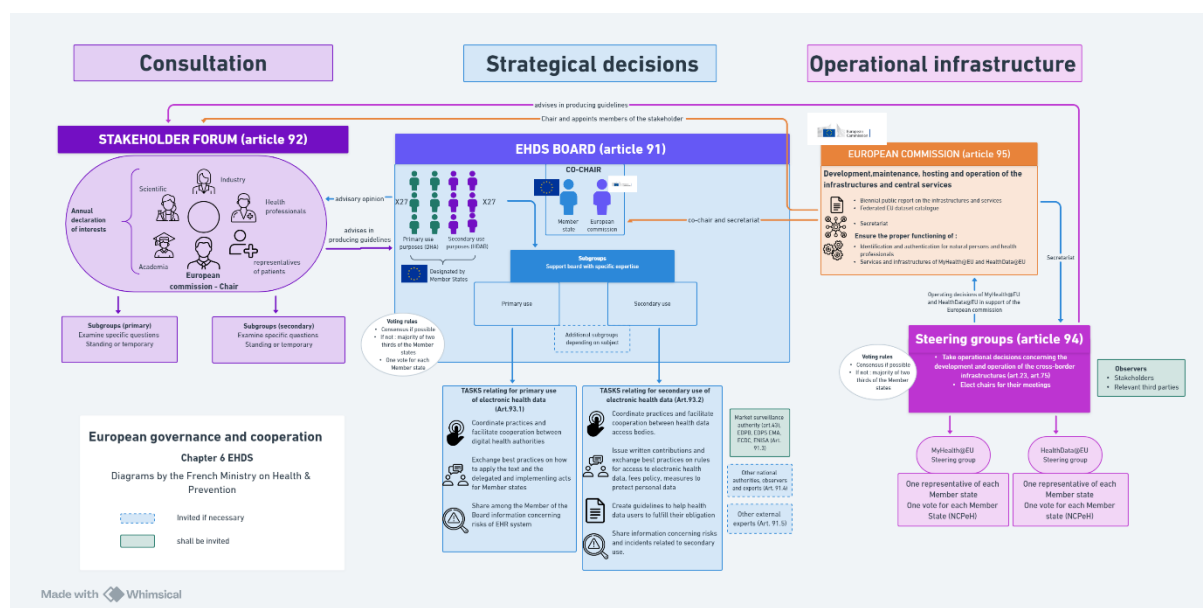
Priority 2: Preparing for European governance and services needed for EHDS (co-lead both MS and EC)

Action 2.1 - Start transition from eHN to EHDS Board

Taking in the lessons learned from the current eHN governance:

- How to build EHDS Board, what should we keep and what should we change?
- What text needs to evolve (e.g. rules of procedure, definition of mandate)?
- How to ensure a good coordination and communication within the EHDS board which will include both primary and secondary use representatives?
- Specification of what is expected from the members of the EHDS governance bodies, to best allocate the appropriate experts?

How to secure a good cooperation and steering workflow between the different bodies? Clear division of roles between the technical groups (where not all MS are represented) and the governance bodies (where decisions are expected to be made)?



Action 2.1: Expected deliverables

Assess the (human) resources allocated to eHN, eHMSEG (taskforces included), the EHDS2 Community of Practice, and joint actions (Xt-EHR, TEHDAS2) as well as the needs attached to the future EHDS governance bodies. Identify possibilities for streamlining structure to optimize resources.

Anticipate the role, composition, and mandate of the stakeholder forum.

Primary use:

- Adapt the subgroup workplan and share key decision planning to make sure we are on track for EHDS implementation on primary use;
- Identify the appropriate areas of expertise for the Board subgroups and steering groups for primary use, to help MS to identify the right person to be designated in the right group.

Secondary use:

- Foster mutual knowledge and information exchange between the eHN, TEHDAS2 and the Community of Practice of (future) HDABs: updates during CAs and participation of the Chair of the CoP in eHN meetings (and vice-versa for eHN co-chairs in CoP meetings).

Action 2.1: Responsibility

Action 2.1 to be jointly led by:

- Sweden
- Portugal

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Action 2.2 Distribution of roles for central services

EHDS Regulation provides some detailed information about EC role as central services provider, summarised in article 96 (see below the last draft wording of this article, from ongoing corrigendum procedure).

Article 96

Roles and responsibilities of the Commission regarding the functioning of the EHDS

1. *In addition to its role in making available electronic health data held by Union institutions, bodies, offices or agencies, in accordance with Article 55, Article 56 and Article 75(2), and its tasks under Chapter III, in particular Article 40, the Commission shall develop, maintain, host and operate the infrastructures and central services required to support the functioning of the EHDS, for all relevant connected entities, in the following forms:*
 - (a) *an interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Article 16(3) and (4);*
 - (b) *the central services and infrastructures for digital health of MyHealth@EU, in accordance with Article 23(1);*
 - (c) *compliance checks for connecting authorised participants to MyHealth@EU, in accordance with Article 23(9);*
 - (d) *the additional cross-border digital health services and infrastructures referred to in Article 24(1);*
 - (e) *as part of HealthData@EU, a service to submit health data access applications for making available electronic health data from health data holders in multiple Member States or from other authorised participants in HealthData@EU and to automatically forward the health data access applications to the relevant contact points, in accordance with Article 67(3);*
 - (f) *the central services and infrastructures of HealthData@EU in accordance with Article 75(6) and (7);*
 - (g) *a secure processing environment in accordance with Article 75(9), in which health data access bodies can decide to make data available in accordance with Article 68(8);*
 - (h) *compliance checks for connecting authorised participants to HealthData@EU, in accordance with Article 75(11);*
 - (i) *a federated EU dataset catalogue connecting the national dataset catalogues, in accordance with Article 79;*
 - (j) *a secretariat for the EHDS Board, in accordance with Article 92(9);*
 - (k) *a secretariat for the steering groups, in accordance with Article 95(8).*
2. *The services referred to in paragraph 1 of this Article shall meet sufficient quality standards in terms of availability, security, capacity, interoperability, maintenance, monitoring and level of development to ensure the EHDS functions effectively. The Commission shall provide those services in accordance with the operational decisions of the relevant steering groups established in Article 95.*
3. *The Commission shall prepare a report on the infrastructures and services supporting the EHDS that it provides in accordance with paragraph 1 every two years and make it publicly available.*

Action 2.2: Expected deliverables

- Dedicated workshop to go into the details of the provisions of this article, as well as into the open-source testing environment to be developed by the EC, in order to analyse the role of EC, and of MS, to make sure that data exchange actually works at scale.

Action 2.2: Responsibility

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